

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,

Petitioner,

INARI MEDICAL, INC.,

Patent Owner.

Case No. IPR2025-00156

U.S. Patent No. 11.697-012

VIDEOTAPED DEPOSITION OF PAUL J. ZALESKY, Ph.D.

LOS ANGELES, CALIFORNIA

AUGUST 27, 2025

Reported by: Leslie A. Todd, CSR No. 5129 and RPR

DIGITAL EVIDENCE GROUP

1730 M Street, NW, Suite 812

Washington, D.C. 20036

(202) 232-0646

Imperative Care v. Inari Medical
IPR2025-00728
Imperative Care Ex. 1045

1 Deposition of PAUL J. ZALESKY, Ph.D.,
2 held at the offices of:
3
4
5 PERKINS COIE
6 1888 Century Park East
7 Suite 1700
8 Los Angeles, California 90067
9
10
11
12
13
14 Pursuant to notice, before Leslie Anne
15 Todd, California Certified Shorthand Reporter in
16 and for the State of California, who officiated in
17 administering the oath to the witness.

18
19
20
21
22
23
24
25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

A P P E A R A N C E S

ON BEHALF OF PETITIONER:

JOSH STOWELL, ESQUIRE
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street
14th Floor
Irvine, California 92614
(949) 760-0404

ON BEHALF OF RESPONDENT:

JOSEPH HAMILTON, ESQUIRE
PERKINS COIE
633 West 5th Street
Suite 5850
Los Angeles, California 90071
(310) 788-3271

ALSO PRESENT:

JINAH CHOI, Videographer

1 C O N T E N T S

2	EXAMINATION OF PAUL J. ZALESKY	PAGE
3	By Mr. Stowell	7, 187
4	By Mr. Hamilton	183

5
6
7
8

9 E X H I B I T S

10 (Attached to transcript)

11	ZALESKY DEPOSITION EXHIBITS	PAGE
12	No. INARI- Declaration of Paul J. Zalesky,	
13	2001 Imperative Care, Inc. v. Inari	
14	Medical, Inc.	27
15	No. INARI- Supplemental Declaration of	
16	2008 Paul J. Zalesky, Imperative	
17	Care, Inc. v. Inari Medical, Inc.	32
18	No. 1001 United States Patent No.	
19	11,697,012	80
20	No. 1005 United States Patent Application	
21	Publication No. 2003/0225379 A1	127
22	No. 1006 United States Patent Application	
23	Publication No. 2003/0116731 A1	150
24	No. 1007 United States Patent	
25	No. 9,980,813	171

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

E X H I B I T S C O N T I N U E D

(Attached to transcript)

ZALESKY DEPOSITION EXHIBITS

PAGE

No. 1008 Illustrations - Composite Statis

Valve, Inventors Name: David

Schaffer

129

No. 1013 Portions of Dorland's Illustrated

Medical Dictionary, 32nd Edition

54

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

2 -----

3 THE VIDEOGRAPHER: This is file
4 number one of the videotaped deposition
5 of Paul Zalesky, taken by counsel for
6 Petitioner in the matter of Imperative
7 Care, Inc. versus Inari Medical, Inc.,
8 filed in the United States Patent and
9 Trademark Office, before the Patent
10 Trial and Appeal Board, Case No.
11 IPR2025-00156.

12 This deposition is being held at
13 888 Century Park East, Suite 1700, Los
14 Angeles, California 90067.

15 Today's date is August 27, 2025,
16 and the time on the monitor is 9:09 a.m.

17 My name is Jinah Choi. I'm the
18 videographer. And the court reporter is
19 Leslie Todd, representing Digital
20 Evidence Group.

21 Counsel will state their
22 appearances for the record, after which
23 the court reporter will swear in the
24 witness.

25 MR. STOWELL: Joshua Stowell of

1 Knobbe Martens on behalf of the
2 Petitioner, Imperative Care.

3 And just to correct the read-on,
4 the deposition is taking place at 1888
5 Century Park. Sorry. 1888, three 8s.

6 MR. HAMILTON: And this is Joe
7 Hamilton of Perkins Coie, representing
8 the Patent Owner and the witness.

9 PAUL J. ZALESKY, Ph.D.,
10 first having duly been sworn, was
11 examined and testified as follows:

12 EXAMINATION

13 BY MR. STOWELL:

14 Q. Good morning, Dr. Zalesky.

15 Can you say and spell your name?

16 A. So Paul, P-A-U-L, J. Z-A-L-E-S-K-Y.

17 Q. And what is your home address?

18 A. 124 Gilbert Stuart Drive, East
19 Greenwich, Rhode Island.

20 Q. And you understand that you've been
21 retained to serve as an expert on behalf of the
22 patent owner, Inari Medical, in this IPR; is that
23 correct?

24 A. Yes.

25 Q. And you understand that today's

1 deposition relates to some declarations that you
2 have submitted in that IPR?

3 A. Yes.

4 Q. I know you've been deposed before,
5 but I'll just go over the rules. It's always good
6 to have a reminder.

7 You understand that you are under
8 oath today, just as if you were testifying in a
9 court of law?

10 A. Yes.

11 Q. All of your answers today will need
12 to be verbal so that the court reporter can
13 transcribe them. Does that make sense?

14 A. Yes. Understood.

15 Q. We'll try to avoid, as best we can,
16 talking over each other, so please wait for me to
17 finish my question. I'll do my best to finish --
18 to -- or wait until you finish your answer before I
19 ask another question; is that fair?

20 A. That is.

21 Q. Okay. If at any point today you
22 don't understand one of my questions, please let me
23 know. If you don't speak up, the presumption will
24 be that you understood the question; is that fair?

25 A. Yes.

1 Q. Your counsel may make short
2 objections today. However, you'll still have to
3 answer all of my questions to the best of your
4 ability unless you're specifically instructed not
5 to answer by your counsel. Do you understand?

6 A. Yes.

7 Q. If you need a break today, just let
8 me know. The only thing I'll ask is that we finish
9 the line of questioning we're on before we take the
10 break; is that fair?

11 A. It is.

12 Q. And is there any reason you can't
13 provide truthful and accurate testimony today?

14 A. No.

15 Q. Have you had any food, drink, or
16 medication that would inhibit your ability to tell
17 the truth or to remember facts?

18 A. No.

19 Q. You were deposed in June in a related
20 IPR between Imperative Care and Inari, correct?

21 A. Yes.

22 Q. And do you recall that that IPR
23 related to another patent owned by Inari that we
24 sometimes refer to as the '011 patent?

25 A. Yes.

1 Q. Have you had an opportunity to review
2 your transcript from that IPR?

3 A. I have briefly, yes.

4 Q. And when you say briefly, what do you
5 mean?

6 A. I looked at my declaration, skimmed
7 over the boilerplate aspects, looked at some of the
8 basic issues that were raised or addressed.

9 Q. Okay. There may be some confusion,
10 so I'm asking after your last deposition, there was
11 a written transcript of everything that was said at
12 the deposition. Did you get a chance to review
13 that transcript?

14 A. No, I did not.

15 Q. Okay. After your deposition, did
16 you -- the prior deposition, did you discuss that
17 deposition with anybody?

18 A. I think over the last several weeks,
19 Joe Hamilton and I may have had a brief --

20 MR. HAMILTON: I just want you
21 to caution you. You can say if you've
22 discussed it but not reveal --

23 THE WITNESS: Okay.

24 MR. HAMILTON: -- the content of
25 any communications.

1 THE WITNESS: Right.

2 Just, yes, very briefly.

3 BY MR. STOWELL:

4 Q. Okay. So you discussed your prior
5 deposition with your counsel, Mr. Hamilton?

6 A. Very briefly, yes.

7 Q. Okay. And have you discussed that
8 prior deposition with anybody else?

9 A. No.

10 Q. Since your last deposition regarding
11 the '011 patent, have you given any other
12 depositions in other matters?

13 A. No.

14 Q. And have you testified in court since
15 your last deposition relating to the '011 IPR?

16 A. No.

17 Q. What do you consider your area of
18 expertise?

19 A. The category I generally use is
20 called medical specialty devices, which are medical
21 devices with very specific either diagnostic or
22 therapeutic instructions or indications for use.

23 Q. When you say specific diagnostic
24 indications, what are you referring to there?

25 A. There are a variety of devices,

1 typically disposable components, with a complex
2 system associated with it for measuring things like
3 blood gas, pressures, images, ultrasonic
4 reflections, and probably 10 or 20 other diagnostic
5 data that the treating physician will use to
6 diagnose and treat.

7 Q. And so these diagnostic devices, they
8 collect data and information that the physician
9 will then use in a procedure?

10 A. Yes. And I meant to say therapeutic
11 as well, so not just diagnostic, but also
12 therapeutic, such as angioplasty, thrombectomy,
13 stents, and so forth.

14 Q. And why do you refer to these as
15 specialty devices?

16 A. Typically, I'm working with a
17 physician specialist: the interventional
18 cardiologist or an interventional radiologist or
19 orthopedic surgeon. So the normal state of affairs
20 in developing medical specialty devices is
21 collaborating with a specialized physician, not a
22 general physician.

23 Q. And for the therapeutic devices, you
24 had mentioned angioplasty devices, stents. Are
25 there any types of other therapeutic devices that

1 you consider to be part of your area of specialty?

2 A. It's actually pretty broad. I worked
3 in cardiopulmonary bypass, as an example, where
4 there's a fairly complex system used for bypassing
5 the heart while it's stopped for open-heart
6 surgery. There are probes and adjuncts and various
7 devices used in that procedure. Similarly for
8 gastrointestinal, both diagnostic and therapy. So
9 the list would be quite long.

10 Q. And do you consider yourself to be an
11 expert in the design of medical specialty devices?

12 A. Yes. I -- almost all of my product
13 development projects have involved some involvement
14 in design. In some cases they come from an
15 external source, in which case the design has
16 already been completed, but, in general, yes.

17 Q. And do you consider yourself to be an
18 expert in the use of medical specialty devices?

19 A. Yes.

20 Q. And do you consider yourself to be an
21 expert in the manufacture of medical specialty
22 devices?

23 A. Yes.

24 Q. Do you consider yourself to be a
25 professional expert witness?

1 MR. HAMILTON: Objection.

2 Vague.

3 THE WITNESS: I don't normally
4 used that term when asked. I usually
5 say consultant.

6 BY MR. STOWELL:

7 Q. And in your mind, what's the
8 difference between a professional expert witness
9 and a consultant?

10 MR. HAMILTON: Objection.

11 Vague.

12 THE WITNESS: Expert witness to
13 me and to some colleagues is more
14 limiting than a consultant for medical
15 specialty technology.

16 BY MR. STOWELL:

17 Q. And how would expert witness be more
18 limiting?

19 A. Expert witness is typically this
20 dynamic associated with this current case, where
21 I'm reviewing patents, intellectual property,
22 various issues, and opining in the form of a
23 declaration and, of course, today in a deposition.

24 In a general sense, I consult not
25 only on intellectual property, but the underlying

1 technology or technology alternatives or
2 development strategies and plans and so forth.

3 Q. And so when you think of an expert
4 witness, you're thinking of serving as an expert
5 witness in a legal capacity; is that accurate?

6 A. Yes.

7 Q. And what percentage of your current
8 working time is dedicated to expert witness work?

9 A. It certainly varies month to month,
10 but right now I'd say approximately 50 percent.

11 Q. And looking back at the last four
12 years of your career, has that 50-percent level
13 generally remained consistent?

14 A. As I said, it's varied from month to
15 month. But I think if I looked at an overall
16 average, yes.

17 Q. And the other 50 percent of your
18 working time, what is that dedicated to?

19 A. It's probably best if I give an
20 example.

21 In one case that's ongoing, I needed
22 to identify, initiate, supervise, and manage --

23 MR. HAMILTON: And I'll just
24 interject. Objection to the extent the
25 answer requires confidential

1 information. You don't -- you're not
2 required to disclose other clients'
3 information. But if you can talk
4 generally about it, that's fine.

5 THE WITNESS: Yeah. Just in a
6 general sense, as I said, initiated,
7 organized, managed, supervised, testing
8 at a -- an ISO-certified laboratory to
9 produce some key technical data for
10 assessment by the client.

11 BY MR. STOWELL:

12 Q. And so then is it fair to say that 50
13 percent of your time is dedicated to expert witness
14 work and 50 percent of your time is dedicated to
15 assisting your clients with the underlying
16 technology?

17 A. In general, yes.

18 Q. Does your consulting business have a
19 name?

20 A. Just my name.

21 Q. Just your name. Okay.

22 And did you enter into a consulting
23 agreement for this case?

24 A. Yes.

25 Q. And what party did you enter into

1 that agreement with?

2 A. With Perkins Coie.

3 Q. Okay. Did you enter into any
4 agreements with Inari Medical?

5 A. No.

6 Q. Did you enter into any agreements
7 with Stryker?

8 A. No.

9 Q. And are you aware that Stryker has
10 acquired Inari Medical?

11 A. Yes.

12 Q. Who do you submit your invoices to in
13 this matter?

14 A. For this case, to this gentleman
15 right here, Joe.

16 Q. Okay. And is it your understanding
17 that Perkins Coie then pays your invoices?

18 A. Yes.

19 Q. And I understand you're charging \$300
20 per hour for your work on this matter; is that
21 correct?

22 A. Yes.

23 Q. And during the course of your
24 consulting agreement, has that number changed at
25 all?

1 A. No.

2 Q. And is that the rate that you charge
3 for all of the consulting work that you do?

4 A. No.

5 Q. Okay. How does it differ?

6 A. That's the low end.

7 Q. Okay. And when you say "the low
8 end," what is your range of consulting fees that
9 you charge to your customers?

10 A. 300 an hour being the low end; 750
11 being the high end.

12 Q. And how do you determine how much you
13 will charge on any given matter?

14 A. There are various issues involved
15 including how I'm being recruited or by whom I'm
16 being recruited. In some cases it's by a
17 professional organization who will use my rate and
18 then add significantly to it. In other cases I
19 just deal directly with the prospective client.

20 Q. For this range, \$300 to \$750 an hour,
21 does that range apply to the work you perform as an
22 expert witness in legal matters?

23 A. Yes.

24 Q. Okay. So there are some legal
25 matters that you work on where your rate is \$750

1 per hour; is that right?

2 A. No. The 750 would apply to non-legal
3 issues.

4 Q. Okay. So for the expert witness work
5 you do in legal matters, what is the range of the
6 amounts you charge per hour?

7 A. 300 to 500.

8 Q. And so for those matters, how do you
9 decide -- for the legal matters, how do you decide
10 how much you'll charge in that 300 to \$500 range?

11 A. There's a bit of negotiation or,
12 depending on the client, how I'm approached. And
13 it's really a case-by-case basis of determining
14 that rate.

15 Q. Are there any factors you typically
16 consider when you're deciding on the rate you're
17 going to charge to a client?

18 A. I'll usually get some sort of
19 synopsis of what the case is going to be and what
20 the likely evolution will be, including the time
21 and the requirements. And the longer time periods
22 with semi-minimal requirements would justify a
23 lower rate.

24 Q. And in this case, why did you decide
25 that you would only charge \$300 per hour?

1 A. I was recruited directly by a junior
2 member of Perkins Coie via telephone, followed up
3 by e-mail. And I had used that rate for certain
4 other clients. And she and I quickly agreed that
5 would be acceptable.

6 Q. And have you performed expert witness
7 services for Perkins Coie before?

8 A. No.

9 Q. Do you work with any expert witness
10 organizations to obtain your expert witness
11 positions?

12 A. There are a few that come to mind
13 like Forensis, as an example, will often reach out
14 in a recruitment. And there are probably four or
15 five others around the country.

16 Q. And when you say Forensis, how do you
17 spell that, just so we have the record clear?

18 A. F, as in frank, O-R-E-N-S-I-S.

19 Q. And are there any other expert
20 witness recruiting firms that you recall working
21 with?

22 A. There are, but it's been probably two
23 years since I've worked with them, and so I don't
24 have them on the top of my head.

25 Q. But in this case, you were directly

1 contacted by an attorney from Perkins Coie; is that
2 correct?

3 A. Yes.

4 Q. How much have you billed Perkins Coie
5 for your work on the Imperative Care versus Inari
6 matters?

7 A. Do you mean year to date or project
8 to date?

9 Q. Why don't we do project to date
10 first.

11 A. This is just a swag. I would say
12 maybe \$40,000.

13 Q. Okay. And what about year to date?

14 A. Less than half that.

15 Q. And other than the \$300 per hour that
16 you're receiving for your work on this case, are
17 you receiving any other sort of monetary or
18 financial payment for your work on this case?

19 A. Only reimbursement of travel or
20 sundry expense.

21 Q. Is there any sort of success fee
22 attached to your work on this case?

23 A. No.

24 Q. Okay. Have you been offered any
25 equity in Inari or Stryker as a result of your work

1 on this case?

2 A. No.

3 Q. Have you been promised any additional
4 work for Perkins Coie based on your performance on
5 this case?

6 A. No.

7 Q. Have you been promised any additional
8 work by Inari Medical or Stryker based on your
9 performance in this case?

10 A. No.

11 Q. Are you aware that there is a
12 District Court proceeding that is occurring in
13 parallel to the IPR proceedings between Inari
14 Medical and Imperative Care?

15 A. I'm aware of it without detail.

16 Q. Okay. What do you know about the
17 District Court case?

18 A. I know very little other than it
19 involves the same subject matter.

20 Q. Have you reviewed any articles about
21 the District Court case?

22 A. I don't recall.

23 Q. Have you reviewed any of the papers
24 that have been filed in the District Court case?

25 A. I don't believe so.

1 Q. Have you reviewed any of the
2 declarations that Inari has submitted or served in
3 the District Court litigation?

4 A. Are you talking about declarations by
5 or from Inari?

6 Q. Correct.

7 A. I don't believe so.

8 Q. Okay. Have you had the opportunity
9 to inspect Inari's ClotTrievers or FlowTrievers
10 products?

11 A. Only virtually.

12 Q. What do you mean by virtually?

13 A. Online.

14 Q. And can you explain how that process
15 went?

16 A. I'm not sure what you're asking.

17 Q. Who participated in the virtual
18 demonstration of the products?

19 A. Just myself.

20 Q. Okay. And what did you do to learn
21 about the products?

22 A. Because of my background, I'm
23 generally familiar with thrombectomy procedures and
24 associated devices, so this is just a quick review
25 of Inari's approach.

1 Q. And how did you review their
2 approach?

3 A. As I said, online.

4 Q. And what websites did you access to
5 learn about Inari's approach?

6 A. Primary site was Inari, Inari's
7 website.

8 Q. And why did you decide to go to
9 Inari's website to look at their product?

10 A. I probably do that in virtually every
11 case, either just before or at the time of
12 recruitment to be involved in a project.

13 Q. And did your review of Inari's
14 products inform your opinions that you've offered
15 in the declarations in this IPR?

16 A. I would say, in general, no.

17 Q. Did you rely on your review of the
18 Inari products in forming the opinions that are in
19 your declarations in this IPR?

20 A. Same answer, in general, no.

21 Q. And you're saying "in general." Is
22 there a way that they were used in forming your
23 opinions?

24 A. Only as background of considerations
25 for the actual procedures associated with

1 thrombectomy, but not directly associated with
2 opinions on IP.

3 Q. And you say you were familiar with
4 thrombectomy before you were retained to work on
5 this case; is that correct?

6 A. Yes.

7 Q. And had you seen procedures similar
8 to the operation of Inari's device prior to your
9 retention on this case?

10 A. Over a long period of time, I
11 certainly have seen certain thrombectomy
12 procedures, yes.

13 Q. And were those procedures similar to
14 the procedure that Inari currently does with its
15 FlowTrievers and ClotTrievers system?

16 MR. HAMILTON: Objection.

17 Vague.

18 THE WITNESS: Similar in a sense
19 of the basic principles which are
20 applying some sort of vacuum pressure to
21 withdraw thrombus volume.

22 BY MR. STOWELL:

23 Q. And as you're thinking back to your
24 career, what time period are you thinking about
25 when you learned about thrombectomy procedures?

1 A. Starting probably in the 1990s, early
2 1990s.

3 Q. What were the circumstances of
4 learning about thrombectomy procedures?

5 A. I've spent a lot of time in operating
6 rooms and what are called "specialty procedure
7 laboratories," like cardiac catheterization labs,
8 as well as vascular labs and so forth. And on
9 occasion, a thrombectomy procedure would be
10 associated with another device or procedure that we
11 were developing. So I was there as an observer.

12 Q. And if I understand correctly, you
13 have not been able to -- or you have not had the
14 opportunity to physically inspect Inari's
15 ClotTrievers and FlowTrievers; is that correct?

