

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner

v.

INARI MEDICAL, INC.,
Patent Owner.

IPR2025-00156
Patent 11,697,012 B2

Record of Oral Hearing
Held: January 20, 2026

Before JEFFREY N. FREDMAN, ERIC C. JESCHKE, and
TIMOTHY G. MAJORS, Administrative Patent Judges.

APPEARANCES:

ON BEHALF OF THE PETITIONER:

JOSHUA J. STOWELL, ESQ.
BRIAN C. BARNES, ESQ.
of: Knobbe, Martens, Olson & Bear, LLP
2040 Main Street
14th Floor
Irvine, CA 92614
949-760-0404
Joshua.stowell@knobbe.com
Brian.barnes@knobbe.com

ON BEHALF OF THE PATENT OWNER:

JOSEPH HAMILTON, ESQ.
Perkins Coie LLP
633 West Fifth Street
Suite 5850
Los Angeles, CA 90071
310-788-3271
Hamilton-ptab@perkinscoie.com

The above-entitled matter came on for hearing Tuesday,
January 20, 2026, commencing at 9:06 a.m. EST, at the U.S. Patent
and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

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

(9:06 a.m.)

JUDGE MAJORS: Good morning everyone. This is Judge Majors, and with me are Judges Fredman and Jeschke. This is the final oral hearing in IPR 2025-00156. It concerns U.S. Patent 11,697,012. Our parties are Imperative Care, Inc. as the Petitioner and Inari Medical, Inc. as Patent Owner. Our court reporter is present, and we will enter a transcript of this hearing in due course.

Counsel for Petitioner, would you identify who is present and let us know who is going to be doing the presentation today?

MR. STOWELL: Good morning, your honor, is Joshua Stowell of Knobbe Martens. I will be arguing on behalf of the Petitioner, Imperative Care. Joining me today is my colleague, Mr. Brian Barnes, also from Knobbe Martens.

JUDGE MAJORS: Thank you.

And Patent Owner's counsel, would you identify yourself and let us know who's going to be doing your presentation today?

MR. HAMILTON: Good morning, your honor. It's Joseph Hamilton from Perkins Coie for Patent Owner. I will be doing the argument today. I also want to mention that a representative of Stryker Corporation, Dr. Samantha Pak, IP counsel at Stryker, is on the public line, and there

1 may be others from representative client. Thank you.

2 JUDGE MAJORS: Okay. Thank you, Mr.
3 Hamilton.

4 Good to see you both again. As set forth in our
5 December 15th, 2025 order, each side has 60 minutes to
6 present this argument in this case. The panel will do our
7 best to track the time, but I would also suggest that you do
8 likewise.

9 Petitioner, as you bear the burden of proof, you will
10 be presenting your argument first. Would you like to
11 reserve -- Petitioner, would you like to reserve any time for
12 rebuttal?

13 MR. STOWELL: Yes, Your Honor. Given the
14 Board's decision in the related '011 patent IPR last Friday,
15 Petitioner does not intend to re-argue the findings of fact
16 and issues of law that this Board has already resolved. I'll
17 explain why those findings of fact and conclusions of law
18 apply here. I notified Counsel early yesterday morning to
19 let him know that this would be Petitioner's position.

20 Because of that, I don't plan to re-argue all of my
21 slides. In fact, I plan to go through a very small fraction of
22 them. I don't expect my opening argument take more than
23 10 or maybe 15 minutes. I'll reserve the rest of my time to
24 respond to the arguments made by Patent Owner. I'm not
25 sure right now what those arguments will be. So I'll reserve
26 my time to respond.

1 JUDGE MAJORS: Okay. And Patent Owner, would
2 you like to reserve any rebuttal time?

3 MR. HAMILTON: Yes, Your Honor, 20 minutes.
4 And I don't know if we heard an actual time from Petitioner
5 on what's reserved.

6 JUDGE MAJORS: I think we'll just put the 60
7 minutes on the clock and, obviously, the whatever they use
8 for rebuttal needs to be in rebuttal. It would not be an
9 opportunity to argue issues that were not raised in his
10 presentation. Right.