16 A. Yes. That's correct.

17 Q. Have you inspected any of Imperative
18 Care's products either virtually or in person?

19 A. I believe quite a while back I did a
20 cursory look at their website as well, but very
21 briefly.

22 Q. And did you -- did you rely on your
23 view of the Imperative Care website in forming any
24 of the opinions in your declarations in this IPR?

25 A. No, not really.

1 Q. You have prepared two declarations
2 for this IPR, correct?

3 A. Yes.

4 Q. I'll hand you what's been previously
5 marked in this IPR as Inari-2001; and that's the
6 exhibit number.

7 (Exhibit No. Inari-2001 was
8 previously marked for
9 identification.)

10 MR. STOWELL: Thank you.

11 BY MR. STOWELL:

12 Q. Dr. Zalesky, do you recognize Exhibit
13 Inari-2001?

14 A. Yes.

15 Q. And what is Exhibit 2001?

16 A. It's my declaration dated
17 February 25th of this year.

18 Q. And on the cover of your declaration,
19 there's a reference to U.S. patent number 11697012.

20 Do you see that?

21 A. Yes.

22 Q. Okay. And is it your understanding
23 that the IPR that we're conducting this deposition
24 about today relates to U.S. patent number
25 11,697,012?

1 A. Yes.

2 Q. And for shorthand, is it okay if we
3 refer to that as the '012 patent today?

4 A. Yes.

5 Q. If we turn to page 109 of your
6 declaration, which is the last page before the
7 attachments, is that your signature?

8 A. Yes.

9 Q. And did you sign this document on
10 February 25, 2025?

11 A. Yes, I did.

12 Q. And where were you when you signed
13 this document?

14 A. In East Greenwich, Rhode Island.

15 Q. And is that your handwritten
16 signature on this page?

17 A. Yes.

18 Q. When you signed the declaration, you
19 attested that all the statements made in the
20 declaration, to your knowledge, were true and the
21 statements were made on the -- made on information
22 and belief that the statements are true. Is that
23 still true today?

24 A. Yes.

25 Q. Do you still believe that all the

1 statements in this first declaration, Exhibit 2001,
2 are correct and accurate?

3 A. Yes.

4 Q. Are you aware of any errors or
5 misstatements in the first declaration,
6 Exhibit 2001?

7 A. I'm not aware of misstatements. When
8 you say "errors," I may have not expanded as much
9 on certain areas as I might have, but I wouldn't
10 call that an error.

11 Q. Are you aware of anything in the
12 declaration that is inaccurate?

13 A. No.

14 Q. Do you wish to change any of the
15 opinions that you've offered in this first
16 declaration, Exhibit 2001?

17 A. No.

18 Q. Other than working with counsel, did
19 you work with anyone else to create Exhibit 2001?

20 A. Only with Perkins' counsel.

21 Q. In drafting Exhibit 2001, did you
22 rely on any conversations with anybody besides
23 counsel?

24 A. No.

25 Q. In preparing Exhibit 2001, did you

1 have any conversations with anyone at Inari Medical
2 or Stryker?

3 A. No.

4 Q. Do you know anyone that works at
5 Inari Medical?

6 A. No.

7 Q. Do you know anyone that works at
8 Stryker?

9 A. Not that I'm aware, no.

10 Q. And what was the process for creating
11 your declaration, Exhibit 2001?

12 MR. HAMILTON: Objection.

13 Vague.

14 THE WITNESS: It started with my
15 reviewing basic materials which, of
16 course, were the patents -- or the
17 patent I went to in particular for this
18 declaration.

19 MR. HAMILTON: I'll just, again,
20 object to the extent the question calls
21 for communications or drafts or anything
22 between us that I'm instructing you not
23 to answer on. But if you can answer the
24 question otherwise, please.

25 THE WITNESS: I then put down my

1 own outline and worked with counsel to
2 draft the contents.

3 BY MR. STOWELL:

4 Q. And roughly how long did you spend
5 working to draft Exhibit 2001?

6 A. I'm guesstimating, 30 hours.

7 Q. And did you exchange drafts of the
8 declaration with counsel?

9 A. Yes.

10 Q. Was there any information in the
11 drafts that you relied on in forming your opinions
12 that does not appear in Exhibit 2001?

13 MR. HAMILTON: Objection. I'm
14 instructing you not to answer to the
15 extent the question relates to
16 information in any draft between
17 counsel.

18 THE WITNESS: So could you
19 repeat that?

20 BY MR. STOWELL:

21 Q. Sure. Was there any information in
22 the drafts that you relied on in forming the
23 opinions that are in Exhibit 2001 that's not
24 referenced or mentioned in Exhibit 2001?

25 A. No.

1 Q. I will hand you what's been marked in
2 this case as Exhibit Inari-2008.

3 Thank you.

4 (Exhibit No. Inari-2008 was
5 previously marked for
6 identification.)

7 BY MR. STOWELL:

8 Q. Dr. Zalesky, do you recognize
9 Exhibit 2008?

10 A. Yes.

11 Q. And what is Exhibit 2008?

12 A. It's a supplemental declaration
13 regarding the '012 patent that I signed on
14 July 15th of this year.

15 Q. And if we look at page 109 of Exhibit
16 2008, is that your signature on that page?

17 A. Yes.

18 Q. And did you sign this declaration on
19 July 15th, 2025?

20 A. Yes.

21 Q. And where were you located when you
22 signed the declaration?

23 A. In East Greenwich, Rhode Island.

24 Q. And again, on this declaration, you
25 attested that the statements in the declaration

1 were true or that they were based on a belief that
2 they were true; is that correct?

3 MR. HAMILTON: Objection. The
4 document speaks for itself.

5 THE WITNESS: Yes.

6 BY MR. STOWELL:

7 Q. Okay. And do you still believe that
8 the statements that you made in this supplemental
9 declaration, Exhibit 2008, are true and accurate?

10 A. Yes.

11 Q. Are you aware of any errors or
12 misstatements in the declaration?

13 A. No.

14 Q. Are you aware of any opinions or
15 statements that are inaccurate in the declaration?

16 A. No.

17 Q. Why did you provide a supplemental
18 declaration?

19 A. It was requested by the client.

20 Q. Okay. Had your opinions changed
21 between your first declaration, Exhibit 2001, and
22 this supplemental declaration, Exhibit 2008?

23 A. No.

24 Q. What was the process for creating
25 Exhibit 2008?

1 MR. HAMILTON: Objection. I'm
2 instructing the witness not to answer
3 with respect to content of
4 communications or drafts or any other
5 communication between counsel and the
6 witness.

7 THE WITNESS: So similar to the
8 first declaration, my composing an
9 outline and then exchanging
10 communications with counsel.

11 BY MR. STOWELL:

12 Q. And so you recall for Exhibit 2008
13 that you created your own outline for the
14 supplemental declaration?

15 A. Yes.

16 Q. And how did you go about creating the
17 outline?

18 MR. HAMILTON: Objection, again.
19 I'll instruct the witness not to reveal
20 the content of any communication or
21 information relating to drafts or the
22 preparation of the declaration.

23 THE WITNESS: Just a general
24 review, again, of the patent followed by
25 a list.

1 BY MR. STOWELL:

2 Q. And the reason I ask is that
3 Exhibit 2001 is quite similar to Exhibit 2008. Did
4 you use Exhibit 2001 as a roadmap for your outline
5 for Exhibit 2008?

6 A. To a limited extent, yes. Just to
7 make sure I remembered the key issues in the
8 original declaration.

9 Q. But is it fair to say you did a new
10 analysis to generate Exhibit 2008?

11 A. I would call it incremental, not
12 generally new because some of the same issues were
13 on the docket, if you will.

14 Q. Would it be fair to say that Exhibit
15 2008 contains all of the opinions that you have
16 regarding this IPR?

17 MR. HAMILTON: Objection.

18 Vague.

19 THE WITNESS: I believe so. You
20 know, I -- as I understand your
21 question, you're asking could there be
22 some other issue that I did not address?
23 Is that your question?

24 BY MR. STOWELL:

25 Q. Well, as you sit here today, you have

1 opinions about this IPR. Are all of those opinions
2 set forth in Exhibit 2008?

3 A. I believe so.

4 Q. Does Exhibit 2008 supersede
5 Exhibit 2001?

6 MR. HAMILTON: Objection.

7 Vague.

8 THE WITNESS: That wasn't my
9 interpretation. I thought the
10 supplemental descriptor was accurate.

11 BY MR. STOWELL:

12 Q. Okay. Are there any opinions you're
13 aware of that appear in Exhibit 2008 that don't
14 appear in Exhibit 2001?

15 A. I don't believe so.

16 Q. And how much time do you recall
17 spending to prepare Exhibit 2008?

18 A. Probably a bit less than the original
19 declaration, so I'd approximate 15 hours.

20 Q. And other than working with counsel
21 at Perkins Coie to prepare Exhibit 2008, did you
22 work with anybody else to prepare the supplemental
23 declaration?

24 A. No.

25 Q. And did you have any conversations

1 with anybody at Inari Medical or Stryker regarding
2 the supplemental declaration, Exhibit 2008?

3 A. No.

4 Q. Did you have any conversations with
5 anyone else regarding the supplemental declaration,
6 Exhibit 2008?

7 A. No.

8 Q. Can you turn to paragraph 64 of
9 Exhibit 2008, and just let me know when you're
10 there.

11 A. Okay.

12 Q. In paragraph 64, you state, "I do not
13 analyze the details of Garrison."

14 Is that an accurate statement?

15 A. Yes.

16 Q. Okay. And in the next sentence, in
17 paragraph 64, it says that you reserve the right to
18 further assess any reason -- any independent
19 reasons of patentability for the claims and view of
20 Garrison.

21 Have you made any such further
22 assessment of Garrison?

23 A. Only to myself.

24 Q. And have you formed any opinions
25 about Garrison as they relate to this IPR?

1 A. Not specifically opinions, no.

2 Q. And so is it fair to say that with
3 respect to this IPR relating to the '012 patent
4 that you do not have any opinions about the
5 Garrison reference?

6 A. That's a very broad question. In
7 terms of opinions related to the -- to the
8 associated patent, not directly, no.

9 Q. And in your supplemental declaration,
10 you do not offer any opinions regarding the
11 Garrison reference, correct?

12 A. If memory serves, I think I had a
13 sentence related to Garrison in some other part of
14 the text, but I'd have to go back and look at it.

15 Q. Okay. And so do you believe that the
16 statement in paragraph 64 where you say "I do not
17 analyze the details of Garrison" is not completely
18 accurate?

19 A. That's not what I'm saying.

20 I had looked at the Garrison patent.
21 At first glance, I didn't understand how it had any
22 association with the case; hence, my comment about
23 a broad question, but did not express an opinion in
24 that regard.

25 Q. If we could turn to paragraph 75 of

1 Exhibit 2008, and let me know when you are there.

2 A. Okay.

3 Q. In paragraph 75, you state that you
4 do not analyze the construction of aspiration in
5 the preamble of Claim 1. Is that an accurate
6 statement?

7 A. Yes.

8 Q. You then say that you may, if asked,
9 further review and assess the proper construction
10 of this term.

11 Have you been asked to assess the
12 construction of aspiration?

13 A. No.

14 Q. And so is it fair to say that in this
15 IPR relating to the '012 patent, that you have not
16 offered an opinion regarding the construction of
17 aspiration?

18 A. That's correct.

19 Q. Can we turn now to paragraph 165, and
20 let me know when you get there.

21 A. Okay.

22 Q. In paragraph 165, you say that you
23 have not rendered any opinions on secondary
24 considerations of non-obviousness at this time.

25 I understand the "at this time" to

1 refer to the date that you signed the supplemental
2 declaration; is that accurate?

3 A. Yes.

4 Q. And was it a correct statement that
5 you did not offer any opinions on secondary
6 considerations of non-obviousness?

7 A. Yes.

8 Q. You then go on and you say that you
9 reserve the right to analyze evidence of secondary
10 considerations if asked to do so.

11 Have you been asked to evaluate or
12 analyze evidence of secondary considerations in the
13 IPR relating to the '012 patent?

14 A. No, I have not.

15 Q. And so is it fair to say that in this
16 IPR, you do not have any opinions regarding the
17 secondary considerations of non-obviousness?

18 A. That's correct.

19 Q. While we're at the back of Exhibit
20 2008, there is an Attachment 1 that I understand
21 includes your resume. Is that what's reflected in
22 Attachment 1?

23 A. Yes.

24 Q. And is this version of your resume
25 current?

1 A. Yes. I believe so.

2 Q. Okay. Is there anything that you
3 would update or change on the resume?

4 A. No. Not at this time.

5 Q. Okay. If we can turn just to the
6 last page of your resume, there's a heading towards
7 the bottom that says "Other."

8 Do you see that?

9 A. Yes.

10 Q. And underneath that it says, "During
11 the past five years, 2015 to 2020."

12 Do you see that?

13 A. Yes, I do.

14 Q. Okay. And obviously that -- the past
15 five years are not 2015 to 2020, so is this an
16 older section from your resume?

17 A. Yes. I failed to catch that.

18 Q. Have you served as an expert witness
19 during the past five years from 2020 to 2025?

20 A. Yes.

21 Q. And do you keep a list of your expert
22 witness engagements?

23 A. In my home office, I have an
24 abbreviated list, yes.

25 Q. And does that list cover the last

1 five years, 2020 to 2025?

2 A. Yes.

3 Q. And is that something that you could
4 easily retrieve if you were asked to retrieve it?

5 A. Yes.

6 Q. In the last five years, 2020 to 2025,
7 roughly how many depositions do you think you've
8 sat for?

9 A. I would say at least six.

10 Q. And in this other section, you
11 mention testifying in arbitrations. Have you
12 testified in any arbitrations in the last five
13 years?

14 A. I have to go back to my records.
15 There was an arbitration case involving a Stanford
16 start-up, and I just don't recall the exact dates
17 from beginning to end. I think it may have, in
18 fact, gone beyond 2020, but I'd have to check.

19 Q. Have you given any court testimony in
20 the last five years?

21 A. No.

22 Q. In the last five years, have any of
23 your legal engagements involved hemostasis valves
24 other than the current set of matters?

25 A. No.

1 Q. Have any of your engagements in the
2 past five years involved catheters?

3 A. Yes.

4 Q. Okay. And the matters that have
5 involved catheters, what type of catheters were
6 involved?

7 A. The most significant case is called a
8 guide extension catheter which is used in
9 interventional cardiology procedures.

10 Q. And what is the guide extension
11 catheter used for?

12 A. It's used in conjunction with what's
13 called a standard guide catheter that's placed in
14 the ostium of the coronary arteries. The guide
15 extension goes inside that catheter, is advanced
16 into the coronary vasculature to enable the
17 interventionalist to access more distal lesions and
18 to navigate difficult anatomy.

19 Q. There is an Attachment 2 to your
20 declaration, Exhibit 2008.

21 Do you see that?

22 A. Yes.

23 Q. And the title of this attachment, or
24 at least at the top of the chart, it says
25 "Materials Considered."

1 Do you see that?

2 A. Yes.

3 Q. So what is Attachment 2 intended to
4 reflect?

5 A. Basically a summary of the sources of
6 information for me to review prior to expressing an
7 opinion.

8 Q. And did you review all of the
9 documents that are listed in Attachment 2?

10 A. I believe so.

11 Q. And do you believe that you read each
12 of the documents cover to cover?

13 A. I honestly don't know, but I believe
14 so.

15 Q. Okay. And I --

16 A. Excuse me. I didn't read the
17 Collegiate Dictionary cover to cover.

18 Q. Okay. So when you say the Collegiate
19 Dictionary, you're referring to Exhibit 2002?

20 A. Yes.

21 Q. And there are other dictionaries
22 listed here. It's fair to say you didn't read the
23 entire dictionary for all the dictionary references
24 or exhibits; is that fair?

25 A. That's fair.

1 Q. Okay. There are a number of
2 deposition transcripts of Troy Thornton listed on
3 the second page. Did you review those deposition
4 transcripts?

5 A. I don't recall if I reviewed all
6 three. I certainly reviewed some portion.

7 Q. And when you say "some portion," how
8 did you determine what portion of the deposition
9 transcript to review?

10 A. I honestly don't recall.

11 Q. One of the papers listed in this list
12 is paper six, it's on the first page, and it says
13 "Institution Decision."

14 Do you see that?

15 A. Yes.

16 Q. And do you recall reviewing the
17 institution decision for this '012 IPR?

18 A. I recall seeing a document that I
19 didn't pay much attention to, quite frankly, since
20 it's in the legal frame and not the technical
21 frame.

22 Q. Okay. So is it fair to say you did
23 not review that document in depth?

24 A. Yes.

25 Q. Are you aware that the Board in that

1 institution decision disagreed with some of the
2 opinions you offered in Exhibit 2001?

3 MR. HAMILTON: Objection.

4 Mischaracterizes the document.

5 THE WITNESS: I only know some
6 limited comments from counsel.

7 BY MR. STOWELL:

8 Q. Okay. Do you recall reviewing any
9 portions of the institution decision where the
10 Board disagreed with your opinions?

11 A. I recall reviewing a paragraph or
12 two, yes.

13 Q. And what did those paragraphs relate
14 to?

15 A. I'd have to go back and look, quite
16 honestly.

17 Q. And how was it that you identified
18 those specific paragraphs to review?

19 A. Probably just blatant disagreement on
20 my part.

21 Q. Blatant disagreement meaning you
22 disagreed with what the Board was saying?

23 A. In very selected cases, yes.

24 Q. And if you didn't review the
25 institution decision in detail, how was it that you

1 identified the portions of the decision where you
2 had disagreement?

3 A. When you've got numerous documents,
4 you have to pick and choose which ones you're going
5 to scrutinize versus really dwell on. And 95
6 percent of my action was on the patent language and
7 patent issues; 5 percent on other documents such as
8 the one you're referring to. So very skimming kind
9 of review.

10 Q. Is there any document that you
11 considered in forming the opinions in Exhibit 2008
12 that is not listed in Attachment 2?

13 A. Not that I'm aware of at the time.

14 Q. Are there any documents not listed in
15 Attachment 2 that you considered in preparation for
16 your deposition today?

17 A. No.

18 Q. And what did you do to prepare for
19 your deposition today?

20 A. I reviewed the declaration probably
21 over a period of two or three hours.

22 Q. And when you say "the declaration,"
23 are you referring to the supplemental declaration,
24 Exhibit 2008?

25 A. Yes.

1 Q. Did you also review Exhibit 2001 in
2 preparation for your deposition?

3 A. Briefly I did, yes.

4 Q. And when you say "briefly," how much
5 time do you think you spent reviewing Exhibit 2001?

6 A. About an hour and a half on an
7 airplane.

8 Q. Okay. So an hour and a half on
9 Exhibit 2001 and two to three hours on Exhibit
10 2008; is that correct?

11 A. I think that's appropriate, yes.

12 Q. Did you spend time reviewing any
13 other documents besides your declaration in
14 preparation for your deposition today?

15 A. I reviewed, again, the patent
16 specific language and figures, yes.

17 Q. And when you say "the patent," are
18 you referring to the '012 patent?

19 A. Yes.

20 Q. Did you also review any of the prior
21 art patents that are at issue in this IPR?

22 A. Not in preparation for this depo, no.

23 Q. And when I refer to "prior art," is
24 that a term that you are familiar with?

25 A. Yes.

1 Q. And what's your understanding of what
2 "prior art" is?

3 A. In general, publications prior to the
4 patent application that we're talking about, '012,
5 that involve patents, publications, scientific
6 journal articles, and the like.

7 Q. And so in preparation for your
8 deposition today, other than the two declarations
9 in Exhibit 1001, the '012 patent, did you review
10 any other documents?

11 A. No, I don't believe I did.

12 Q. Other than conversations with
13 counsel, did you discuss your deposition with
14 anyone else?

15 A. No.

16 Q. Did you meet with counsel to prepare
17 for your deposition today?

18 A. Yes.

19 Q. And how many times did you meet with
20 counsel?

21 A. We met virtually briefly and then in
22 person once.

23 Q. And "virtually briefly," what do you
24 mean by that?

25 A. A video conference call for

1 significantly less than an hour.

2 Q. And when was that virtual meeting?

3 A. Last week.

4 Q. And who participated in that virtual
5 meeting?

6 A. Just Joe Hamilton and myself.

7 Q. And then you also met with counsel in
8 person one time; is that correct?

9 A. Yes.

10 Q. And when was that meeting?

11 A. Yesterday.

12 Q. And who was present at that meeting?

13 A. Again, just Joe and myself.

14 Q. And how long did that meeting last?

15 A. Approximately four hours.

16 Q. And did you review any documents
17 during that meeting that refreshed your
18 recollection about any of your opinions?

19 A. Yes. We specifically looked at --

20 MR. HAMILTON: Just, you can
21 reveal the identity of documents but not
22 the content of our communications.

23 THE WITNESS: Yeah. We just
24 reviewed certain selected aspects of
25 both declarations.

1 BY MR. STOWELL:

2 Q. And were there any other documents
3 you reviewed during that meeting that refreshed
4 your recollection about your opinions?

5 A. The '012 patent and one or two of the
6 prior art patents.

7 Q. And do you remember what prior art
8 patents?

9 A. Hartley and Eller, in particular.

10 Q. What about the Schaffer reference, do
11 you remember --

12 A. Oh, sorry. And Schaffer.

13 Q. Any other documents you remember
14 reviewing that refreshed your recollection about
15 your opinions?

16 A. A couple dictionary excerpts.

17 Q. Okay. Do you remember reviewing any
18 documents that refreshed your recollection about
19 your opinions that are not listed in Attachment 2
20 of Exhibit 2008?

21 A. No.

22 Q. Have you had the opportunity to
23 review Mr. Thornton's declaration that was
24 submitted for this '012 IPR?

25 A. Yes.

1 Q. And did you review that declaration
2 prior to preparing your declarations, Exhibits 2001
3 and 2008?

4 A. I can't honestly recall the sequence
5 of events, but certainly I responded to his
6 declaration.

7 Q. Did you review Mr. Thornton's
8 declaration in preparation for your deposition
9 today?

10 A. Not in any detail, no.

11 MR. STOWELL: Okay. We've been
12 going a little over an hour. Why don't
13 we take a break.

14 MR. HAMILTON: Sounds good.

15 THE VIDEOGRAPHER: We're off the
16 record at 10:12 a.m.

17 (Recess.)

18 THE VIDEOGRAPHER: This marks
19 the beginning of media number 2. We're
20 on the record at 10:24 a.m.

21 BY MR. STOWELL:

22 Q. Dr. Zalesky, did you talk to anybody
23 about the subject matter of your deposition during
24 the break?

25 A. No.

1 Q. And did you review any documents
2 during the break?

3 A. No.

4 Q. I understand from your previous
5 deposition that you served as the director of R&D
6 at Boston Scientific; is that correct?

7 A. Yes.

8 Q. Okay. And during what years were you
9 the director of R&D?

10 A. 1984 to '86.

11 Q. And I understand that during that
12 time, one of the projects you were involved with
13 was for a guide catheter; is that right?

14 A. Yes.

15 Q. What is a catheter?

16 A. In general, a catheter is a -- is a
17 tube made of various polymers with a lumen, or in
18 some cases, multiple lumens, for the conveyance of
19 either secondary devices or blood withdrawal or
20 tissue sampling, that sort of thing.

21 Q. And are all catheters made with
22 polymers?

23 A. Probably 99 percent.

24 Q. And based on your experience, what
25 are the other one percent made of?

1 A. There are certain limited devices
2 made from, as an example, stainless steel
3 hypotubing. And there's probably a related metal
4 alternative I'm not thinking of right now. But
5 very limited.

6 Q. I'm going to hand you what has been
7 previously marked in this IPR as Exhibit 1013.

8 (Exhibit No. 1013 was
9 previously marked for
10 identification.)

11 BY MR. STOWELL:

12 Q. Dr. Zalesky, did you have an
13 opportunity to review Exhibit 1013 as part of your
14 work on this case?

15 A. I honestly don't recall looking at
16 this.

17 Q. Okay. Are you familiar with
18 Dorland's Illustrated Medical Dictionary from your
19 time in the medical field?

20 A. Yes.

21 Q. Okay. Is it a dictionary that you've
22 used before?

23 A. On limited occasions, yes.

24 Q. And is it generally accepted in the
25 field as a reputable dictionary for medical

1 devices?

2 A. I think -- I believe so, yes.

3 Q. Okay. At the bottom of each page,
4 there are some page numbers. If you could turn to
5 page 306 of the Dorland's Medical Dictionary, and
6 let me know when you're there.

7 A. I'm there.

8 Q. Okay. In the upper right-hand
9 corner, there is a definition for "catheter" that
10 reads, "A tubular, flexible, surgical instrument
11 that is inserted into a cavity of the body to
12 withdraw or introduce fluid."

13 Do you see that?

14 A. I do.

15 Q. And is that definition consistent
16 with your understanding of what a catheter is?

17 A. I think that's one limited aspect of
18 what a catheter is.

19 Q. Okay. Would your definition of
20 catheter be more expansive?

21 A. Yes.

22 Q. And what -- how would your definition
23 be different than the definition that's shown on
24 page 306?

25 A. It would include a much broader

1 category of uses in addition to withdrawing or
2 introducing fluid. As I mentioned a moment ago,
3 the introduction of therapeutic devices or
4 secondary diagnostic devices or adjunct devices.
5 So much broader.

6 Q. Okay. Would you make any other
7 changes to this definition beyond expanding the
8 identified uses?

9 A. I think tubular and flexible are
10 certainly accurate. Surgical is a bit difficult to
11 interpret. Most people would associate that with
12 an operating room. A large number of catheters are
13 not used just in an operating room but bedside,
14 special procedure labs, and even at home. So,
15 again, in my opinion, it would be broadened.

16 Q. And is there a word you would use
17 that you would suggest replacing surgical with?

18 A. Perhaps medical.

19 Q. Other than broadening the identified
20 uses and broadening the term "surgical," are there
21 any other changes you would make to the definition
22 of catheter on page 306?

23 A. I mean, not offhand, no.

24 Q. Okay. So at Boston Scientific, when
25 you were working on the guide catheter, what is a

1 guide catheter?

2 A. As the name suggests, it's really a
3 conveyance tool. And so in the great majority of
4 interventional procedures, whether it's coronary,
5 cerebral, or peripheral vascular, the guide
6 catheter is inserted, either with or in adjunction
7 with a guide wire to approximate the treatment site
8 that's going to be managed by the physician.

9 In the case of coronary artery
10 disease or heart disease, the guide catheter is a
11 100-plus-centimeter long hollow tube basically; has
12 a sandwich construction that is inserted in the --
13 either the groin or the radial artery of the arm,
14 advanced to the ostium of the coronary arteries,
15 and left there as a guide for other devices to be
16 advanced through it or inside of it.

17 And that same general procedure
18 applies to cerebral vascular, peripheral vascular,
19 and other procedures.

20 Q. And so is it fair to say that the
21 guide catheter acts as a conduit for other devices
22 or catheters to be inserted through?

23 A. Yes. I think that's a good word.

24 Q. Are -- does the term "guide catheter"
25 suggest to you any specific structural features for

1 the catheter?

2 A. They can be quite diverse, from a
3 simple single polymer tube to a -- also a typical
4 sandwich construction which has a layer of polymer,
5 a coil of stainless steel, followed by another
6 layer of polymer, which it adds the resistance and
7 kinkability to the device. But lots of variations
8 on a theme.

9 Q. In your mind, is there any difference
10 between a catheter and a guide catheter?

11 A. Per our recent dictionary discussion,
12 catheter is a broader term. A guide catheter,
13 using your word conduit, is used in certain
14 procedures. A guide catheter is not used, for
15 instance, in urethral applications, but a catheter
16 is used in that indication.

17 Q. Do you still consider guide catheters
18 to be catheters, based on the definition of
19 catheter we previously discussed?

20 A. Yes. It's a subdivision of the
21 broader category of catheters.

22 Q. I believe that you testified that the
23 guide catheter you had worked on while you were at
24 Boston Scientific was 6 to 8 French; is that
25 correct?

1 A. Yes, that's my recollection.

2 Q. And did you have two sizes, one 6,
3 and one 8 French?

4 A. Actually, three: 6, 7, and 8.

5 Q. Okay. And were there any challenges
6 that you faced in enlarging the 6 French catheter
7 to an 8 French catheter?

8 A. Not specifically, no. It's the
9 same -- the same technology, the same process used
10 in all three sizes.

11 Q. In your experience, when you were at
12 Boston Scientific, was it common to have multiple
13 sizes of catheters for a specific product line?

14 A. The user required that, depending on
15 what procedure and what other device he was
16 planning on using in a procedure.

17 Q. And why would the user require
18 multiple sizes of catheters?

19 A. Smaller is better in most procedures.
20 But there are certain procedures or certain patient
21 categories where either a larger therapeutic device
22 is going to be used or more than one device will be
23 advanced through that same guide catheter; hence,
24 the need for a larger lumen.

25 Q. While you were at Boston Scientific,

1 was an 8 French catheter the largest catheter you
2 worked on?

3 A. I believe so.

4 Q. In your time in industry, have you
5 ever worked on catheters that were larger than 8
6 French?

7 A. You know, I'm trying to go through a
8 memory here. But at Baxter and working in
9 cardiopulmonary bypass, there were certain adjunct
10 cannulas, for instance, that were larger than that,
11 yes.

12 Q. What do you mean by an "adjunct
13 cannula"?

14 A. So the way bypass works is you're
15 pulling blood from the heart and injecting it into
16 the aorta distal to the heart. And, typically, a
17 cannula, which is another catheter of sorts, it's a
18 hollow tube, is used on both ends of that process.

19 Q. And so based on the definition of
20 catheter we looked at previously, would the
21 cannulas you worked with at Baxter be considered a
22 catheter?

23 A. Yes.

24 Q. And what was the size of the cannulas
25 you worked on while you were at Baxter?

1 A. There was a range, depending on the
2 patient category, from pediatric through adults. I
3 do remember certainly 16 and 18 French devices
4 being involved.

5 Q. And what years did you work at
6 Baxter?

7 A. 1990 to 1994.

8 Q. And were you aware of 16 French and
9 18 French catheters being used in other
10 applications before you used them for the cannulas
11 at Baxter?

12 A. You know, I honestly don't recall.

13 Q. Do you believe that Baxter invented
14 the 16 French or 18 French cannula?

15 A. I don't know the history of the
16 development of those cannulas. They were fairly
17 commonplace at that point in time.

18 Q. Is the 18 French catheter the largest
19 catheter that you've worked on in your career?

20 A. As I said, I recall specifically 16
21 and 18s, but there may -- there may well have been
22 a 20 or even larger French catheter in that
23 cardiopulmonary bypass setting.

24 Q. And why do you suspect that there
25 could have been a larger catheter in that setting?

1 A. There was the occasional extremely
2 large patient with large volumes of blood involved
3 that would require even larger lumens; hence, the
4 larger size.

5 Q. And in making or in increasing the
6 size of a catheter from 16 French to 20 French,
7 were there any particular hurdles or challenges
8 that Baxter faced in creating those devices?

9 A. As I recall, the only real concern
10 was the wall thickness that would minimize kinking
11 of such a large catheter.

12 Q. And so in moving from a 16 French
13 catheter to a 20 French catheter, would the wall
14 thickness of the catheter change?

15 A. Not necessarily, but it could.

16 Q. The modification of wall thickness of
17 a catheter, was that something that a catheter
18 engineer would routinely try to optimize during
19 catheter design?

20 A. Yes. In the spirit that smaller is
21 better, the proverbial requirement that we
22 engineers have responded to is they want an
23 infinite ID and a zero OD. So the challenge is
24 always to minimize that wall thickness while
25 retaining certain handling and physical properties.

1 Q. And so at this time in the 1990s,
2 would a person of ordinary skill in the art have
3 possessed the knowledge to make those changes to
4 catheter thickness?

5 A. Yes.

6 Q. We've talked about your experience at
7 Baxter. Are there any other experiences you can
8 recall where you worked with a catheter that was 16
9 French or larger?

10 A. Not offhand, no.

11 Q. I understand from the prior
12 deposition that while you were at Boston Scientific
13 working on the guide catheter that there were some
14 physicians who used that guide catheter to aspirate
15 material from a patient. Is my understanding
16 correct?

17 A. I don't recall specifying that level
18 of detail, no.

19 Q. Okay. Do you ever recall the guide
20 catheter that you worked on with Boston Scientific
21 being used as an aspiration catheter?

22 A. No, I do not. Its primary indication
23 was as a conduit.

24 Q. Okay. Have you ever worked on any
25 catheters that were used as aspiration catheters?

1 A. I'm sure I have. But I'd have to dig
2 through my memoirs to figure out exactly when that
3 was and what that was. And I say that because
4 physicians are always entrepre- -- not always,
5 they're often entrepreneurial, and can take a
6 catheter with another indication and use it for
7 their own indications, such as taking a standard
8 hollow single-lumen catheter and using it for a
9 thrombectomy procedure.

10 Q. And in your experience, do you recall
11 observing that, where a physician would take a
12 catheter intended for some other purpose and use it
13 for aspiration thrombectomy?

14 MR. HAMILTON: Objection.

15 Vague. Mischaracterizes the testimony.

16 THE WITNESS: I saw that happen
17 on a few occasions in a special
18 procedures lab, yes. I can't recall the
19 details, but I do recall the general
20 sense.

21 BY MR. STOWELL:

22 Q. What is a special procedures lab?

23 A. Typically, it involves a patient
24 table, not different from an operating room table,
25 with x-ray equipment and additional imaging

1 equipment used to both diagnose and to guide the
2 procedure such as angioplasty or stent placement.

3 Q. And these procedures you observed in
4 the special procedures lab, what time period
5 would -- would this have taken place?

6 A. All the way from 1984 through 2015 or
7 so.

8 Q. And during those years, you recall
9 instances where a physician would use a catheter
10 intended for a different purpose for aspiration
11 thrombectomy?

12 MR. HAMILTON: Objection.

13 Mischaracterizes the testimony.

14 THE WITNESS: I recall some
15 occasions where that was done, yes.

16 BY MR. STOWELL:

17 Q. And in those occasions, do you recall
18 if the physicians needed to make any modifications
19 to the catheters in order to use them for
20 aspiration?

21 MR. HAMILTON: Objection.

22 Vague.

23 THE WITNESS: The only
24 modification I can recall is taking a
25 catheter or two, in certain

1 circumstance, and adjusting its
2 geometry. So some of these catheters
3 are formable in the sense that you can
4 modify the tip geometry to a curvature.

5 BY MR. STOWELL:

6 Q. And how does the doctor make that
7 modification to the geometry?

8 A. Simply with his hands.

9 Q. So the physician physically bends the
10 catheter; is that right?

11 A. Yes. Pretty much.

12 Q. In the aspiration thrombectomy
13 procedures that we're talking about, how was the
14 suction or negative pressure created for the
15 catheter?

16 A. Simply with a syringe.

17 Q. And how would the syringe be
18 connected to the catheter?

19 A. In virtually every case, there's a
20 Tuohy Borst connector, and within that is a
21 hemostasis valve, which is an axial valve, if you
22 will. And the catheter is simply inserted through
23 that Tuohy Borst into the patient.

24 Q. And then how is the syringe attached
25 to the catheter to generate the negative pressure?

1 A. I recall seeing a stopcock proximal
2 to the Tuohy Borst and then the syringe attached to
3 the two-way stopcock.

4 Q. And did the stopcock have some sort
5 of connector on it that the syringe could be
6 attached to?

7 A. The stopcock would have at least two
8 ports, one of which would be attached to the
9 syringe.

10 Q. And would the stopcock have some sort
11 of standard connector that could be used to attach
12 other devices to it?

13 A. As I said, it would have at least two
14 ports so the secondary port could be utilized for
15 something else. I don't recall seeing that, but it
16 could be.

17 Q. But you recall the syringe being
18 attached to one of the ports of the stopcock; is
19 that correct?

20 A. Yes.

21 Q. And do you recall if that connector
22 was a standard lure-type connector?

23 A. Yes. There was nothing specialized
24 about it.

25 Q. When I say "lure-type connector," do

1 you know what type of --

2 A. Yes.

3 Q. -- connecter I'm referring to?

4 And in this time period from the
5 mid-1980s through 2015, did you have experience
6 using lure connectors in the medical devices that
7 you worked on?

8 A. Probably as routine as the Tuohy
9 Borst.

10 Q. So very common?

11 A. Yes, very common.

12 Q. Okay. Were there any other types of
13 standard connectors that you dealt with frequently
14 between the mid-'80s and 2015, other than a
15 lure-type connecter?

16 A. No. None that -- not that I can
17 recall.

18 Q. Okay. Have you ever worked with
19 barbed connectors?

20 A. I don't believe so.

21 Q. And do lure connectors come in
22 different sizes?

23 A. Yes. Because of their need to mate
24 with the other device or devices.

25 Q. When do you first remember using

1 lure-type connectors?

2 A. That same time period. So going back
3 to 1984.

4 Q. On the aspiration procedures we were
5 talking about that you observed between the
6 mid-'80s and 2015, do you ever remember any other
7 devices used to create negative pressure, other
8 than a syringe?

9 A. Not in the clinical setting, and by
10 that I mean patient setting, no.

11 Q. What about in the experimental
12 setting?

13 A. I recall seeing -- but I couldn't
14 tell you precisely when or where -- a small pump
15 being used in an animal study.

16 Q. And the pump would be used to create
17 negative pressure for an aspiration catheter?

18 A. Yes.

19 Q. And would that experience have been
20 before, say, 2015?

21 A. Yes.

22 Q. The term "aspiration catheter," does
23 that term make you think of any specific structural
24 features of the catheter?

25 MR. HAMILTON: Objection.

1 Beyond the scope.

2 THE WITNESS: No. No.

3 MR. HAMILTON: I'm also going to
4 add an objection, vague, to the last
5 question.

6 BY MR. STOWELL:

7 Q. In your experience, can most
8 catheters be used as an aspiration catheter if the
9 catheter has the appropriate connector and there's
10 no syringe available?

11 MR. HAMILTON: Objection.

12 Vague. Beyond the scope.

13 THE WITNESS: I don't think I'd
14 say most catheters, no.

15 BY MR. STOWELL:

16 Q. And why not?

17 A. As I mentioned earlier, there's a --
18 a large variety of specialized catheters for
19 specialized indications with one lumen, multiple
20 lumens, various tip designs, various indications
21 for use. Whereas, aspiration requires at least one
22 channel that's clean and clear from one end to the
23 other.

24 BY MR. STOWELL:

25 Q. Would you agree that most single

1 lumen catheters could be used as an aspiration
2 catheter?

3 MR. HAMILTON: Objection.

4 Beyond the scope. Vague.

5 THE WITNESS: I think most, yes.

6 BY MR. STOWELL:

7 Q. Let's look at paragraph 16 of your
8 supplemental declaration, which is Exhibit 2008.
9 Why did you feel it was important to include
10 paragraph 16 in this section of your report?

11 A. I prepared this background statement
12 for, frankly, multiple uses with -- obviously,
13 tailored to each particular client. But this to me
14 was part of the pertinent background.

15 Q. And this paragraph focuses on the
16 years 1995 to 2005.

17 Is there a reason that you focus on
18 that time period in this paragraph?

19 A. That's when I was most directly
20 involved with angioplasty procedures and
21 angioplasty devices, all of which required a guide
22 catheter.

23 Q. In the angioplasty procedures that
24 you worked on between 1995 and 2005, were any other
25 subcategories of catheters used in those procedures

1 besides a guide catheter?

2 A. There were diagnostic catheters, of
3 course, which included blood sampling or electrode
4 catheters to measure electrical activity in various
5 parts of the heart, as well as infusion of
6 pharmaceuticals or special agents, dye for contrast
7 angiography studies, diagnostic what's called
8 intervascular ultrasound to characterize the inside
9 of a diseased vessel. And I'm sure I could come up
10 with 10 or 20 others. Quite a lot.

11 Q. And in the typical angioplasty
12 procedure, were all of those ancillary catheters
13 inserted through the guide catheter?

14 A. Almost all, I would say.

15 Q. In paragraph 16, you list some of the
16 catheter configurations that were developed and
17 tested. Was the size or the, let's say, the
18 diameter of the catheter one of the configurations
19 that was developed or changed between these
20 catheters?

21 A. The size was driven primarily by the
22 indication for use. A peripheral venous catheter
23 would almost always be larger than an
24 interventional coronary catheter as an example.

25 Q. And so the -- during this time

1 period, 1995 to 2005, the catheter size would
2 typically be chosen based on the procedure?

3 A. It would be based primarily on the
4 procedure and what the physician intended to treat
5 with.

6 Q. And who would make the decision about
7 what catheter to use to treat a patient?

8 A. Always the treating physician.

9 Q. And do you know what factors the
10 treating physician would consider in selecting the
11 size of catheter in this time period, 1995 to 2005?