11 As noted earlier, this hearing is open to the public.
12 And although I don't believe there's any confidential
13 information that has been filed in this case, the panel has the
14 entire record, including demonstratives. We would
15 encourage the parties when you're making your presentation
16 and referring to a particular demonstrative to identify that
17 demonstrative by its page number and just give us a
18 moment to catch up with you. We expect that the parties
19 will not interrupt the other parties presentation unless
20 absolutely necessary.

21 And lastly, if either party notices a technical issue
22 that's affecting your presentation today, please let one of the
23 judges know or let one of the staff there know in the hearing
24 room, and we will try to get that fixed. So Judge Fredman,
25 I guess, like I said we'll put 50 -- or 60 minutes on the clock
26 for Petitioner, and then we'll stop that and we'll revisit if

1 necessary depending on how the initial presentation goes.

2 JUDGE FREDMAN: Sounds good. Let's proceed
3 when you're ready, I guess.

4 MR. STOWELL: Thank you, Your Honors, and may
5 it please the Board. Petitioner has filed several IPRs against
6 related patents owned by the Patent Owner. And last
7 Friday, the Board issued a final written decision in IPR
8 2024-01157 that related to the '011 Patent. Petitioner
9 submits that that final written decision addresses and
10 resolves all of the disputes that are raised in this IPR, and
11 most importantly, it resolves the dispute of whether a
12 person of ordinary skill in the art would have been
13 motivated to combine Schaffer with Hartley or Eller.

14 And we have reached the conclusion that the '011
15 Patent resolves -- that the IPR resolves issues in this case
16 based on a number of factors. First, there are a common set
17 of facts across the IPRs. The '011 Patent and the '012
18 Patent share the same specification. They are continuations
19 of a common application. The patents have similar patent
20 claims. Today, I intend to briefly discuss the differences
21 between the claims and explain why those aren't material to
22 the arguments that have been raised here today.

23 Patent Owner also relies on the same evidence in the
24 '012 Patent IPR that it relied on in the '011 Patent IPR to
25 contest the grounds of unpatentability. Patent Owner relied
26 on the depositions from this IPR, the '012 IPR in the '011

1 IPR. So those transcripts were part of the record there.
2 Patent Owner has used the same expert as has Petitioner in
3 this IPR. They have provided substantially similar
4 declarations across both IPRs. Petitioner has also raised
5 overlapping references across the IPRs. I'm going to refer
6 to Petitioner's demonstratives, and I'll go to slide four of
7 Petitioner's demonstrative, which sets forth the grounds in
8 the '012 IPR.

9 Judge Jeschke, do you?

10 JUDGE JESCHKE: No I was just asking if it could
11 get put up over there, but it's okay. I can see it over there.
12 And we have it here. It's fine.

13 MR. STOWELL: Okay.

14 JUDGE JESCHKE: I didn't mean to interrupt.

15 MR. STOWELL: No, no. I want to make sure
16 everybody can see. So in the '012 Patent IPR, as it did in
17 the '011 IPR, Petitioner has raised the ground 3, Schaffer
18 plus Hartley. Petitioner has also, again, raised ground 4,
19 which is Schaffer plus Eller, and those overlap with the
20 grounds that the Board relied upon in the '011 Patent IPR to
21 find the claims in that patent unpatentable.

22 If we turn to slide five of Petitioner's demonstratives,
23 we see with respect to grounds 3 and 4 the exact same issue
24 that was raised in the '011 Patent IPR has been raised by the
25 Patent Owner in this IPR, and that is whether a person of
26 ordinary skill in the art would have been motivated to

1 combine Schaffer plus Hartley and Eller. And that is the
2 only dispute Patent Owner has raised with respect to
3 grounds 3 and 4 in this IPR, just as it did in the '011 Patent
4 IPR. And the Board noted the similarities of the arguments
5 across the IPR and the institution decision at footnote 18,
6 particularly with respect to the Schaffer plus Hartley or
7 Eller grounds.

8 The Board fully addressed the motivation to combine
9 Schaffer plus Hartley or Eller in the '011 Patent IPR. In its
10 final written decision, it dedicated almost 20 pages to
11 addressing all of the arguments that Patent Owner raised,
12 addressing all the evidence, and it concluded that claims 1
13 through 9 were unpatentable because they would have been
14 obvious over Schaffer plus Hartley or Eller. And if the
15 Board applies that same reasoning here, which it should,
16 then claims 1 through 9 of the '012 Patent would also be
17 obvious.