12 A. The same two factors I mentioned,
13 which is the patient's anatomy and his intended
14 therapeutic or diagnostic device for that
15 particular patient.

16 Q. You indicate in paragraph 16 that
17 variations in thrombectomy were being developed in
18 this time period of 1995 to 2005. What do you mean
19 by thrombectomy?

20 A. Simply the removal of thrombus in
21 vasculature.

22 Q. And during this time period, was --
23 were variations of aspiration thrombectomy being
24 developed?

25 A. I don't recall specific attention to

1 just aspiration. I recall more attention to
2 dislodgement or fragmentation of the thrombus.

3 Q. And those methods to dislodge the
4 thrombus, would there have been an aspiration
5 component to those systems?

6 A. Typically, a single-lumen catheter
7 could deliver a disruptive device, such as an
8 ultrasonic probe or mechanical device or a chemical
9 agent like a thrombo lysine, and then that same
10 catheter being used to apply suction to remove the
11 remains of the thrombus.

12 Q. And during this time period, 1995 to
13 2005, do you remember observing catheters being
14 used to aspirate emboli from a patient?

15 A. Yes. In a special procedures lab.

16 Q. And so do you consider the use of an
17 aspiration catheter to remove a blood clot from a
18 patient a thrombectomy procedure?

19 A. Yes.

20 MR. HAMILTON: For that last
21 question, I'm going to add an objection.

22 Vague. Calls for a legal conclusion.

23 BY MR. STOWELL:

24 Q. Have you ever performed an aspiration
25 procedure yourself?

1 A. No.

2 Q. And have you ever designed an
3 aspiration system for a thrombectomy procedure?

4 A. No, I have not.

5 Q. The aspiration thrombectomy
6 procedures you recall seeing in 1995 to 2005, what
7 parts of the body was the blood clot being
8 aspirated from?

9 A. Primarily the coronary arteries of
10 the heart.

11 Q. Do you recall seeing procedures in
12 any other parts of the body?

13 A. I recall seeing, you know, a limited
14 number of procedures involving the peripheral
15 veins.

16 Q. Do you ever remember seeing any
17 procedures where aspiration was performed in the
18 cerebral vasculature during the 1995 to 2005 time
19 period?

20 A. I believe I saw a small number of
21 those in a Boston hospital in that time period.

22 Q. Do you recall seeing any aspirational
23 procedures to remove blood clots that were done in
24 the pulmonary vasculature during the 1995 to 2005
25 time period?

1 A. I only saw images taken on videotape,
2 but not the actual procedure.

3 Q. But was it your understanding that
4 blood clots were removed from the pulmonary
5 vasculature in the proceedings where you viewed the
6 video?

7 A. Yes.

8 Q. And in these aspiration procedures
9 that you witnessed from 1995 to 2005, were the same
10 types of catheters used in each procedure?

11 MR. HAMILTON: Objection.

12 Vague.

13 THE WITNESS: I honestly don't
14 recall.

15 BY MR. STOWELL:

16 Q. Do you recall if all of the
17 procedures involved a single-lumen catheter?

18 A. I honestly don't recall.

19 Q. Do you recall whether the sizing of
20 the catheter differed at all between the
21 procedures?

22 A. Certainly the coronary procedures
23 were smaller catheters and peripheral venous, and
24 the cerebral vascular were even smaller.

25 Q. And when you say the coronary was

1 smaller, what size are you thinking?

2 A. Six French would be big for a
3 coronary procedure.

4 Q. And what about for peripheral?

5 A. Eight or 10 French would not be
6 extreme.

7 Q. And what about cerebral?

8 A. Probably less than 5 French.

9 Q. And the catheters that were used in
10 the aspiration procedures you observed between 1995
11 and 2005, were those catheters specifically
12 designed for aspiration thrombectomy?

13 A. I honestly don't know.

14 Q. Could they have been catheters
15 designed for another purpose that the doctor
16 decided to use for aspiration?

17 MR. HAMILTON: Objection. Asked
18 and answered.

19 THE WITNESS: Yes.

20 BY MR. STOWELL:

21 Q. You mentioned that in some of the
22 procedures you observed, there was a stopcock that
23 would be used to connect the syringe to the
24 aspiration catheter; is that accurate?

25 A. Yes.

1 Q. And how would the stopcock be used in
2 the procedure?

3 A. The stopcock essentially allowed the
4 connection of a syringe to put in line with a
5 catheter, and could be open or closed depending on
6 what was going on.

7 Q. And were there specific instances
8 where you recall the stopcock being closed during
9 the procedure?

10 A. Yes. Typically during manipulation
11 of the catheter.

12 Q. And do you ever recall the stopcock
13 being closed while the syringe was pulled back and
14 pressurized?

15 A. I don't recall the details, to be
16 honest.

17 Q. Were you familiar with Y-arm
18 connectors during this period, 1995 to 2005?

19 A. It's not ringing a bell. I may have
20 but it's not ringing a bell.

21 Q. Okay. You're not -- why I say the
22 term a "Y-arm connector," that doesn't mean
23 anything?

24 A. Not a term that I used, no.

25 Q. Okay. Let's look at paragraph 78 of

1 Exhibit 2008.

2 So I understand that in rendering the
3 opinions in Exhibit 2008, you have applied the
4 Petitioner's definition of a person of ordinary
5 skill in the art; is that correct?

6 A. Yes. With the disclaimer that's in
7 this paragraph 78.

8 Q. And what disclaimer is that?

9 A. Even under this too low definition of
10 ordinary skill.

11 Q. Okay. So you think that the
12 definition of a POSITA that was proposed by the
13 Petitioner is too low; is that correct?

14 A. I don't know if "low" is the right
15 phrase, but I didn't believe it was sufficient.

16 Q. Okay. You believe that the person of
17 ordinary skill in the art would have had more
18 experience than is reflected in Petitioner's
19 definition; is that correct?

20 A. Yes. In particular with regard to
21 medical procedures and medical devices.

22 Q. Okay. And then despite that
23 difference of opinion, when you were rendering the
24 opinions in Exhibit 2008, you still applied the
25 definition of a POSITA that the Petitioner used,

1 right?

2 A. Yes.

3 Q. Okay. I'm going to hand you what has
4 been previously marked in this IPR as Exhibit 1001.
5 (Exhibit No. 1001 was
6 previously marked for
7 identification.)

8 BY MR. STOWELL:

9 Q. Dr. Zalesky, do you recognize
10 Exhibit 1001?

11 A. This is the '012 patent which is the
12 subject matter of my supplemental declaration.

13 Q. Okay. And is this a patent that you
14 have reviewed in preparing your supplemental
15 declaration, Exhibit 2008?

16 A. Yes. I believe so.

17 Q. Okay. And do you believe this to be
18 a complete copy of the '012 patent that you
19 reviewed?

20 A. Again, I believe so.

21 Q. And how many times do you think
22 you've reviewed this patent?

23 A. Probably 10 or 12 times.

24 Q. When you've reviewed this patent,
25 have there been any portions of it that you have

1 not understood?

2 A. I don't believe so.

3 Q. The -- there are some inventors
4 listed on the first page of the patent. Have you
5 ever spoken to any of the inventors?

6 A. No.

7 Q. Have you ever reviewed any literature
8 other than this patent, that was authored by any of
9 the inventors?

10 A. I don't believe so.

11 Q. Prior to becoming involved in the
12 matters between Imperative Care and Inari Medical,
13 were you aware or familiar with any of these
14 inventors?

15 A. No.

16 Q. If you could turn to Figures 6 and 7
17 of the '012 patent.

18 And let me know when you're there.

19 A. Okay.

20 Q. So starting with Figure 6, what does
21 Figure 6 show?

22 MR. HAMILTON: Objection.

23 Vague.

24 THE WITNESS: It depicts a
25 single filament in a configuration of a

1 loop.

2 BY MR. STOWELL:

3 Q. And there's an area, 604, identified
4 with an arrow.

5 Do you see that?

6 A. Yes.

7 Q. And am I correct in stating that in
8 the actual device, the tubular element would extend
9 through that area 604?

10 MR. HAMILTON: Objection.

11 Vague.

12 THE WITNESS: Yes.

13 BY MR. STOWELL:

14 Q. And in Figure 6, the tubular element
15 is not shown, correct?

16 A. Yes.

17 Q. And is it your understanding that the
18 filament shown in Figure 6 would circumferentially
19 constrict a tubular member that's extending through
20 that opening 604?

21 MR. HAMILTON: Objection. Calls
22 for a legal conclusion.

23 THE WITNESS: It would
24 circumferentially constrict around the
25 outside of that tubular member.

1 BY MR. STOWELL:

2 Q. Okay. And do you see at the top how
3 the -- of Figure 6, how the filaments are parallel
4 to each other?

5 A. Yes.

6 Q. If the gap between those two portions
7 of the filament were wider, say a couple of
8 centimeters, do you believe that the filament would
9 still constrict or circumferentially constrict a
10 tubular member going through opening 604?

11 MR. HAMILTON: Objection.

12 Vague. Calls for a legal conclusion.

13 THE WITNESS: I'm not sure what
14 you're referring to as "the gap."

15 BY MR. STOWELL:

16 Q. Sure. So at the top of the figure,
17 there's a place where the filament is parallel to
18 each other, correct?

19 A. Correct.

20 Q. Okay. So if there were a gap between
21 those two portions of the filament that are
22 parallel to each other a few millimeters so that
23 it's observable --

24 Are you with me?

25 A. Yes.

1 Q. Okay.

2 If there was a gap between those two
3 portions of the filament, would you still opine
4 that the filament circumferentially constricts a
5 tubular member going through opening 604?

6 MR. HAMILTON: Objection.

7 Incomplete hypothetical. Beyond the
8 scope.

9 THE WITNESS: With a significant
10 gap, I don't expect it to be
11 circumferential.

12 BY MR. STOWELL:

13 Q. And why is that?

14 A. Circumferentially, of course, implies
15 a circle or a circular configuration. With a
16 significant gap, you would lose the circular
17 configuration.

18 Q. And how big would the gap have to be
19 between the portions of the filament for the
20 filament to no longer circumferentially constrict
21 the tubular member?

22 MR. HAMILTON: Objection.

23 Incomplete hypothetical. Beyond the
24 scope.

25 THE WITNESS: I honestly don't

1 know how to answer that. I -- I think
2 the only word I can use is
3 "significant."

4 BY MR. STOWELL:

5 Q. And in your mind, does significant,
6 within the context of this invention, have any
7 specific measurements or dimensions?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical. Beyond the
10 scope.

11 THE WITNESS: No. I can't
12 honestly think of a particular
13 dimension. It would be very small.

14 BY MR. STOWELL:

15 Q. And what do you mean by "very small"?

16 MR. HAMILTON: Objection.

17 Incomplete hypothetical. Beyond the
18 scope.

19 THE WITNESS: I think a
20 millimeter would be very small.

21 BY MR. STOWELL:

22 Q. And so is it your opinion that if the
23 two -- the filament -- the two portions of the
24 filament in Figure 6 were more than a millimeter
25 apart, that the filament would not

1 circumferentially constrict a tubular member going
2 through the opening 604?

3 MR. HAMILTON: Objection.

4 Incomplete hypothetical. Beyond the
5 scope.

6 THE WITNESS: Frankly, my answer
7 can only be pure speculation.

8 BY MR. STOWELL:

9 Q. Would it be correct to say that you
10 don't have an opinion on how far apart the portions
11 of the filament would need to be for the filament
12 not to circumferentially constrict a tubular
13 member?

14 MR. HAMILTON: Objection.

15 Incomplete hypothetical. Beyond the
16 scope.

17 THE WITNESS: I think it's a
18 theoretical question; hence, my
19 reluctance to speculate.

20 BY MR. STOWELL:

21 Q. Earlier you had testified that the --
22 you believe that the filament that is pictured in
23 Figure 6 would circumferentially constrict a
24 tubular member going through opening 604, correct?

25 A. Yes.

1 Q. And what led you to that conclusion?

2 MR. HAMILTON: Objection.

3 Vague.

4 THE WITNESS: The combination of
5 the figures -- this particular figure
6 and the written description in the claim
7 all speak to the ability of a thin, for
8 lack of a better term, flexible filament
9 to decrease its radius as either -- and
10 it's pulled around a tubular element, is
11 consistent with a circumferential
12 reduction around the tubular element.

13 BY MR. STOWELL:

14 Q. In Figure 6, are you interpreting
15 Figure 6 to show that the two portions of the
16 filament at the top of the figure are touching each
17 other?

18 MR. HAMILTON: Objection.

19 Vague.

20 THE WITNESS: I would say yes,
21 in general, to that.

22 BY MR. STOWELL:

23 Q. Okay. Why do you say "in general"?

24 A. When you say "touching," it implies
25 absolutely no spacing, whatsoever, not even a

1 micron. Because of the nature of physical
2 structures, they might be one micron apart so
3 they're not actually touching, but to the naked
4 eye, that would be undetectable.

5 Q. And so if there were a very small
6 space between the portions of the filaments at the
7 top of Figure 6, you would still consider the
8 filament to circumferentially constrict a tubular
9 member extending through opening 604?

10 MR. HAMILTON: Objection.
11 Incomplete hypothetical.

12 THE WITNESS: As I said, this is
13 just speculation. In general, I
14 perceive this as them touching or just
15 about touching; hence, the term
16 "garrotte."

17 BY MR. STOWELL:

18 Q. When you were forming your opinions
19 about the '012 patent, what did you understand the
20 term "circumferentially constrict" to mean?

21 MR. HAMILTON: Objection.
22 Vague.

23 THE WITNESS: The word
24 "circumferential" means precisely that:
25 It includes a complete circumference or

1 a full 360-degree circle, and the
2 reduction or compression, or whatever
3 term you want to use, is associated with
4 an equal force coming from that entire
5 circumference.

6 BY MR. STOWELL:

7 Q. And so are you understanding the term
8 "circumferentially constrict" to require the device
9 that is constricting to form a circle?

10 MR. HAMILTON: Objection.
11 Vague.

12 THE WITNESS: Yes. With
13 reference to Figure 6, yes.

14 BY MR. STOWELL:

15 Q. And do you believe that Figure 6
16 illustrates a circle?

17 A. Yes, I do.

18 Q. When you were forming your opinions
19 about the '012 patent, what did you understand the
20 term "loop" to mean?

21 A. My understanding of "loop" is a
22 complete circle; hence, the word "circumferential"
23 associated with a complete circle.

24 Q. In your understanding of the term
25 "loop," is there any difference between a "loop"

1 and a "circle"?

2 MR. HAMILTON: Objection.

3 Vague.

4 THE WITNESS: Not in this
5 particular context. In another context,
6 a loop could have a different geometry.
7 In this context, it's a circle.

8 BY MR. STOWELL:

9 Q. And so in the context of the '012
10 patent, you understand the term "loop" to be
11 synonymous with "circle"; is that correct?

12 MR. HAMILTON: Objection.

13 Mischaracterizes the testimony. Vague.

14 THE WITNESS: Yes.

15 BY MR. STOWELL:

16 Q. And outside of the '012 patent, you
17 would agree that "loop," the term "loop," could
18 mean configurations other than only a circle,
19 correct?

20 MR. HAMILTON: Objection.

21 Vague. Beyond the scope.

22 THE WITNESS: I've seen the word
23 used with respect to things like
24 jewelry, as an example.

25 BY MR. STOWELL:

1 Q. And when you refer to jewelry, are
2 you referring to examples of jewelry where the loop
3 in the jewelry does not form a perfect circle?

4 A. In that context, outside of this,
5 yes.

6 Q. And is it your opinion that a person
7 of ordinary skill in the art, in September of 2017,
8 reviewing the '012 patent would have viewed the
9 term or would have understood the term "loop" to be
10 synonymous with "circle"?

11 MR. HAMILTON: Objection.

12 Mischaracterizes the testimony.

13 THE WITNESS: Yeah, I believe
14 the specification makes it clear cut.

15 MR. HAMILTON: For that last
16 question, also vague. Objection.

17 Vague.

18 BY MR. STOWELL:

19 Q. Do you believe that the filament
20 depicted in Figure 6 of the '012 patent has a loop?

21 MR. HAMILTON: Objection. Asked
22 and answered.

23 THE WITNESS: Yes.

24 BY MR. STOWELL:

25 Q. And is there a portion of the

1 filament that's pictured in Figure 6 that you would
2 consider to be the loop?

3 A. The loop is a central circular
4 depiction.

5 Q. So if we look at Figure 6 and we look
6 at the top of the figure, there are two little
7 lines at the top there where the filament portions
8 are parallel to each other. Would the portion of
9 the filament that is between those two lines be the
10 loop in your opinion?

11 MR. HAMILTON: Objection.

12 Vague. Beyond the scope.

13 THE WITNESS: If I understand
14 your question correctly, I don't believe
15 so. The loop is where the 360-degree
16 completion occurs with the two ends of
17 the filament.

18 BY MR. STOWELL:

19 Q. And on Figure 6, where do you believe
20 that would occur?

21 A. In this figure right where they
22 appear to be tangential. So just to the left of
23 the lower mark that you just referenced.

24 Q. So at the top of Figure 6, there's a
25 mark on the filament that is to the left of the

1 second mark, and you're saying that the place where
2 the filaments are tangential is just to the left of
3 that first mark; is that right?

4 MR. HAMILTON: Objection.

5 Vague.

6 THE WITNESS: I think it's
7 important to note what you're seeing is,
8 you know, one particular aspect of a
9 loop formation that is being constricted
10 over time. And so this is a snapshot of
11 a particular dimension that changes as
12 the filaments are tugged or pulled. So
13 at this particular moment where they
14 cross is the completion of that
15 360-degree circuit.

16 BY MR. STOWELL:

17 Q. What are we seeing in Figure 7 of the
18 '012 patent?

19 MR. HAMILTON: Objection.

20 Vague.

21 THE WITNESS: My understanding
22 of this is just another embodiment that
23 involves two loops instead of one loop.

24 BY MR. STOWELL:

25 Q. And based on your review of the '012

1 patent, are there any benefits to having two loops?

2 MR. HAMILTON: Objection.

3 Beyond the scope.

4 THE WITNESS: Only in theory.

5 BY MR. STOWELL:

6 Q. In theory, what would the benefits be
7 for two loops?

8 MR. HAMILTON: Objection.

9 Vague. Beyond the scope.

10 THE WITNESS: The ability to
11 apply a greater total amount of force of
12 constriction.

13 BY MR. STOWELL:

14 Q. And how would two loops apply a
15 greater amount of force?

16 A. Put a little bit differently, at two
17 different points in the enclosed tubular structure.

18 Q. And so would the area of constriction
19 increase with two loops as opposed to one loop?

20 MR. HAMILTON: Objection.

21 Vague.

22 THE WITNESS: No, not
23 necessarily.

24 BY MR. STOWELL:

25 Q. Okay. And so when you say a greater

1 total amount of force at two different points in
2 the enclosed tubular structure, what are you
3 referring to?

4 A. When I say two different points, I
5 mean axially or longitudinally along the tubular
6 member.

7 Q. And what would be the benefit of
8 applying a constricting force at two different
9 points along the tubular member?

10 MR. HAMILTON: Objection.

11 Incomplete hypothetical.

12 THE WITNESS: In practice, I'm
13 honestly not sure. In theory, under
14 some dire high-pressure event going on
15 inside the tubular structure, there
16 could be an advantage, but
17 theoretically.

18 BY MR. STOWELL:

19 Q. And you mentioned a "dire
20 high-pressure event." What -- why did you specify
21 a dire high-pressure event?

22 A. If you're dealing with a patient
23 medicated with a blood thinner, with elevated blood
24 pressure, and you're dealing with a thrombus in a
25 high-pressure artery, that would probably be the

1 most challenging valve function case. So "dire" is
2 probably the wrong word. But a more challenging
3 circumstance of the pressure inside the tubular
4 structure.

5 Q. And in that type of procedure, you
6 could see an advantage to having two loops around
7 the tubular member of the hemostasis valve?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical. Vague.

10 THE WITNESS: As I said, in
11 practice, I'm not at all sure it would
12 help. I only mention in theory. I
13 think I could put together an equation,
14 but theoretical.

15 BY MR. STOWELL:

16 Q. Do you ever recall any instances
17 where you observed two filaments being used to
18 constrict or ligate the tubular member?

19 MR. HAMILTON: Objection.

20 Vague.

21 THE WITNESS: No.

22 BY MR. STOWELL:

23 Q. Would including two looped filaments
24 in the hemostasis valve described in the '012
25 patent make the valve more difficult to

1 manufacture?

2 A. I could only speculate on that
3 without seeing a particular configuration.

4 Q. So is it fair to say you don't have
5 an opinion on whether two loops would make it more
6 difficult to manufacture?