18 In order for Patent Owner to prevail in this IPR, it
19 effectively would need the Board to reconsider its final
20 written decision in the '011 Patent IPR, and that is a high
21 standard. The Board reviews request for reconsideration for
22 abuse of discretion. It requires the Patent Owner to identify
23 the areas that the Board either misapprehended or
24 overlooked in the arguments, and I submit that the Board
25 did not overlook or misapprehend any of the arguments that
26 were made in the '011 Patent IPR that have been repeated in

1 this IPR. In fact, throughout the 20 pages, the Board does a
2 very thorough job of addressing every argument raised by
3 the parties.

4 We also have the acting Undersecretary's September
5 2025 memo, which encourages consistency across IP
6 matters and would require additional explanation if the
7 Board were to adopt an inconsistent position here, which,
8 again, based on the overlapping facts and the common law
9 would not be appropriate.

10 It is worth just briefly touching upon the issues that
11 are not in dispute in this IPR. If we go to Petitioner's
12 demonstrative 6, critically, as in the '011 IPR, there is no
13 dispute that Hartley and Eller disclose a filament that forms
14 a loop. Patent Owner has raised no arguments regarding
15 grounds 5 through 7, which rely on the Garrison reference
16 outside of this motivation to combine argument with
17 Schaffer and Hartley. Patent Owner has not argued that
18 Garrison could not be combined with Schaffer or that a
19 person of ordinary skill in the art would not have been
20 motivated to do so.

21 Patent Owner raises no unique arguments regarding
22 defendant claims 2 through 9. There is no dispute that the
23 preamble of claim 1 is not limiting, and I'll discuss that in a
24 minute because that is a unique aspect of this case. There's
25 no dispute that the Petitioner's references qualify as prior
26 art. There's no evidence of secondary considerations has

1 been submitted. There are no motions to exclude. There
2 are no motions to strike.

3 So at this point, I think it's worth looking at the
4 claims of the '011 Patent and just doing a quick comparison
5 to the claims of the '012 Patent, and explain why those
6 differences don't impact the Board's findings of fact and
7 conclusions of law from the '011 Patent. On the screen, it's
8 just a comparison of the claims. On the left hand side is
9 claim 1 through 4 of the '011 Patent. The '011 Patent is of
10 record in this IPR. It is Exhibit 1022. On the right hand
11 side is just claim 1 of the -- there's claims 1 through 4 of the
12 '012 Patent. The '012 Patent is Exhibit 1001 in this case.

13 And so the first difference we see is that the preamble
14 is different. In the '011 Patent, the preamble recited a valve.
15 In the '012 Patent, the preamble recites an aspiration
16 catheter. There is no dispute in this case that the Schaffer
17 reference in grounds 3 and 4 and the Garrison reference and
18 grounds 5 through 7 disclose an aspiration catheter. So
19 there is no dispute that the prior art discloses an aspiration
20 catheter.

21 Petitioner's evidence is un rebutted on that issue. It's
22 set forth in Schaffer. It set forth in the petition at Pages 24
23 through 29 and the declaration of Mr. Thornton at Exhibit
24 1003, Paragraphs 62 through 76. The Garrison discussion
25 is in the petition at Pages 85 to 93 and Exhibit 1003,
26 Paragraphs 174 to 199. So again, that evidence is

1 unrebutted.

2 There is discussion in the papers about whether the
3 preamble is limiting. Again, Petitioner in its petition took
4 the position that the preamble is not limiting and explained
5 why that was the case. However, it addressed the claims
6 also in the alternative with the presumption that the
7 preamble is limiting. So, Petitioner covered it both ways.
8 That the preamble is not limiting is not in dispute in this
9 case.

10 If we turn to slide 47, Brian, of Petitioner's
11 demonstratives, we can see that the Patent Owner states on
12 the right hand side of the slide that this claim construction
13 issue is not germane to Patent Owner's arguments here. So
14 Patent Owner did not dispute, but the preamble is not
15 limiting. Now, because Petitioner has shown how the prior
16 art meets this limitation under either construction, limiting
17 or not limiting, the Board does not necessarily need to
18 resolve whether the preamble is limiting to resolve this IPR.