7 MR. HAMILTON: Objection.
8 Mischaracterizes the testimony.
9 Incomplete hypothetical.

10 THE WITNESS: I don't really
11 have a strong opinion.

12 BY MR. STOWELL:

13 Q. Do you have any opinion?

14 MR. HAMILTON: Again, same
15 objections. incomplete hypothetical;
16 mischaracterizes the testimony.

17 THE WITNESS: When you have more
18 components or more materials, you could
19 argue you have more structure to deal
20 with. By that definition, it could be
21 incrementally more difficult, but not
22 particularly.

23 BY MR. STOWELL:

24 Q. Do you think it would have been so
25 much more difficult that it would have discouraged

1 a person of ordinary skill in the art from using
2 two loops?

3 MR. HAMILTON: Objection.

4 Beyond the scope. Incomplete
5 hypothetical.

6 THE WITNESS: No.

7 BY MR. STOWELL:

8 Q. Would using two filaments that form
9 two loops have any advantages for the durability of
10 the valve that you can think of based on your
11 experience?

12 MR. HAMILTON: Objection.

13 Incomplete hypothetical. Vague.

14 THE WITNESS: No.

15 BY MR. STOWELL:

16 Q. Would having two filaments forming
17 two loops create a redundancy in the system that
18 could be advantageous?

19 MR. HAMILTON: Again, objection.

20 Incomplete hypothetical. Vague.

21 THE WITNESS: As I'm sure you
22 know, redundancy in any device is an
23 added protective feature. So in that
24 sense, yes. But, again, theoretical in
25 this case.

1 BY MR. STOWELL:

2 Q. Let's look at Figures 8 and 9. Are
3 these figures that you have reviewed as part of
4 forming your opinions in Exhibit 2008?

5 A. Yes.

6 MR. HAMILTON: Just for a quick
7 moment, can we pause for just a second.
8 My realtime is no longer working.

9 THE VIDEOGRAPHER: We're off the
10 record at 11:31 a.m.

11 (Recess.)

12 THE VIDEOGRAPHER: This marks
13 the beginning of media number 3.

14 We're on the record at
15 11:37 a.m.

16 BY MR. STOWELL:

17 Q. Dr. Zalesky, during the break, did
18 you review any documents?

19 A. No.

20 Q. And did you talk to anybody about the
21 subject matter of your deposition testimony?

22 A. No.

23 Q. And do you have Figures 8 and 9 of
24 the '012 patent in front of you still?

25 A. I do.

1 Q. And based on your review of the '012
2 patent, what do you understand Figure 8 to depict?

3 MR. HAMILTON: Objection.
4 Vague.

5 THE WITNESS: From the
6 specification, these are so-called bites
7 made from the same filamentous material
8 in a different configuration.

9 BY MR. STOWELL:

10 Q. And do you understand that the bites
11 in Figures 8 and 9 are interlocking?

12 A. Yes.

13 Q. And do you understand that the patent
14 also explains that the bites could be
15 non-interlocking?

16 A. I recall some reference to that.

17 Q. Do you want to review the reference
18 to refresh your recollection?

19 A. Can you point me?

20 Q. Yeah. If you look at paragraph 13 --
21 or sorry, column 13, starting at line 36.

22 A. 13, 36?

23 Q. Yeah.

24 A. Okay. Yes.

25 Q. And is that the portion of the '012

1 patent you were thinking of when you said you
2 recalled a portion referring to non-interlocking
3 bites?

4 A. Yes.

5 Q. Okay. In Figures 8 and 9, do you
6 have an understanding of how these figures would
7 change if the bites were non-interlocking?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical.

10 THE WITNESS: I don't understand
11 the question.

12 BY MR. STOWELL:

13 Q. And what part of the question was
14 unclear?

15 A. Just -- if you could just restate it,
16 please.

17 Q. Do you have an understanding of how
18 Figures 8 and 9 would change if the bites were
19 non-interlocking?

20 MR. HAMILTON: Objection.

21 Incomplete hypothetical. Vague.

22 THE WITNESS: Without a
23 particular representation, I believe so.

24 BY MR. STOWELL:

25 Q. And how would, for example, Figure 8

1 change if the bites were non-interlocking?

2 MR. HAMILTON: Objection.

3 Vague. Incomplete hypothetical.

4 THE WITNESS: My interpretation

5 would be they would be positioned

6 parallel and touching each other.

7 BY MR. STOWELL:

8 Q. In Figure 8, there is an area between
9 the bites that's labeled with an arrow and the
10 number 814.

11 Do you see that?

12 A. Yes.

13 Q. And I believe the patent refers to
14 that as an "encircled area." Is that consistent
15 with your understanding?

16 MR. HAMILTON: Objection. The
17 document speaks for itself.

18 THE WITNESS: Yes.

19 BY MR. STOWELL:

20 Q. And is it your understanding that the
21 tubular member would extend through the encircled
22 area in the valve?

23 A. Yes.

24 Q. In the embodiment pictured in
25 Figure 8, do you believe that the filaments would

1 circumferentially constrict a tubular member
2 extending through the encircled area 814?

3 A. Yes. I perceive that where the bites
4 cross, if you will, they form a circumference
5 around the tubular member.

6 Q. If the bites were non-interlocking,
7 would they circumferentially constrict a tubular
8 member extending through the encircled area?

9 A. Yes. Pretty much the same answer to
10 the -- the former question.

11 Q. There are some arrows on Figure 8:
12 810 and 812.

13 Do you have an understanding of what
14 those arrows reflect?

15 A. The direction of tensioning or
16 pulling the bites.

17 (Technical interruption.)

18 THE VIDEOGRAPHER: We're off the
19 record at 11:43 a.m.

20 (Brief pause.)

21 THE VIDEOGRAPHER: We're back on
22 the record at 11:45 a.m.

23 BY MR. STOWELL:

24 Q. In Figure 8 of the '012 patent, do
25 you believe that the bites would form a loop around

1 a tubular member extending through the encircled
2 area 814?

3 MR. HAMILTON: Objection.
4 Vague.

5 THE WITNESS: It really gets
6 back to the definition of "loop" which
7 we identified earlier as a complete
8 circle. So it certainly creates an
9 encirclement of an area. I'd have to
10 think further about does it satisfy the
11 loop definition.

12 BY MR. STOWELL:

13 Q. Have you formed an opinion on whether
14 the bite embodiment shown in Figure 8 form a loop
15 around a tubular member going through the encircled
16 area?

17 A. I thought I just answered that.

18 Q. What was your answer?

19 A. It forms a circumference, so it does
20 do a circumferentially constriction of an area, an
21 enclosed area. But I'm not -- I have to think
22 further about its consistency with our loop
23 definition of a 360-degree circle specifically.

24 Q. So as we sit here, you don't have an
25 opinion on whether the bite embodiments in Figure 8

1 would form a loop around a tubular member that
2 extends through the encircled area; is that
3 correct?

4 MR. HAMILTON: Objection.

5 Mischaracterizes his testimony.

6 THE WITNESS: Let me say this a
7 different way. I think, again, putting
8 these in motion as opposed to looking at
9 a static still shot, at some point you
10 probably have a complete circle or a
11 loop. But the bites, by definition, are
12 bringing two arcs together that are then
13 circumferentially tightening. And so as
14 they tighten further, the shape is
15 probably not circular. So it's an
16 encirclement shape, but not a loop,
17 quote/unquote.

18 BY MR. STOWELL:

19 Q. At the stage that's shown in
20 Figure 8, would you consider the bite embodiments
21 to form a loop?

22 A. That looks a lot look a circle to me
23 at that particular stage.

24 Q. And earlier we defined loop to mean a
25 circle, correct?

1 MR. HAMILTON: Objection.

2 Mischaracterizes the testimony. Beyond
3 the scope of his opinion in his expert
4 report.

5 THE WITNESS: Yes.

6 BY MR. STOWELL:

7 Q. If the filaments shown in Figure 8
8 were non-interlocking but otherwise formed a
9 similar shape encircled area, would you consider
10 those filaments to form a loop?

11 A. It's really the same answer.

12 Q. I understand that you have opined
13 that the filaments depicted in Figures 8 and 9 are
14 flexible.

15 Do I understand your opinion
16 correctly?

17 A. Yes.

18 Q. And in reaching your opinion that the
19 filaments in Figures 8 and 9 are flexible, what
20 have you relied on to reach that conclusion?

21 A. Both the specification and the
22 claims -- specification including, of course, the
23 figures and written description that produce a
24 circumferential constriction that could only happen
25 if the filaments were flexible.

1 Q. Is there anything about the drawings
2 in Figures 8 and 9 that lead you to believe that
3 the filaments are flexible?

4 A. I look at these figures, again, as
5 like one snapshot in time. So as I envision
6 the circumferential constriction, there's inherent
7 flexibility to achieve that result.

8 Q. Would you agree with me that the
9 shape of each individual bite does not change
10 between Figures 8 and 9?

11 MR. HAMILTON: Objection.

12 Vague.

13 THE WITNESS: That's what it
14 appears to be.

15 BY MR. STOWELL:

16 Q. And would you expect that to be the
17 case if the filaments were flexible?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical. Vague.

20 THE WITNESS: I don't know what
21 you're asking.

22 BY MR. STOWELL:

23 Q. If the filaments were flexible, would
24 you expect their configuration to change between
25 Figures 8 and 9?

1 A. Not necessarily. But this is simply
2 an embodiment figure, not to scale. No reason to
3 go either way.

4 Q. Is it fair to say that simply
5 reviewing Figures 8 and 9 would not tell you
6 whether the filaments are flexible?

7 MR. HAMILTON: Objection.

8 Vague. Mischaracterizes the testimony.

9 THE WITNESS: In the context of
10 this patent, flexibility is essential.

11 BY MR. STOWELL:

12 Q. Right. But looking at Figures 8
13 and 9, is there anything in the figures that
14 demonstrate to you that the filaments must be
15 flexible?

16 MR. HAMILTON: Objection. Asked
17 and answered. Vague. Incomplete
18 hypothetical.

19 THE WITNESS: As I said, this is
20 one photo in time. As I envision the
21 actual dynamic, the figures connote an
22 inherent flexibility. That's my
23 interpretation.

24 BY MR. STOWELL:

25 Q. And what about the figures, what

1 specific feature connotes an inherent flexibility?

2 MR. HAMILTON: Objection. Asked
3 and answered.

4 THE WITNESS: The fact that they
5 are going to accommodate the outside
6 dimension of the enclosed tubular
7 structure.

8 BY MR. STOWELL:

9 Q. And so are you identifying the arc of
10 the bite as indicating flexibility?

11 MR. HAMILTON: Objection.
12 Mischaracterizes the testimony.

13 THE WITNESS: Yes. Sort of. In
14 a sense that that bite is going to
15 change its geometry as it accommodates
16 and circumferentially constricts around
17 the tubular member.

18 BY MR. STOWELL:

19 Q. And so in Figure 9 we agree that the
20 geometry of the bite has not changed from Figure 8,
21 correct?

22 MR. HAMILTON: Objection.
23 Vague.

24 THE WITNESS: That's what it
25 appears to be, even though the

1 dimensions are different.

2 BY MR. STOWELL:

3 Q. In an actual device using the
4 embodiments or the bites in Figures 8 and 9, would
5 you anticipate Figure 9 to -- or would you
6 anticipate that the bites in Figure 9 would look
7 different?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical. Vague.

10 THE WITNESS: I don't know what
11 you mean by "would look different."
12 What would look different?

13 BY MR. STOWELL:

14 Q. Would their geometry be different?

15 A. Would the geometry of the bites be
16 different --

17 Q. Yes.

18 A. -- because they're in parallel as
19 opposed to interlocked?

20 Q. No. If this device were used in an
21 actual valve, would you expect the geometry of the
22 bites to change between the configuration in
23 Figure 8 and the configuration in Figure 9?

24 MR. HAMILTON: Objection.

25 Incomplete hypothetical.

1 THE WITNESS: The radius of
2 curvature of the arc of the bites would
3 change as the circumferential
4 constriction occurs, and that
5 necessitates flexibility because
6 otherwise the radius of curvature could
7 not change.

8 BY MR. STOWELL:

9 Q. And you'll agree with me that in
10 Figures 8 and 9 the radius of curvature of the bite
11 does not change, correct?

12 A. These don't depict the actual
13 constriction mechanism, so that doesn't make sense
14 what you just said. This is just showing one
15 particular snapshot of a space in time.

16 Q. And in these two snapshots in
17 Figures 8 and 9, the radius of curvature of the
18 bites is the same, correct?

19 A. Because they're not to scale, I can't
20 opine on that.

21 Q. As we sit here, do you recognize any
22 differences in the radius of curvature?

23 A. It appears to have a smaller radius
24 of curvature in Figure 9 than Figure 8. But since
25 they're not to scale, that's speculation.

1 Q. Are there any portions of the
2 specification that you have relied on for your
3 opinion that the radius of curvature of the bites
4 would change as the device constricts the tube?

5 MR. HAMILTON: Objection.

6 Vague.

7 THE WITNESS: The key term used
8 both in the description or spec in the
9 claims is there's circumferential
10 constriction, which implies a reduction
11 in radius as the constriction dynamic
12 occurs.

13 BY MR. STOWELL:

14 Q. And so you're relying on the term
15 "circumferentially constrict" for your
16 understanding that the radius of curvature of the
17 bites would change as the device constricts the
18 tube; is that correct?

19 MR. HAMILTON: Objection.

20 Vague. Asked and answered.

21 THE WITNESS: Those -- those two
22 words are certainly a driver, in
23 conjunction with the use of a filament
24 and the necessary properties of a
25 filament or filaments.

1 BY MR. STOWELL:

2 Q. If we look at column 14 of the '012
3 patent -- let me know when you're there.

4 A. Okay.

5 Q. I'm going to read from line 6 where
6 it says, quote: "The filaments 150 forming the
7 bites 800 can each apply an arcuate line or narrow
8 longitudinal zone of pressure to the elongate
9 member 132."

10 Do you see where I'm at?

11 A. Yes.

12 Q. Okay. And do you have an
13 understanding of what it means when it says, the
14 bites can each apply an arcuate line?

15 A. Yes.

16 Q. What does that mean?

17 A. For lack of a better term, "arcuate"
18 connotes a more diffuse zone of pressure compared
19 to a line of pressure.

20 Q. And so does that indicate that the
21 pressure is applied around the arc of the bite?

22 MR. HAMILTON: Objection.

23 Vague.

24 THE WITNESS: That's what this
25 sentence suggests.

1 BY MR. STOWELL:

2 Q. Now, it also says that the bites can
3 each apply a "narrow longitudinal zone of
4 pressure." Do you have an understanding of what
5 that means?

6 A. My interpretation of that is a more
7 focused zone of pressure.

8 Q. And so if we flip back to Figure 8,
9 can you explain how the embodiment in Figure 8
10 would provide a narrow longitudinal zone of
11 pressure?

12 MR. HAMILTON: Objection.

13 Vague.

14 THE WITNESS: I'm not the
15 attorney here, but that seems to be out
16 of the scope of my opinion.

17 BY MR. STOWELL:

18 Q. Have you considered that portion of
19 the '012 patent in forming your opinions in your
20 declaration, Exhibit 2008?

21 A. I didn't pay particular attention to
22 those two different potential properties, no.

23 Q. And as we sit here today, are you
24 able to explain to me how Figure 8 would apply --
25 how the embodiment in Figure 8 would apply a narrow

1 longitudinal zone of pressure to the elongate
2 member?

3 MR. HAMILTON: Objection. Asked
4 and answered.

5 THE WITNESS: I can't know what
6 the authors had in mind here, but
7 certainly I could envision a
8 non-circular tubular member inside the
9 constricting space such that as the
10 circumferential tightening or
11 constricting is occurring, there's an
12 increased pressure at one particular
13 locus because of the non-circular
14 geometry of the tubular structure. But
15 I'm speculating. I don't know what --
16 if that's exactly what they had in mind.

17 BY MR. STOWELL:

18 Q. Do you believe that the bite could
19 apply a narrow longitudinal zone of pressure to the
20 elongate member if the device inserted through the
21 valve was circular?

22 MR. HAMILTON: Objection. The
23 document speaks for itself. Vague.
24 Beyond the scope.

25 THE WITNESS: I don't believe

1 so.

2 BY MR. STOWELL:

3 Q. So it's your interpretation of this
4 phrase, "narrow longitudinal zone of pressure" that
5 that would only apply to instruments inserted
6 through the valve that are non-circular?

7 MR. HAMILTON: Objection.

8 Vague. Beyond the scope. Incomplete
9 hypothetical.

10 THE WITNESS: I'm speculating on
11 that, without really having considered
12 this in great detail.

13 BY MR. STOWELL:

14 Q. Is it fair to say you don't have an
15 opinion on that?

16 A. That's probably the right answer.

17 Q. Okay. Would you agree that the '012
18 patent explains that the filaments can have a
19 variety of cross-sectional shapes?

20 A. Can you point me to a reference?

21 Q. Column 14 describes the filament, or
22 it's at least one area that describes the filament,
23 so that may be a good place to start. Column 14 at
24 line 6.

25 A. Yes.

1 Q. Okay. And so we agree that a
2 filament, as that term is used in the '012 patent,
3 could have a rectangular cross-section, correct?

4 A. Between lines 30 and 35, that's what
5 he has written.

6 Q. If you could turn to column 9 of the
7 '012 patent.

8 Around line 13, the patent explains
9 that the filament can be made from a variety of
10 materials, including, for example, a polymer, a
11 synthetic, and/or a metal.

12 Do you see where I'm at?

13 A. Yes.

14 Q. And what, if any, role did that
15 description of the materials play in your
16 understanding that the filaments disclosed in the
17 '012 patent are flexible?

18 MR. HAMILTON: Objection. Asked
19 and answered.

20 THE WITNESS: Again, in the
21 context of the patent material and the
22 indication for use, the simple
23 implication was, no matter the material
24 used for the construction, either the
25 processing or the application of that

1 particular material would result in a
2 small cross-section, very flexible
3 filament.

4 BY MR. STOWELL:

5 Q. And so is it your opinion that a
6 polymer can be flexible?

7 A. Yes. There certainly are flexible
8 polymers.

9 Q. And it also mentions a synthetic. Do
10 you have an understanding of what it means by
11 "synthetic"?

12 A. As in a synthesized material, an
13 artificial material.

14 Q. And would a synthetic differ from a
15 polymer?

16 A. It could include a polymer.

17 Q. Could a synthetic include other types
18 of materials?

19 A. Yes. In addition to polymer, yes.

20 Q. Okay. What other types of materials
21 would be encompassed within a synthetic?

22 A. There could be some small amount of a
23 metal strand or a carbon strand or some other
24 material.

25 Q. And is it your opinion that a

1 synthetic could be flexible?

2 A. Yes.

3 Q. Lastly, it identifies a metal. Is it
4 your opinion that a metal could be flexible?

5 A. In very specialized configurations,
6 yes.

7 Q. And when you say "specialized
8 configurations," what do you mean?

9 A. In the form of, for example, an
10 incredibly small cross-sectional soft metal wire --
11 keyword being "soft" -- to enable flexibility, or
12 in a braided or entwined configuration of fibrils,
13 metal fibrils.

14 Q. Earlier you had testified that it was
15 your opinion that a polymer could be flexible.
16 Would the polymer need to have a specialized
17 configuration to be flexible?

18 A. It would have to be generally small,
19 but the more important credential would be its
20 constitution.

21 Q. And when you say "constitution," what
22 do you mean?

23 A. Is it a high-density polymer, for
24 instance, or a low-density polymer? To reduce
25 stiffness, lower is better. Or I should say for

1 increased flexibility.

2 Q. The section goes on to describe some
3 specific materials. One of those is stainless
4 steel. Do you consider stainless steel to be a
5 soft metal?

6 A. The two words that come to mind are
7 "context" and "configuration." So in general,
8 stainless steel, we've all observed -- "we" being
9 POSITAs -- as a semi-rigid or rigid material in its
10 normal configuration of sheets or struts or similar
11 things.

12 It's -- it's technically possible to
13 take a stainless steel in an extremely small
14 cross-sectional diameter, possibly doped with some
15 other materials, to give it flexibility.

16 Q. Do you believe that the filaments
17 illustrated in Figures 8 and 9 would be flexible if
18 they were made of stainless steel?

19 MR. HAMILTON: Objection.

20 Incomplete hypothetical.

21 THE WITNESS: As I just answered
22 on the last question, under special
23 circumstances of constitution and
24 configuration, yes, they could be.

25 BY MR. STOWELL:

1 Q. Would the circumstances of
2 constitution and configuration for making stainless
3 steel flexible have been something that was known
4 to a POSITA before September 2017?

5 A. I'm speculating, but, yes, I would
6 think so.

7 Q. The patent also mentions nitinol. Do
8 you understand nitinol to be a soft metal?

9 A. I think that's a decent
10 categorization.

11 Q. And do you believe that if the
12 embodiments in Figures 8 and 9 of the '012 patent
13 were made of nitinol that they would be flexible?

14 MR. HAMILTON: Objection.

15 Incomplete hypothetical.

16 THE WITNESS: Analogous to the
17 previous question and answer. There are
18 different grades of nitinol, most of
19 which are very temperature sensitive.
20 So given the right constitution at the
21 right cross-sectional configuration and
22 the right temperature, yes.

23 BY MR. STOWELL:

24 Q. At the bottom of the paragraph that
25 we're looking at, it says, In some embodiments, the

1 filament can comprise one or several threads,
2 lines, cords, rope, ribbon, flat wire, sheet, or
3 tape, end quote.

4 Do you see where I am?

5 A. Yes.

6 Q. Okay. And do you agree that any one
7 of those items listed there could form a filament?

8 MR. HAMILTON: Objection.

9 Vague.

10 THE WITNESS: I struggle with
11 ribbon and sheet. But, again, via what
12 I said just a minute ago, given some
13 unusual construction and a very, very
14 small cross-sectional configuration, I
15 think it's conceivable.

16 BY MR. STOWELL:

17 Q. When you say you struggle with
18 ribbon, why do you struggle with that term?

19 A. The configurations I've seen in that,
20 you know, metal or other material have not been
21 very flexible. They would -- they would take a
22 form, if you will, meaning that if I bend it, it
23 won't go back to its original form.

24 Q. If you can bend it, doesn't that
25 indicate, though, that it's flexible?

1 MR. HAMILTON: Objection.

2 Vague.

3 THE WITNESS: "Flexible" is a
4 very relative term. I think the key to
5 flexible with regard to the '012 patent
6 is the context where it's flexibility
7 around a relatively small dimension
8 tubular element.

9 BY MR. STOWELL:

10 Q. And when you're using the term
11 "flexible" in rendering your opinions on the '012
12 patent, what -- what definition of that term are
13 you using?

14 MR. HAMILTON: Objection.

15 Vague.

16 THE WITNESS: In general, the
17 ability to accommodate the external
18 surface of a small structure.

19 BY MR. STOWELL:

20 Q. And when you say "accommodate the
21 external surface of a small structure," what do you
22 mean?

23 MR. HAMILTON: Objection.

24 Vague.

25 THE WITNESS: To achieve the

1 main driver that we've discussed of this
2 patent, which is a circumferential
3 constriction -- the keyword being
4 "circumferential" -- the accommodation
5 would be the adaptation of a flexible
6 element or filament to that curved
7 surface.

8 BY MR. STOWELL:

9 Q. And is it your opinion that a rigid
10 filament could not conform to a tubular body?

11 A. Again, in -- you know, "rigid" is a
12 relative term, but a rigid compared to flexible
13 would not accommodate, or would not accommodate
14 well.

15 Q. But it could accommodate at least a
16 little, correct?

17 MR. HAMILTON: Objection.

18 Vague.

19 THE WITNESS. Yeah. I'm just
20 not sure what that means, "a little."

21 BY MR. STOWELL:

22 Q. You said it "would not accommodate
23 well." And what do you mean by "would not
24 accommodate well"?

25 A. Adapting or coopting to a

1 three-dimensional curved or multi-geometry element.

2 Q. You also indicated that you had some
3 issues with the term "sheet" in that portion of
4 column 9 that we looked at. Why do you struggle
5 with the word "sheet"?

6 MR. HAMILTON: Objection.
7 Mischaracterizes the testimony.

8 THE WITNESS: As a POSITA with
9 medical device experience, I've not seen
10 metal sheets utilized in required
11 flexible medical products.

12 BY MR. STOWELL:

13 Q. When you were rendering your opinions
14 that are set forth in Exhibit 2008, did you do so
15 with the understanding that ribbons and sheets
16 could form flexible filaments?

17 MR. HAMILTON: Objection.
18 Vague.

19 THE WITNESS: With the
20 restrictions that I previously limited,
21 yes.

22 BY MR. STOWELL:

23 Q. In that statement at the bottom of
24 the paragraph we're looking at in the column lines
25 9 to 22, are there any examples there that you

1 would cancel out or strike from the list of
2 materials that can be a filament?

3 MR. HAMILTON: Objection.

4 Vague.

5 THE WITNESS: No.

6 BY MR. STOWELL:

7 Q. And just looking back at Figures 8
8 and 9, we had talked about the arrows 810 and 812.
9 Do you see those?

10 A. Yes.

11 Q. And is your -- is it your
12 understanding that the bites, when tension is
13 applied to them, will move in the direction of the
14 arrows?

15 A. Yes.

16 Q. And so, for example, subfilament
17 150-B in Figure 8 would move in the direction of
18 arrow 810?

19 A. Yes.

20 MR. STOWELL: So we're going to
21 transition. Do you want to break for lunch? It's
22 about 12:20.

23 MR. HAMILTON: That sounds good.

24 THE WITNESS: Sure.

25 MR. STOWELL: Okay. Why don't

1 we break.

2 THE VIDEOGRAPHER: We're off the
3 record at 12:18 p.m.

4 (Lunch recess.)

5 THE VIDEOGRAPHER: This marks
6 the beginning of media number 4. We're
7 on the record at 12:50 p.m.

8 BY MR. STOWELL:

9 Q. Welcome back, Dr. Zalesky. Did you
10 review any documents during the lunch break?

11 A. No.

12 Q. And did you speak with anybody about
13 the subject matter of your testimony during the
14 break?

15 A. No.

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

18 (Exhibit No. 1005 was
19 previously marked for
20 identification.)

21 BY MR. STOWELL:

22 Q. Dr. Zalesky, do you recognize
23 Exhibit 1005?

24 A. Yes.

25 Q. And what is Exhibit 1005?

1 A. A copy of the Schaffer patent.

2 Q. Okay. And do you recognize this as
3 one of the prior art references that Petitioner has
4 relied upon in its petition?

5 A. Yes.

6 Q. Okay. And is this a prior art
7 reference that you considered in forming the
8 opinions that are in Exhibit 2008?

9 A. Yes.

10 Q. Okay. And when was the last time you
11 reviewed the Schaffer reference?

12 A. Only sporadically yesterday, not in
13 any kind of detail.

14 Q. Okay. And prior to yesterday, had
15 you reviewed the Schaffer reference?

16 A. I had but it's been some weeks since
17 I really scrutinized it.

18 Q. There are some inventors listed on
19 the front of the Schaffer patent. Are you familiar
20 with any of those individuals?

21 A. No.

22 Q. And the assignee of this patent was
23 MedAmicus, Inc.

24 Are you -- were you familiar with
25 that company?

1 A. I'm not. Was not.

2 Q. Okay. And if we refer to this patent
3 as the Schaffer patent, is that okay for today?

4 A. Yes.

5 Q. You'll understand what patent I'm
6 referring to?

7 A. Yes.

8 Q. Okay. I'm also going to provide you
9 with what has been previously marked as
10 Exhibit 1008 in this IPR.

11 (Exhibit No. 1008 was
12 previously marked for
13 identification.)

14 BY MR. STOWELL:

15 Q. Dr. Zalesky, do you recognize
16 Exhibit 1008?

17 A. I do. I do. I'm not sure what title
18 it has, but I do recognize it.

19 Q. Okay. Is this a document that you
20 reviewed in forming your opinions?

21 A. Yes.

22 Q. And do you understand this to be the
23 figures from the Schaffer patent publication?

24 A. Yes.

25 MR. HAMILTON: Objection.

1 Mischaracterizes the testimony. Vague.

2 BY MR. STOWELL:

3 Q. Okay. And so as I ask you questions
4 about Schaffer, you're welcome to refer to
5 Exhibit 1008 if necessary.

6 In this IPR, Petitioner has focused
7 on Figures 30 through 34 of Schaffer. Have you
8 reviewed those figures in detail?

9 A. Yes.

10 Q. Okay. And based on your review of
11 Schaffer, do you understand how the valve in
12 Figures 30 through 34 operates?

13 A. Yes.

14 Q. And how does -- how is the valve
15 operated?

16 MR. HAMILTON: Objection.

17 Vague.

18 THE WITNESS: On either side of
19 the enclosed tubular element is a
20 hemicylindrical, or half moon, if you
21 will, rigid structure on either side,
22 not opposing but staggered. In other,
23 words side by side.

24 When -- when they are actuated
25 to press down on the enclosed structure,

1 they create what I would call a pinching
2 closure effect. And integral to that is
3 a seal member surrounding the tubular
4 structure that has compliance properties
5 that augment the pinching effect.

6 BY MR. STOWELL:

7 Q. And what is your understanding of the
8 purpose of the Schaffer valve?

9 MR. HAMILTON: Objection.
10 Vague.

11 THE WITNESS: Its indication for
12 use is as a hemostasis valve, so the
13 intention is to occlude an enclosed
14 structure to prevent back bleed or back
15 fluid flow or gas flow.

16 BY MR. STOWELL:

17 Q. And is it your opinion that
18 Schaffer's valve will seal perfectly regardless of
19 the diameter of the device that's inserted through
20 the valve?

21 MR. HAMILTON: Objection.
22 Incomplete hypothetical.

23 THE WITNESS: That wasn't really
24 part of my assignment and I certainly
25 wouldn't say perfectly.

1 BY MR. STOWELL:

2 Q. If the device that's inserted through
3 the valve is much smaller than Schaffer's valve, do
4 you have an opinion on whether Schaffer's valve
5 would seal perfectly?

6 A. I have no opinion but, again, I'd be
7 reluctant to say perfectly.

8 Q. Why would you be reluctant to say
9 perfectly?

10 A. It connotes that without exception
11 there's complete closure of any gas or fluid flow.

12 Q. And so can you envision scenarios
13 where Schaffer's valve would not result in complete
14 closure to gas or fluid flow?

15 MR. HAMILTON: Objection.

16 Incomplete hypothetical.

17 THE WITNESS: I don't have any
18 specific scenarios in mind. I'm just
19 talking about the practicality of
20 materials, and so certain instruments
21 and catheters are not uniform. Even
22 though they look like they might be,
23 they're not.

24 So it's another way of saying
25 it's not so much a function of the valve

1 as it is the underlying structure or
2 deformities, of sorts.

3 BY MR. STOWELL:

4 Q. In your experience working with
5 hemostasis valves, did you encounter situations
6 where the instruments inserted through the valve
7 were not uniform, and that resulted in less than a
8 perfect seal?

9 MR. HAMILTON: Objection.
10 Incomplete hypothetical.

11 THE WITNESS: My experience is
12 almost exclusively with Touhy Borst, and
13 oftentimes out of roundness is a
14 characteristic we use often with
15 catheters and disposable devices that,
16 on paper, they appear to be completely
17 round, but, in reality, either because
18 of extrusion variations or other
19 fabrication variations, they're slightly
20 elliptical or otherwise not quite round.
21 And so they presented a particular
22 challenge to get a complete seal with
23 the Tuohy Borst.

24 BY MR. STOWELL:

25 Q. And what would the result be if they

1 didn't provide a complete seal, the Tuohy Borst
2 valves?

3 A. Well, leakage.

4 Q. Would you anticipate with Schaffer's
5 valve that if an out-of-round instrument was
6 inserted through the valve that there could be some
7 leakage?

8 MR. HAMILTON: Objection.
9 Incomplete hypothetical.

10 THE WITNESS: Yeah, I really
11 don't have an opinion on that. I'd have
12 to touch and feel and test it.

13 BY MR. STOWELL:

14 Q. Okay. So you haven't -- as part of
15 your forming your opinions in this case, you
16 haven't considered whether the Schaffer valve would
17 leak with an out-of-round device inserted through
18 it; is that correct?

19 MR. HAMILTON: Objection.
20 Incomplete hypothetical.
21 Mischaracterizes the testimony.

22 THE WITNESS: Correct. I have
23 not.

24 BY MR. STOWELL:

25 Q. And as part of forming your opinions

1 in this case, have you considered whether the size
2 of the instrument inserted through Schaffer's valve
3 would or could result in leakage?

4 MR. HAMILTON: Objection.
5 Incomplete hypothetical.

6 THE WITNESS: Indirectly. In
7 particular -- I mean, we can go to my
8 supplemental declaration if that makes
9 sense. But I recall very specifically
10 looking at a configuration of more than
11 one instrument inside of a tubular
12 structure presented a challenge to
13 complete closure.

14 BY MR. STOWELL:

15 Q. And I'm focused more right now on the
16 size or, let's say, the diameter of the instrument
17 inserted through the valve. Did you form any
18 opinions on how the diameter of the instrument
19 inserted through Schaffer's valve would impact the
20 seal created by the valve?

21 MR. HAMILTON: Objection.
22 Incomplete hypothetical.

23 THE WITNESS: Not explicitly,
24 no.

25 BY MR. STOWELL:

1 Q. I understand from your prior
2 deposition that you have experience working with
3 hemostasis valves, correct?

4 A. Yes.

5 Q. Earlier we had looked at the period
6 of 1995 to 2005 as a period of your career where
7 you had a lot of experience with catheters. During
8 that time period, would you say you also had a lot
9 of experience using hemostasis valves?

10 A. During that period and significantly
11 prior to that period, in particularly, the Tuohy
12 Borst.

13 Q. And did you ever have any experience
14 designing a hemostasis valve?

15 A. I didn't specifically design a
16 hemostasis valve such as a Tuohy Borst from
17 scratch. But on occasion, we would modify the
18 Tuohy Borst dimensions to accommodate a different
19 configuration of a catheter and a disposable
20 device.

21 Q. And when you say "modify the Tuohy
22 Borst dimensions," what dimensions are you
23 referring to?

24 A. Primarily length and lumen size.

25 Q. And why would you need to modify the

1 length of the valve?

2 A. There could be some devices that were
3 not uniform axially or longitudinally. And so one
4 aspect would be larger, if you will, on the OD than
5 another aspect.

6 Q. And why would you need to modify the
7 lumen size of the Tuohy Borst valves?

8 A. For that same reason.

9 Q. And when you're talking about these
10 modifications you made, what time period are you
11 talking about?

12 A. Between 1987 and probably the early
13 2000s.

14 Q. And the modifications you made to the
15 valves, were you using techniques to modify those
16 valves that would have been available to a person
17 of ordinary skill in the art at the time?

18 MR. HAMILTON: Objection.

19 Vague.

20 THE WITNESS: Yes. In general,
21 it was simple machining.

22 BY MR. STOWELL:

23 Q. And so when you modified the
24 dimensions of the valve to have -- to change the
25 lumen size, what specifically would you do to the

1 valve; what modifications would you make?

2 A. Using the equivalent of a drill
3 press, some coring of a certain portion of the
4 length of the Tuohy Borst.

5 Q. And were you typically, in these
6 situations, modifying the valve to have a larger
7 lumen size?

8 A. I would say in all cases it was a
9 matter of taking a commercially available Tuohy
10 Borst and increasing the lumen size at least in
11 some portion.

12 Q. And other than using a drill press to
13 core a portion of the valve, were there any other
14 modifications you would need to make to the valve?

15 A. Not that come to mind, no.

16 Q. And was the process of modifying
17 existing valves to have larger lumens, is that
18 something that was commonly done in the medical
19 device industry?

20 A. Commonly done for experimentation
21 purposes primarily. In other words, preclinical,
22 which includes bench and animal; and clinical,
23 which is controlled patient studies, not for
24 general commercialization.

25 Q. And when you were modifying the

1 valves to increase the lumen size, how did you
2 determine how large the lumen needed to be?

3 A. Simply measuring the dimensions of
4 the device that we needed to seal around.

5 Q. And so is it common in using
6 hemostasis valves to select a valve where the lumen
7 of the valve approximates the outer diameter of the
8 device that's going through it?

9 A. That's a fair statement. There,
10 obviously, has to be some tolerance to allow a
11 smooth advance and withdrawal of the catheter or
12 device. But, in general, there's a matching
13 process.

14 Q. Do you have an opinion on whether
15 Schaffer's valve will seal perfectly regardless of
16 the shape of the device that's being inserted
17 through the valve?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical.

20 THE WITNESS: Well, first of
21 all, perfectly, as I've said earlier, I
22 don't think applies without hands-on
23 experience. But I didn't opine on that
24 particular issue.

25 BY MR. STOWELL:

1 Q. Let's turn to paragraph 77 of the
2 Schaffer reference, which is on page 6 of Schaffer.

3 A. I'm not there. Where are you?

4 Page --

5 Q. Paragraph 77.

6 A. -- 26?

7 Q. Yeah. If you're looking at the pages
8 at the bottom, yes. Sorry about the confusion.

9 A. Okay.

10 Q. And do you see paragraph 77?

11 A. Yes.

12 Q. And so paragraph 77 in the second
13 line refers to "in one option." When the Schaffer
14 patent refers to "in one option," how do you
15 understand that term?

16 A. One of several potential embodiments.

17 Q. If we look at the next column over
18 for paragraph 77, there's a sentence that uses the
19 term "forcibly disengage," and I know you've relied
20 on this in your report. What was your
21 understanding of the meaning of the term "forcibly
22 disengage"?

23 A. Because of the mechanical
24 configuration with effectively rigid components,
25 there's an actuation force of release from the

1 constriction.

2 Q. And what do you mean by "an actuation
3 force of release"?

4 A. A spring created force to bring the
5 constricting elements away from the tubular
6 structure.

7 Q. And so do you -- did you understand
8 the term "forcibly disengaged" to mean "an
9 actuation force of release"?

10 MR. HAMILTON: Objection. Asked
11 and answered.

12 THE WITNESS: Yes.

13 BY MR. STOWELL:

14 Q. In Schaffer's valve, when the buttons
15 are undepressed, would you describe the U-shaped
16 actuating members as being forcibly engaged with
17 the tubular member?

18 MR. HAMILTON: Objection.
19 Incomplete hypothetical.

20 THE WITNESS: There is a
21 spring-created compressive force bearing
22 in the direction of the tubular member.

23 BY MR. STOWELL:

24 Q. And would you describe that
25 spring-created compressive force as meaning that

1 the U-shaped actuating members are forcibly engaged
2 with the tubular member?

3 MR. HAMILTON: Objection.

4 Vague. Asked and answered.

5 THE WITNESS: I'm unsure about
6 the use of the word "engaged." There's
7 creation of a compressive force by those
8 members from the spring force.

9 BY MR. STOWELL:

10 Q. And do you not understand what the
11 term "engaged" means?

12 MR. HAMILTON: Objection.

13 Vague. Beyond the scope.

14 THE WITNESS: It can mean
15 different things. It could include in
16 contact with the tubular structure.

17 BY MR. STOWELL:

18 Q. In the term "forcibly disengage,"
19 what did you understand the term "disengage" to
20 mean in that phrase that's in paragraph 77 of
21 Schaffer?

22 MR. HAMILTON: Objection. Asked
23 and answered.

24 THE WITNESS: To pull the
25 compressive elements away from the

1 surface of the tubular structure.

2 BY MR. STOWELL:

3 Q. Did you understand "disengage" to
4 mean that the U-shaped actuating members were not
5 in contact with the actuating member?

6 A. If they're -- if they're being
7 disengaged, they must have been engaged.

8 Q. Right. But when the actuating
9 members are forcibly disengaged, do you understand
10 that to mean that the actuating members are no
11 longer in contact with the tubular member?

12 MR. HAMILTON: Objection. Asked
13 and answered.

14 THE WITNESS: That was my
15 interpretation.

16 BY MR. STOWELL:

17 Q. Okay. And so if "engaged" means in
18 contact with the tubular member, do you understand
19 that when the buttons are undepressed, the U-shape
20 actuating members would forcibly engage the tubular
21 member?

22 MR. HAMILTON: Objection.
23 Vague.

24 THE WITNESS: I think that's
25 reasonable to say that.

1 BY MR. STOWELL:

2 Q. When you reached your conclusion that
3 "forcibly disengage" means that the U-shaped
4 actuating members are not in contact with the seal
5 module, what portions of the specification or
6 figures were you relying on?

7 A. I would honestly have to go back
8 through all these, but several of the figures -- my
9 understanding of what was -- what was being shown
10 in the figures in particular. And imagine, again,
11 it's a snapshot in time, analogous to what we
12 talked about earlier with respect to the '012,
13 knowing that there's a dynamic involved in
14 compression and release.