19 The next difference in the claims requires an
20 aspiration -- in the '012 Patent is required an aspiration
21 catheter having an elongated, flexible tubular body having a
22 proximal end, distal end, and a central lumen. Again, this
23 limitation is not in dispute in this IPR. The Petitioner has
24 shown that the Schaffer reference meets this limitation.
25 Petitioner has also shown that the Garrison reference meets
26 this limitation, and there has been no dispute.

1 On slide 48 of Petitioner's demonstratives, we see the
2 entirety of Patent Owner's argument from the POR
3 regarding these combinations. What we see is that the
4 Patent Owner focused on the hemostasis valve limitation,
5 and does not dispute that Schaffer and Garrison meet the
6 tubular body hemostasis valve aspiration catheter
7 limitations. So, the preamble and the first limitation of
8 claim 1 -- of the claims in the '012 Patent are not material to
9 the findings of fact and conclusions of law that the Board
10 has already made.

11 If we go back to the claim, there is a difference in
12 plain terminology. The '011 Patent requires a tubular
13 member. The '012 Patent requires a collapsible tubular
14 sidewall in claim 1, and in claim 2 states that the collapsible
15 tubular sidewall comprises a tubular member. Once again,
16 there's no dispute that Schaffer, in grounds 3 and 4,
17 discloses this limitation, the collapsible tubular sidewall.
18 And the evidence that's been supplied by Petitioner on how
19 the prior art meets this limitation. It stands un rebutted.
20 Additionally, there's no dispute that the Garrison reference
21 in grounds 5 through 7 discloses the -- or that -- sorry, that
22 the Schaffer reference in combination with Garrison
23 discloses the collapsible tubular sidewall, and the evidence
24 that has been supplied and that is un rebutted is at Exhibit
25 1003, Paragraphs 82 to 85.

26 Another difference in terminology is that the '011

1 Patent requires an actuator having a first member and a
2 second member. The '012 Patent requires a first actuator
3 and a claim to a second actuator. Again, no dispute that the
4 Schaffer valve has a first actuator and a second actuator in
5 this case. Petitioner's evidence on that stands unrebutted.
6 That is in Exhibit 1003 at Paragraphs 87 to 89 and 129 to
7 131.

8 And then next in the '012 Patent, there is a limitation
9 in claim 1 that requires a first filament formed into a loop
10 around the collapsible tubular sidewall, and the claim ends
11 with the requirement that the diameter of the valve lumen
12 decreases in response to reducing the diameter of the loop.
13 The loop requirement did appear in the '011 Patent in
14 dependent claim 3. So it has been addressed in the '011
15 Patent final written decision. Here there is no dispute,
16 again, that the Hartley and Eller references disclose a loop
17 that a first filament formed into a loop around the
18 collapsible tubular sidewall, and there's no dispute that the
19 diameter of the valve lumen decreases in response to
20 reducing the diameter of Hartley and Eller's loop. So that
21 issue also was undisputed, and Petitioner's evidence for that
22 is at Exhibit 1003, 96 through 125.

23 There are some other small differences. For
24 example, claim 1 requires a biasing system. Claim 1 of the
25 '011 Patent. Claim 1 of the '012 Patent requires a first
26 spring and a second spring. Again, no dispute that the

1 Schaffer reference discloses the springs.

2 And so now that we've been through the differences
3 between claim 1 of the '011 Patent and claim 1 of the '012
4 Patent, we see that the claim differences do not impact the
5 findings of fact and conclusions of law that the Board made
6 in the '011 Patent IPR in that final written decision. That
7 those findings of fact and conclusions of law should apply
8 in this case as well because of this overlap, in fact, and no
9 change in law since the Board issued its opinion on Friday.
10 So with that, the Board, based on the '011 final written
11 decision, in this case should also find claims 1 through 9
12 invalid based on the combination of Schaffer plus Hartley
13 and the combination of Schaffer plus Eller.