15 Q. If we look at Figures 30 to 34,
16 specifically, are -- do you believe any of those
17 figures illustrate the U-shaped actuating members
18 being forcibly disengaged from the seal module?

19 A. I think Figure 34 comes the closest
20 to that. And, in particular, comparing it to an
21 earlier figure, such as 32, going from closure to
22 opening, suggests that a forcible disengagement has
23 occurred.

24 Q. And so earlier you had explained
25 disengagement as being the U-shaped actuating

1 members being out of contact with the seal module.

2 Do you believe that that's shown in Figure 34?

3 A. This is a really ugly figure, but
4 it's not clear.

5 Q. What if you look at Exhibit 1008,
6 which has the cleaner image of Figure 34, does that
7 help you at all answer the question?

8 A. I'm sorry. Which figure?

9 Q. Figure 34.

10 A. As depicted here, the compressive
11 elements appear to be in contact, but I don't know
12 that that means this is a complete retraction of
13 those elements. This could be partly, not
14 completely.

15 Q. So you believe Figure 34 may only
16 reflect a partial compression of the buttons and
17 springs; is that correct?

18 A. Correct.

19 Q. And do you have any basis or any
20 references in the specification that lead you to
21 believe that the -- that Figure 34 can be a partial
22 compression?

23 A. I'd have to re-review the written
24 description to find a particular clause or sentence
25 that speaks to that. But from my vantage point, as

1 I mentioned earlier, the figures in particular
2 suggest a dynamic range, if you will. It's not
3 simply on or off.

4 Q. Does the lumen of the seal module in
5 Figure 34 appear to be fully open?

6 A. Hard to know. If you assume that the
7 rightmost portion of that is a totally relaxed
8 lumen, then, yes. But that's an assumption.

9 Q. And I think you had indicated that
10 you thought Figure 34 would be the closest figure
11 among Figures 30 to 34 to showing the forcibly
12 disengaged element, correct?

13 A. I think that's correct. You could
14 argue that Figure 33 shows a potentially partial
15 disengagement. But it's hard to tell from the
16 figure.

17 Q. In the Schaffer reference, back in
18 paragraph 77 -- let me know when you get there.

19 A. Okay.

20 Q. The very last sentence of
21 paragraph 77 explains that the lumen of the third
22 seal member 165 is able to retract in an unsealed
23 configuration.

24 Do you see where I'm at?

25 A. No. Where are you?

1 Q. So the last sentence in paragraph 77.

2 A. Oh, top right?

3 Q. Top right, correct.

4 A. Okay. Say again.

5 Q. It -- that sentence ends, "The lumen
6 193 of the first seal member 165 is able to retract
7 to an unsealed configuration."

8 Do you see that?

9 A. Yes.

10 Q. Okay. And do you understand the
11 mechanism of action for the seal member to be able
12 to retract to an unsealed configuration?

13 A. I believe it's a characteristic of
14 that seal member that essentially restores the
15 lumen as it expands.

16 Q. And so is it your understanding that
17 the properties of the seal member permit it to
18 retract to its unsealed configuration?

19 A. Yes. In essence, it's a resilience
20 of the seal member.

21 Q. If we turn to page 27 of Schaffer,
22 paragraph 82, the paragraph starts that, "The
23 stasis valve, in one option, is made from
24 preexisting amounts of metals and/or plastics."

25 Do you see where I'm at?

1 A. Yes.

2 Q. And then it continues that, "The
3 actuating member and the actuating button, in one
4 example, is machined from aluminum and, in another
5 example, it can be machined from plastics."

6 Do you see that?

7 A. Yes.

8 Q. Okay. And so as a person of ordinary
9 skill in the art, in 2017, what other methods of
10 making the actuating members would a person have
11 been aware of?

12 A. Certainly different molding --
13 MR. HAMILTON: Hold on one
14 second.

15 Objection. Vague. Beyond the
16 scope.

17 THE WITNESS: There are other
18 molding operations that could be
19 utilized.

20 BY MR. STOWELL:

21 Q. Any other methods of making the
22 actuating members that you think a POSITA would
23 have known of in 2017?

24 MR. HAMILTON: Same objections.
25 Vague. Beyond the scope.

1 THE WITNESS: I'm most familiar
2 with machining and with molding, so it's
3 hard to imagine a number of different
4 options.

5 BY MR. STOWELL:

6 Q. Do you think that the actuating
7 members could have been drawn?

8 MR. HAMILTON: Objection.
9 Vague. Beyond the scope.

10 THE WITNESS: I think it's
11 technically possible. I'm honestly not
12 sure how practical that would be.

13 BY MR. STOWELL:

14 Q. Would a person of ordinary skill in
15 the art, in 2017, have been familiar with drawing
16 plastics and metals?

17 A. It's not an easy question, because a
18 lot of medical device people would not be involved
19 in that fundamental operation. That would be from
20 a vendor. So it's maybe.

21 Q. What about in terms of the way we've
22 identified the person of ordinary skill in the art
23 in this case, someone with a mechanical engineering
24 degree with two to four years of experience, would
25 that person have been familiar with drawing

1 plastics and metals?

2 A. So it's really the same answer.

3 Typically, an engineer with a few
4 years experience will be familiar and experienced
5 with secondary operations such as machining or
6 polishing or trimming or skiving, but not the
7 fundamental operation of molding or extruding for a
8 drawing.

9 Q. In paragraph 83, there is an example
10 of a way to manufacture or to assemble a valve,
11 correct?

12 A. Yes.

13 Q. Okay. In forming your opinions that
14 you've expressed in Exhibit 2008, did you consider
15 other methods of assembling the described valve?

16 MR. HAMILTON: Objection.

17 Vague.

18 THE WITNESS: That wasn't in my
19 scope, no.

20 BY MR. STOWELL:

21 Q. I'm going to hand you a document that
22 has been previously marked in this IPR as
23 Exhibit 1006.

24 (Exhibit No. 1006 was
25 previously marked for

1 identification.)

2 MR. STOWELL: Thank you.

3 BY MR. STOWELL:

4 Q. Dr. Zalesky, do you recognize
5 Exhibit 1006?

6 A. Yes.

7 Q. And what is Exhibit 1006?

8 A. It appears to be a copy of the
9 Hartley patent.

10 Q. Okay. And when you say it appears to
11 be, is there anything that leads you to believe
12 that this is not a copy of the Hartley patent?

13 A. Not specifically at this point.

14 Q. Does it look to be a complete copy of
15 the Hartley patent?

16 A. Without a half-hour review, yes.

17 Q. And -- well, do you have any reason
18 to believe this isn't a complete copy of the
19 Hartley patent?

20 A. No.

21 Q. And is this one of the patents that
22 you reviewed in forming the opinions in your
23 supplemental declaration, Exhibit 2008?

24 A. Yes.

25 Q. When was the last time you had an

1 opportunity to review the Hartley patent?

2 A. Very cursorily yesterday. In terms
3 of detail, many weeks ago.

4 Q. When you reviewed the Hartley patent,
5 did you understand the disclosure?

6 A. Yes.

7 Q. Were there any parts of the patent
8 that you did not understand?

9 A. No, not specifically.

10 Q. Okay. And would you agree that the
11 Hartley patent describes a type of rotating
12 hemostasis valve?

13 A. Yes. In particular, a single
14 rotating actuator.

15 Q. And do you understand how the
16 described Hartley valve operates?

17 A. Yes.

18 Q. How does the valve close around a
19 device inserted through the valve?

20 MR. HAMILTON: Objection.

21 Vague.

22 THE WITNESS: It applies
23 variable tension to an otherwise
24 constrained string that is partially
25 circumscribed in the enclosed

1 tubular element.

2 BY MR. STOWELL:

3 Q. And when you say "variable tension,"
4 what do you mean by "variable tension"?

5 A. The actuator can be forced down or
6 released to produce variations in tension.

7 Q. And do you believe that the string,
8 as you put it, in Hartley circumferentially
9 constricts the tubular member going through the
10 string?

11 MR. HAMILTON: Objection.

12 Vague. Calls for a legal conclusion.

13 Beyond the scope.

14 THE WITNESS: I don't believe I
15 opined on that.

16 BY MR. STOWELL:

17 Q. That's not something you considered
18 in reaching your opinions in your supplemental
19 declaration?

20 A. I'd have to go back and look at the
21 specific words that I use.

22 Q. As we sit here, you don't recall
23 whether you've opined whether Hartley
24 circumferentially constricts a tubular member going
25 through the device?

1 A. I don't know that I used that
2 particular phrase.

3 Q. As we sit here and you're looking at
4 the figures, do you believe that THE Hartley string
5 circumferentially constricts the tubular element
6 going through the filament?

7 MR. HAMILTON: Objection.

8 Vague. Asked and answered. Beyond the
9 scope.

10 THE WITNESS: It's out of the
11 scope. I'm challenged by the figure not
12 quite representing the reality of the
13 dynamic effect of the actuator.

14 BY MR. STOWELL:

15 Q. What if we look at Figures 1 and 2,
16 does that help you answer the question?

17 MR. HAMILTON: Same objections.

18 THE WITNESS: No.

19 BY MR. STOWELL:

20 Q. You would agree, though, that
21 Figures 1 and 2 show a dynamic effect between
22 Figure 1 and Figure 2, correct?

23 A. Correct.

24 Q. Okay. And from these figures, are
25 you unable to determine whether the string

1 circumferentially constricts the cylindrical
2 diaphragm of a tubular member?

3 A. Because of the angulation of the
4 ports of the string, it's not clear in looking at
5 these figures that you get a circumferential
6 compression.

7 Q. And so that I understand your
8 position, is it fair to say that today you don't
9 have an opinion on whether Hartley
10 circumferentially constricts the cylindrical
11 diaphragm going through the filament?

12 A. I think it's best to say that.

13 Q. Okay. Paragraph 37 of Hartley, let
14 me know when you're there.

15 A. Okay.

16 Q. So paragraph 37 states that "It will
17 be seen that by this invention there is provided an
18 access or constriction valve arrangement which will
19 close over a range of diameters of devices passed
20 through the valve or can close completely down to
21 be self-sealing."

22 Do you see that?

23 A. I do.

24 Q. And do you agree that the Hartley
25 valve would close over a range of diameters of

1 devices passed through the valve?

2 MR. HAMILTON: Objection.

3 Vague. Incomplete hypothetical.

4 THE WITNESS: That appears to be
5 the case.

6 BY MR. STOWELL:

7 Q. Do you have any reason to disagree
8 with that?

9 A. No. Except that I don't know the
10 dimensions of his lumen.

11 Q. And how would the dimensions of the
12 lumen impact your opinion?

13 A. Simple accommodation of size or not.

14 Q. And so how would the dimension of the
15 lumen impact whether the valve would close over a
16 range of diameters of devices?

17 A. I'm not saying it wouldn't enclose
18 over a range. I just don't know what that range
19 would be.

20 Q. And do you agree with the statement
21 in paragraph 37 that the device described in
22 Hartley, the valve, would close completely down to
23 be self-sealing?

24 A. I'm not sure I understand his
25 interpretation of "self-sealing."

1 Q. So when you read the Hartley
2 reference, you're not -- you don't understand
3 that -- that phrase there, "can close completely
4 down to be self-sealing"?

5 A. I understand "close completely down."
6 I'm not sure why he added "self-sealing."

7 Q. What do you understand "close
8 completely down to mean"?

9 A. That there is no residual lumen.

10 Q. And do you believe that that would
11 occur with the Hartley valve?

12 A. He claims that it does.

13 Q. And do you have any reason to
14 disagree with him?

15 A. No.

16 Q. In paragraph 17 Hartley describes
17 that "The flexible member may be a string, suture,
18 or band or other suitable material."

19 Do you see that?

20 A. Yes.

21 Q. And when you read the Hartley
22 reference, what was your understanding of what was
23 meant by a string?

24 A. The very common objects that's either
25 synthetic or cotton or some similar material that

1 we've all used to fly kites and such.

2 Q. And did you understand the term
3 "string" to describe a device or a structure that
4 has multiple strands of material?

5 A. I understood that it could encompass
6 that, yes.

7 Q. Paragraph 17 also mentions a suture.
8 When you reviewed the Hartley reference, what was
9 your understanding of what was meant by a suture?

10 MR. HAMILTON: Objection.

11 Beyond the scope.

12 THE WITNESS: I assumed he
13 intended to describe suture material
14 commonly used in surgical procedures.

15 BY MR. STOWELL:

16 Q. And what is the material that's
17 commonly used in surgical procedures for sutures?

18 A. It's quite variable. It ranges from
19 polypropylene, polyethylene. It's the equivalent
20 of catgut to synthesize resorbables, so it's quite
21 a broad range of materials.

22 Q. And when you read Hartley, did you
23 understand that the use of the term "suture" here
24 was referring to that broad range of materials?

25 A. No.

1 Q. What did you understand suture in
2 Hartley to be referring to?

3 A. My interpretation was it would refer
4 to the stronger family of suture materials.

5 Q. And what materials would you consider
6 to fall into that stronger family?

7 A. Some versions of polyethylene and
8 polypropylene.

9 Q. Anything else you can think of?

10 A. It'll come to me, but not at the
11 moment.

12 Q. Okay. Paragraph 17 also refers to a
13 band for the flexible member. Did you have an
14 understanding of what was meant by band?

15 A. I didn't focus on that particular
16 word, to be frank.

17 Q. Okay. As we sit here, do you have an
18 understanding of what "band" means in paragraph 17?

19 A. What comes to mind is something like
20 a rubber band, but I -- again, I didn't really try
21 to interpret what he was trying to describe.

22 Q. And then it also says "or other
23 suitable materials." In forming your opinions
24 about the Hartley reference, did you consider what
25 other suitable materials could be used for the

1 flexible member?

2 A. I think my declaration shows that my
3 concentration was on his word of string.

4 Q. And so did you form any opinions
5 about what other suitable materials could be used
6 for the flexible member?

7 A. It was out of my scope.

8 Q. Hartley was filed in 2002. Do you
9 see that, December 2002?

10 A. Yes. Mm-hmm.

11 Q. In December 2002, would a person of
12 ordinary skill in the art have been familiar with
13 strings and sutures?

14 A. Yes.

15 Q. Between a string and a suture, would
16 there have been any advantages to one of those over
17 the other, based on your experience?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical.

20 THE WITNESS: I'm speculating,
21 but small diameter strings, in general,
22 lots of exceptions, but, in general,
23 would exhibit better flexibility than
24 certain suture materials.

25 BY MR. STOWELL:

1 Q. Are there any other advantages that
2 either a string or suture would have over the other
3 for use in a hemostasis valve like the one
4 described in Hartley?

5 MR. HAMILTON: Objection.

6 Vague. Incomplete hypothetical.

7 THE WITNESS: The main advantage
8 is inherent strength and a small
9 profile.

10 BY MR. STOWELL:

11 Q. And would -- I think earlier you had
12 explained that you understood suture in paragraph
13 17 to refer to some of the stronger suture
14 materials; is that right?

15 A. Yes.

16 Q. And would you consider a string a
17 strong material as well?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical. Vague.

20 THE WITNESS: I think in most
21 cases in the context of a hemostasis
22 valve, a string would have sufficient
23 strength.

24 BY MR. STOWELL:

25 Q. If we look at Figures 3 and 4 of

1 Hartley, there is a spring with a detent pictured.
2 Do you -- when I say spring in a detent, do you
3 understand what features in Figures 3 and 4 I'm
4 referring to?

5 A. Yes, I do.

6 Q. Okay. It looks like the detent
7 arrangement is described as having a ball 28 and a
8 spring 29, and it looks like those numbers are
9 called out in Figure 3, correct?

10 A. Yes.

11 Q. Okay. And you, based on your review
12 of Hartley, do you have an understanding of the
13 purpose of the spring and ball detent arrangement?

14 MR. HAMILTON: Objection. The
15 document speaks for itself.

16 THE WITNESS: Yes. I think I
17 encompass this in my declaration, but
18 the detent gives you the ability to
19 control the tensioning force at
20 different levels; in other words, fully
21 compressed, partially compressed, fully
22 released.

23 BY MR. STOWELL:

24 Q. And what is your understanding of the
25 purpose of the detent feature?

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

3 THE WITNESS: To give the
4 operator control on the advancement and
5 withdrawal of devices and/or multiple
6 instruments.

7 BY MR. STOWELL:

8 Q. When you say "control," what do you
9 mean by "control"?

10 A. So while he's advancing, he wants
11 minimal friction to interfere with his advancement
12 of the device into the target vasculature.
13 Similarly on withdrawal. But once in position, he
14 wants -- he wants tight -- as tight sealing as
15 possible.

16 So the ability to vary, that gives
17 him control.

18 Q. And so how does the detent feature
19 contribute to how tight the sealing is?

20 MR. HAMILTON: Objection.
21 Vague.

22 THE WITNESS: Well, the detent
23 basically forces the spring into one or
24 another configuration of tension, and so
25 it directly affects the force applied to

1 the compressing string.

2 BY MR. STOWELL:

3 Q. And do you believe that the detent
4 holds the actuator in a specific position?

5 MR. HAMILTON: Objection.

6 Vague. Incomplete hypothetical.

7 THE WITNESS: Yes.

8 BY MR. STOWELL:

9 Q. And was that understanding important
10 to your analysis of the Hartley reference?

11 A. Yes.

12 Q. If we could turn to paragraph 33 of
13 Hartley.

14 A. Okay.

15 Q. This paragraph describes the detent
16 arrangement. In the last sentence, it says, "The
17 rotary actuator may be rotated in either direction
18 to cause constriction of the constriction valve,
19 and the detents provide tactical feel the action of
20 the valve."

21 Do you see that?

22 A. I do.

23 Q. Do you understand what it means by
24 "provide tactical feel"?

25 A. This relates to the operator control

1 I just described.

2 Q. And so what do you understand
3 "provide tactical feel" to mean?

4 A. One measure would be the operator
5 sense a friction in advancing and withdrawing the
6 device.

7 Q. And how does the operator sense the
8 friction?

9 A. It's a simple feeling in the hands.
10 The tension he requires to advance or pull the
11 device.

12 Q. And how is that feeling of tension
13 connected to the detent arrangement?

14 A. The detent has imposed one of two or
15 more forces of constriction which is associated
16 with two or more forces of friction. And so the
17 operator senses that when he's advancing or
18 withdrawing his device.

19 Q. So as you turn Hartley's rotator,
20 rotary actuator, the ball will fall into one of the
21 detent holes, correct?

22 A. Yes.

23 Q. And when that happens, will the user
24 of the actuator be able to feel that ball falling
25 into the hole?

1 MR. HAMILTON: Objection.

2 Vague. Incomplete hypothetical.

3 THE WITNESS: The operator will
4 feel the resistance or the lack of
5 resistance to his manipulation of the
6 device inside the tubular structure.

7 BY MR. STOWELL:

8 Q. And so when paragraph 33 is talking
9 about "The detent provides tactical feel," is it
10 talking about the movement of the ball into one of
11 the holes, that tactical feedback?

12 MR. HAMILTON: Objection. Asked
13 and answered.

14 THE WITNESS: No. The tactile
15 feedback is to the hands of the operator
16 manipulating the device inside the
17 structure.

18 BY MR. STOWELL:

19 Q. I guess what is confusing me about
20 your explanation is that the paragraph 33 says,
21 "The detents provide tactical feel."

22 In your scenario where the operator
23 manipulating the device in the structure is getting
24 tactical feedback, how are the detents involved in
25 the process?

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

3 THE WITNESS: The detents
4 adjust, if you will, the spring tension
5 at a certain point. The spring tension,
6 in response to that, constricts further
7 or less further of the tubular
8 structure. More compression means more
9 friction; less compression means less
10 friction. So one extreme detent would
11 be minimum compression, minimum
12 friction; the other extreme would be
13 maximum compression, maximum friction.

14 BY MR. STOWELL:

15 Q. And do you believe that the spring
16 force from the detent arrangement is causing
17 constriction of the cylindrical diaphragm running
18 through the valve?

19 MR. HAMILTON: Objection.
20 Vague.

21 THE WITNESS: Yeah. Your
22 wording seems awkward to me. All the
23 detent does is physically impose a
24 particular state of spring tension and
25 associated constriction. That's all the

1 detent does.

2 So I don't know if that answers
3 your question.

4 BY MR. STOWELL:

5 Q. Would it be fair to say the ball and
6 the detent gives the user feedback about how far
7 the actuator has been rotated?

8 MR. HAMILTON: Objection.

9 Vague. Asked and answered.

10 THE WITNESS: Yeah, the tactile
11 feedback to the operator is going to be
12 during his manipulation of the enclosed
13 device. It's not going to be tactile
14 feedback from the detent or the spring.

15 BY MR. STOWELL:

16 Q. And so it's your interpretation that
17 in paragraph 33, when the specification says "the
18 detents provide tactical feel," that's referring to
19 the user pushing or pulling the device through the
20 valve, correct?

21 A. Yes.

22 Q. Okay. And that opinion that you
23 have, was that an important opinion to your
24 evaluation of the Hartley reference?

25 MR. HAMILTON: Objection.

1 Vague.

2 THE WITNESS: Yes.

3 BY MR. STOWELL:

4 Q. And is that an opinion you relied
5 upon in interpreting Hartley?

6 MR. HAMILTON: Objection.

7 Vague.

8 THE WITNESS: It was more
9 related to the asserted combination of
10 inventions that, as I opined, obviated
11 the value of the detents in the Hartley
12 patent.

13 BY MR. STOWELL:

14 Q. Do you believe that Hartley requires
15 the detent arrangement in order to constrict the
16 cylindrical diaphragm within the valve?

17 MR. HAMILTON: Objection.

18 Vague. Incomplete hypothetical.

19 THE WITNESS: No, I don't -- I
20 don't believe that it's a requirement.
21 I think it's an additional feature that
22 offers an additional level of control.

23 BY MR. STOWELL:

24 Q. Have you considered, in forming your
25 opinions that are in Exhibit 2008, how Hartley's

1 valve would operate if the detents were not
2 present?

3 MR. HAMILTON: Objection.

4 Beyond the scope.

5 THE WITNESS: Yeah, it's out of
6 the scope.

7 BY MR. STOWELL:

8 Q. That's not something you considered?

9 A. No.

10 MR. HAMILTON: We've been going
11 for a little over an hour. Is this a
12 good spot to break?

13 MR. STOWELL: Sure.

14 THE VIDEOGRAPHER: Okay. We're
15 off the record at 1:52 p.m.

16 (Recess.)

17 THE VIDEOGRAPHER: This is the
18 beginning of media number five. We're
19 on the record at 2 p.m.

20 BY MR. STOWELL:

21 Q. Okay. Dr. Zalesky, did you speak to
22 anybody about the subject matter of your testimony
23 during the break?

24 A. No.

25 Q. Did you review any documents?

1 A. No.

2 Q. Okay. I'm going to hand you what has
3 been previously marked as Exhibit 1007 in this IPR.
4 (Exhibit No. 1007 was
5 previously marked for
6 identification.)

7 MR. STOWELL: Thank you.

8 BY MR. STOWELL:

9 Q. And do you recognize Exhibit 1007?

10 A. Yes.

11 Q. And what is Exhibit 1007?

12 A. It appears to be a copy of the Eller
13 patent.

14 Q. Okay. And is this one of the patents
15 that you studied in preparing your supplemental
16 declaration, Exhibit 2008?

17 A. Yes.

18 Q. Okay. And when was the last time you
19 had an opportunity to review the Eller patent?

20 A. Weeks ago.

21 Q. And Eller describes another type of
22 rotating hemostasis valve, correct?

23 A. Yes.

24 Q. If we look at column 12 of the Eller
25 patent, at line 37 -- and let me know when you're

1 there.

2 A. Okay.

3 Q. So at line 37 it refers to the
4 sleeve. Do you understand what the Eller patent
5 means by "the sleeve 20"?

6 A. Yes.

7 Q. Okay. And what is the sleeve?

8 A. My understanding is a tube that
9 receives the target structure.

10 Q. And is it the tube that is
11 constricted by the filament within Eller's valve?

12 MR. HAMILTON: Objection.

13 Vague. Calls for a legal conclusion.

14 THE WITNESS: Yes.

15 BY MR. STOWELL:

16 Q. And in paragraph -- or in that
17 paragraph we were looking at in column 12, it
18 explains that the sleeve can be formed of any
19 suitable material and using any suitable
20 manufacturing technique. And then it goes on to
21 state that "Skilled artisans will be able to select
22 a suitable material and technique to form a sleeve
23 according to a particular embodiment based on
24 various considerations, including the materials
25 that form the housing of an embodiment."

1 Do you see that?

2 A. I do.

3 Q. And do you agree with Eller that a
4 person of ordinary skill in the art would have
5 possessed the background and knowledge to select a
6 suitable material for the sleeve?

7 MR. HAMILTON: Objection.

8 Vague. Beyond the scope.

9 THE WITNESS: It's unclear.

10 BY MR. STOWELL:

11 Q. And why is it unclear?

12 A. Because of the word "suitable."

13 Q. And why does that make it unclear?

14 A. Very nonspecific.

15 Q. And so is it your testimony that a
16 person of ordinary skill in the art would not have
17 been able to determine what would be a suitable
18 material for the sleeve?

19 MR. HAMILTON: Objection.

20 Incomplete hypothetical.

21 THE WITNESS: The POSITA that we
22 agreed to does not include a great
23 experience or learning in material
24 science. And material science would be
25 involved in that material selection.

1 BY MR. STOWELL:

2 Q. And so the -- the paragraph here goes
3 on to identify example materials considered
4 suitable to form a sleeve, and it lists a number of
5 different materials there.

6 Do you see that?

7 A. Yes.

8 Q. And so is it your position that a
9 person of ordinary skill in the art, as we've
10 defined it, would not have been familiar with these
11 materials that are listed here?

12 A. No. My comment relates to the
13 suitability of those materials.

14 Q. So would a person of ordinary skill
15 in the art, in September of 2017, have been
16 familiar with the specific materials listed in the
17 paragraph we're discussing on page 12, which
18 includes things like elastomeric materials,
19 polymers, polyurethanes, et cetera?

20 A. I think so.

21 Q. And would a person of ordinary skill
22 in the art have been able to select the appropriate
23 materials among that list to form sleeve 20 in the
24 Eller device?

25 A. That's my key question.

1 Suitability's not really defined.

2 Q. And so as you sit here today, do you
3 have an opinion on whether a person of ordinary
4 skill in the art, as of September 2017, would have
5 been able to select a suitable material to form the
6 sleeve in the Eller device?

7 MR. HAMILTON: Objection.

8 Incomplete hypothetical.

9 THE WITNESS: Yeah, as I said
10 before, I'm not sure.

11 BY MR. STOWELL:

12 Q. You don't have an opinion on that
13 today?

14 A. I do not.

15 Q. This paragraph also states that the
16 skilled artisan would be able to select the
17 manufacturing technique for the sleeve. And if you
18 look further down in the paragraph, it gives some
19 examples of techniques including injection,
20 molding, casting, and extrusion.

21 Do you agree that a person of
22 ordinary skill in the art, in September of 2017,
23 would have been able to select the appropriate
24 manufacturing technique for the sleeve identified
25 in the Eller reference?

1 MR. HAMILTON: Objection.

2 Vague. Incomplete hypothetical.

3 THE WITNESS: In general, yes.

4 BY MR. STOWELL:

5 Q. And is there a reason why you think
6 that the person of ordinary skill in the art would
7 have been capable of selecting a suitable
8 manufacturing technique but would not have been
9 capable of selecting the suitable material?

10 MR. HAMILTON: Objection.

11 Incomplete hypothetical.

12 THE WITNESS: Different
13 materials are more easily processed with
14 certain methods than other materials, so
15 extrusion works with some polymers, not
16 all polymers, as an example.

17 BY MR. STOWELL:

18 Q. And would a person of ordinary skill
19 in the art, in September 2017, have known which
20 materials would work with the manufacturing
21 techniques identified in the paragraph on
22 column 12, around line 50?

23 MR. HAMILTON: Objection.

24 Vague. Incomplete hypothetical.

25 THE WITNESS: Yeah, I thought we

1 just asked and answered that.

2 BY MR. STOWELL:

3 Q. And what was your answer?

4 A. Yes.

5 Q. Let's look at column 14, beginning at
6 line 37. And this is describing an embodiment of
7 the Eller valve where there's an attachment between
8 the wire member and a housing or the -- and/or an
9 actuator.

10 Do you see that?

11 A. I'm not sure which line you're
12 looking at.

13 Q. Line 37, column 14.

14 MR. HAMILTON: Objection.

15 Mischaracterizes the document. It
16 speaks for itself.

17 THE WITNESS: So yes, I see the
18 line.

19 BY MR. STOWELL:

20 Q. And do you remember reviewing
21 embodiments in the Eller reference where the wire
22 member was attached to a housing and/or an
23 actuator?

24 A. Yes.

25 Q. It goes on to explain that "Skilled

1 artisans will be able to select a suitable method
2 or technique to attach a wire member to a housing
3 and/or an actuator according to a particular
4 embodiment based on various considerations."

5 Do you see that?

6 A. Yes.

7 Q. And would you agree that the person
8 of ordinary skill in the art, in September of 2017,
9 would have possessed the skills to select a
10 suitable method to attach a wire member to a
11 housing or an actuator?

12 MR. HAMILTON: Objection.

13 Incomplete hypothetical.

14 THE WITNESS: Yes.

15 BY MR. STOWELL:

16 Q. The paragraph goes on to identify
17 some methods or techniques to attach a wire member
18 to a housing or an actuator, including adhesives,
19 welding, fusing, providing a friction fit, and
20 other suitable techniques.

21 Do you see that?

22 A. Yes.

23 Q. Would the techniques of using an
24 adhesive, welding, fusing, or providing a friction
25 fit have been techniques known to a person of

1 ordinary skill in the art, in September of 2017,
2 for attaching a wire to a housing or an actuator?

3 MR. HAMILTON: Objection.

4 Incomplete hypothetical.

5 THE WITNESS: Yes.

6 BY MR. STOWELL:

7 Q. If we look at column 15, line 41 --
8 let me know when you have a chance to --

9 A. Okay.

10 Q. -- find it.

11 Okay. And there it's describing wire
12 members. And it says that they can be formed with
13 any suitable material and using any suitable
14 manufacturing technique.

15 Do you see that?

16 A. Yes.

17 Q. And do you understand that the wire
18 members are the filaments that are used to
19 constrict the sleeve in the Eller valve?

20 A. Yes.

21 Q. And it goes on to explain that the
22 "Skilled artisans will be able to select a suitable
23 material and technique to form a wire member
24 according to a particular embodiment based on
25 various considerations."

1 Would you agree that a person of
2 ordinary skill in the art, in September 2017, would
3 have possessed the skills and knowledge necessary
4 to select a suitable wire member to constrict the
5 sleeve in the Eller device?

6 MR. HAMILTON: Objection.

7 Incomplete hypothetical.

8 THE WITNESS: Yes.

9 BY MR. STOWELL:

10 Q. The paragraph goes on, and if you
11 read the last sentence, it talks about the
12 techniques considered suitable to form a wire
13 member, and it mentions injection, molding,
14 casting, et cetera.

15 Would you agree that a person of
16 ordinary skill in the art, in September of 2017,
17 would have known of the techniques listed in this
18 paragraph for forming a wire member?

19 MR. HAMILTON: Objection.

20 Incomplete hypothetical.

21 THE WITNESS: Yes.

22 BY MR. STOWELL:

23 Q. Then in paragraph -- or sorry, in
24 column 16, there's a paragraph that begins at
25 line 7. It starts with "While the selective fluid

1 barrier device."

2 Let me know when you --

3 A. Okay.

4 Q. Did you find it?

5 A. Yes.

6 Q. And there it's listing an embodiment
7 that has a first wire member, a second wire member,
8 and a third wire member, right?

9 A. Yes.

10 Q. Okay. That paragraph, if you go to
11 the next sentence, it says, "Skilled artisans will
12 be able to select a suitable number of wire
13 members, to include in a selective fluid barrier
14 device, according to a particular embodiment based
15 on various considerations."

16 Do you see that?

17 A. Yes.

18 Q. And do you agree that a person of
19 ordinary skill in the art, in September of 2017,
20 would have been able to select a suitable number of
21 wire members to include in a selective fluid
22 barrier device?

23 MR. HAMILTON: Objection.

24 Incomplete hypothetical. Vague.

25 THE WITNESS: I believe so.

1 BY MR. STOWELL:

2 Q. Earlier we had talked about the rate
3 you charge for your expert witness services in
4 legal matters.

5 What percentage of your legal matters
6 do you charge the rate of \$300 an hour?

7 A. This is the only one.

8 Q. So in your other legal matters, you
9 charge more than \$300 an hour; is that correct?

10 A. Yes.

11 Q. Okay. And what percentage of your
12 legal matters do you charge \$500 an hour?

13 A. Twenty.

14 Q. And then the roughly other 80 percent
15 of your legal matters, what -- what range do you
16 bill those at?

17 A. Three-fifty to four.

18 MR. STOWELL: Okay, Dr. Zalesky,
19 I have no further questions for you
20 today.

21 MR. HAMILTON: All right. Why
22 don't we take a break and I'll see if I
23 have any follow-up. Thanks.

24 THE VIDEOGRAPHER: We're off the
25 record at 2:15 p.m.

1 (Recess.)

2 THE VIDEOGRAPHER: We're back on
3 the record at 2:29 p.m.

4 EXAMINATION

5 BY MR. HAMILTON:

6 Q. Dr. Zalesky, if you could take a look
7 at Exhibit 2008. This is your supplemental
8 declaration.

9 A. Yep.

10 Q. And if you could turn to page 48.

11 A. Yep.

12 Q. If you look at the heading B, can you
13 read that for me.

14 A. "Schaffer does not disclose the first
15 filament formed into a loop around the collapsible
16 tubular sidewall of Claim 1."

17 Q. Is it your opinion that Schaffer does
18 not disclose the first filament formed into a loop
19 around the collapsible tubular sidewall of Claim 1?

20 MR. STOWELL: Objection.

21 Outside the scope of cross.

22 THE WITNESS: Yes.

23 BY MR. HAMILTON:

24 Q. If you could turn to Exhibit 1008
25 and turn to Figure 32 on page 17.

1 A. Yep.

2 Q. Does the embodiment in Figure 2 show
3 side-by-side U-shaped members?

4 MR. STOWELL: Objection.

5 Leading.

6 THE WITNESS: Yes.

7 BY MR. HAMILTON:

8 Q. Do those U-shape members interlock?

9 MR. STOWELL: Objection.

10 Leading.

11 THE WITNESS: No.

12 BY MR. HAMILTON:

13 Q. Take a look at Exhibit 1001. This is
14 the '012 patent.

15 A. Okay.

16 Q. If you could take a look at the
17 last -- second-to-last page, page 30.

18 A. Yep.

19 Q. And you see in column 22, about
20 line 26 --

21 A. Yes.

22 Q. -- you see a reference there to Claim
23 No. 2?

24 A. Yes, I do.

25 Q. And then if you go down to line 38 of

1 that claim --

2 A. Yes.

3 Q. -- you see the phrase "the filament
4 circumferentially constricts the valve lumen."

5 Do you see that?

6 A. I do.

7 Q. Do the U-shaped members shown in
8 Figure 32 of Schaffer that I believe you just said
9 are side by side, do those circumferentially
10 constrict the valve lumen as recited in Claim 2?

11 MR. STOWELL: Objection.

12 Leading.

13 THE WITNESS: No, they cannot
14 physically do that.

15 BY MR. HAMILTON:

16 Q. Okay. Then if you could take a look
17 at your declaration, paragraph 59, I believe. It
18 might be page 59.

19 A. The supplemental or the --

20 Q. Sorry. It's page -- page -- the
21 paragraph beginning on page 59 going into 60.

22 A. My supplemental, yes.

23 Q. Your supplemental declaration, yes,
24 Exhibit 2008.

25 A. Okay.

1 Q. And if you need to, feel free to take
2 a minute to read paragraph 110.

3 A. Okay.

4 Q. Do you understand what's depicted in
5 the Figures 16 through 19 in that paragraph?

6 A. Yes.

7 Q. And does Figure 17 depict -- excuse
8 me.

9 Are Figures 16 through 19 from the
10 Schaffer reference?

11 A. Yes.

12 Q. And does Figure 16 -- excuse me.
13 Figure 17, does that depict a lumen
14 that is completely sealed?

15 A. That's my understanding.

16 Q. And then Figure 19, does that depict
17 a lumen that is sealed to a very small diameter?

18 A. Yes.

19 Q. And then Figure 18, does that depict
20 a lumen that is sealed around an irregularly-shaped
21 item?

22 A. Yes.

23 MR. STOWELL: Objection.

24 Leading. And outside the scope of
25 cross.

1 MR. HAMILTON: With that, I have
2 no further questions.

3 FURTHER EXAMINATION

4 BY MR. STOWELL:

5 Q. Dr. Zalesky, did you discuss your
6 redirect examination with counsel during the break?

7 A. No.

8 Q. Did you discuss any of the topics
9 that might be raised in redirect with your counsel
10 during the break?

11 A. No.

12 MR. STOWELL: Okay. I have no
13 further questions.

14 MR. HAMILTON: Fantastic.

15 THE VIDEOGRAPHER: Mr. Hamilton,
16 would you like to order a video at this
17 time?

18 MR. HAMILTON: I would, yes.

19 THE VIDEOGRAPHER: Would you
20 like the video synced with the
21 transcript?

22 MR. HAMILTON: Please.

23 THE VIDEOGRAPHER: Okay.

24 This concludes the video
25 recorded proceeding of Paul Zalesky.

1 We're off the record at 2:35 p.m.
2 (Whereupon, the deposition of
3 PAUL J. ZALESKY, Ph.D. was concluded
4 at 2:35 p.m.)

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

2 The undersigned Certified Shorthand Reporter
3 does hereby certify:

4 That the foregoing proceeding was taken
5 before me at the place and time therein set forth,
6 at which time the witness was duly sworn; That the
7 testimony of the witness and all objections made at
8 the time of the examination were recorded
9 stenographically by me and were thereafter
10 transcribed, said transcript being a true and
11 correct copy of my shorthand notes thereof; That
12 the dismantling of the original transcript will
13 void the reporter's certificate.

14 In witness thereof, I have subscribed
15 my name this date: August 30, 2025.

16

17

18

19

20



Handwritten signature of Leslie A. Todd in cursive script, with the printed name "LESLIE A. TODD" underneath.

21 (The foregoing certification of
22 this transcript does not apply to any
23 reproduction of the same by any means,
24 unless under the direct control and/or
25 supervision of the certifying reporter.)

1 Paul J. Zalesky, Ph.D., c/o
PERKINS COIE LLP
2 633 West 5th Street, Suite 5850
Los Angeles, California 90071

3
Case: Imperative Care, Inc. v. Inari Medical Inc.
4 Date of deposition: August 27, 2025
Deponent: Paul J. Zalesky, Ph.D.

5
6 Please be advised that the transcript in the above
referenced matter is now complete and ready for signature.
7 The deponent may come to this office to sign the transcript,
8 a copy may be purchased for the witness to review and sign,
9 or the deponent and/or counsel may waive the option of
10 signing. Please advise us of the option selected.
11 Please forward the errata sheet and the original signed
12 signature page to counsel noticing the deposition, noting the
13 applicable time period allowed for such by the governing
14 Rules of Procedure. If you have any questions, please do
15 not hesitate to call our office at (202)-232-0646.

16
17
18 Sincerely,
19 Digital Evidence Group
20 Copyright 2025 Digital Evidence Group
21 Copying is forbidden, including electronically, absent
22 express written consent.

23
24
25

1 Digital Evidence Group, L.L.C.
 1730 M Street, NW, Suite 812
 2 Washington, D.C. 20036
 (202) 232-0646

3
 4 SIGNATURE PAGE
 Case: Imperative Care, Inc. v. Inari Medical Inc.
 5 Witness Name: Paul J. Zalesky, Ph.D.
 Deposition Date: August 27, 2025

6
 I do hereby acknowledge that I have read
 7 and examined the foregoing pages
 of the transcript of my deposition and that:

8
 9 (Check appropriate box):
 () The same is a true, correct and
 10 complete transcription of the answers given by
 me to the questions therein recorded.
 11 () Except for the changes noted in the
 attached Errata Sheet, the same is a true,
 12 correct and complete transcription of the
 13 answers given by me to the questions therein
 14 recorded.

15
 16 _____
 17 DATE WITNESS SIGNATURE

18
 19
 20
 21 _____
 22 DATE NOTARY

23
 24
 25

1 Digital Evidence Group, LLC
 2 1730 M Street, NW, Suite 812
 3 Washington, D.C. 20036
 4 (202)232-0646

5

6

ERRATA SHEET

7

8 Case: Imperative Care, Inc. v. Inari Medical Inc.

9 Witness Name: Paul J. Zalesky, Ph.D.

10 Deposition Date: August 27, 2025

11	Page No.	Line No.	Change
----	----------	----------	--------

12

13

14

15

16

17

18

19

20

21

22

Signature

Date

23

24

25