14 Additionally, going back to my grounds, which were
15 on slide 4. With respect to grounds 6 and 7, there is no
16 dispute that a person of ordinary skill in the art would have
17 been motivated to combine Schaffer and Hartley with
18 Garrison or Schaffer and Eller with Garrison, and there is
19 no dispute that Garrison discloses the aspiration catheter
20 and the elongate, flexible tubular body. Therefore, the only
21 disputes with respect to ground 6 and 7 were whether a
22 person of ordinary skill in the art would have been
23 motivated to combine Schaffer plus Hartley and Eller. That
24 question has been answered in full by the Board, and the
25 final written decision for the '011 Patent. And therefore, the
26 Board should find claims 1 through 9 unpatentable based on

1 ground 6 and 7 as well, relying on the findings of fact and
2 conclusions of law already.

3 JUDGE FREDMAN: Are you defending grounds 1
4 and 2 at all or?

5 MR. STOWELL: I do not intend to address grounds
6 1 and 2 today. I understand that the Board made findings of
7 fact and conclusions of law with respect to grounds 1 and 2.
8 I understand those findings were resolved against Petitioner.
9 I understand that those findings of fact and conclusions of
10 law control until the Board reconsiders and changes that
11 decision. And so I don't plan to reargue those issues today.
12 Thank you for raising that. If there are no further questions,
13 Petitioner would plan to rest there, and I'll respond to ways
14 that Patent Owner may try to distinguish the '011 final
15 written decision.

16 JUDGE MAJORS: Mr. Stowell, before you sit
17 down, quick question about the co-pending litigation. Is
18 that matter still stayed by the court?

19 MR. STOWELL: The matter is still stayed by the
20 court. The court has stayed the case until at least February
21 4th. The parties are currently negotiating on extending that
22 stay. We owe a updated case management conference
23 statement to the court on Wednesday. I think we can file
24 that updated statement with the Board after it's submitted to
25 the court so that the Board can see where we're at in terms
26 of the stay. But we're negotiating extending the stay due to

1 the current status of these IPRs.

2 JUDGE MAJORS: Okay. Thank you. Yeah. Please
3 let us know if there are any material developments before
4 the court. You can send it via email. We authorize any
5 filings as necessary. But given that there are still several
6 related cases that are pending with the Board here, we'd like
7 to at least be aware of what the court is doing.

8 MR. STOWELL: I appreciate that. And just so the
9 timing is clear, we owe a updated case management
10 statement to the court on the 21st, Wednesday. We then
11 have a case management conference currently scheduled for
12 the 28th in front of the court, at which point we'll have
13 some sort of resolution. Thank you, Your Honors.

14 JUDGE FREDMAN: Thank you.

15 JUDGE MAJORS: All right. Mr. Hamilton,
16 whenever you're ready, just let us know.

17 MR. HAMILTON: Thank you, Your Honor.

18 JUDGE FREDMAN: And you wrote 20 minutes,
19 right? You want to do 20 minutes for rebuttal?

20 MR. HAMILTON: Yes, please. Thank you.

21 Morning, Your Honors. I'm ready to begin.

22 JUDGE FREDMAN: Okay.

23 MR. HAMILTON: So this morning, I'd like to focus
24 also on that final written decision issued on Friday.
25 Particularly why this IPR deserves a different result, and
26 primarily why the claims here are not obvious over the

1 combination of Schaffer and Hartley or Schaffer and Eller,
2 that's grounds 2–4, and grounds 6 and 7, which are the same
3 but include Garrison, that doesn't remedy any of the
4 deficiencies that I'm going to discuss to that. I'd like to
5 cover a few things first.

6 What's the proper definition of person of ordinary
7 skill in the art and why that matters here. And then next,
8 why there is no motivation -- and I just want to point out
9 before I go on that, Petitioner said there's no dispute,
10 amongst many things. Of course there are many disputes.
11 Petitioner's obligation here to demonstrate obviousness is
12 not that there's motivation to combine the reference.
13 Petitioner must show that there's motivation -- a reason to
14 combine the references in the claimed manner, not just a
15 reason to combine the references, and that's what I'm going
16 to focus on today, those two aspects.

17 So first, there's no motivation to modify Schaffer to
18 arrive at the claims. Specifically, the purpose of the
19 hemostasis valve is not simply to seal a lumen. The
20 purpose is to introduce tools and instruments and
21 manipulate those instruments to perform a medical
22 procedure. That's what a hemostasis valve is used for. That
23 is the fundamental purpose of the hemostasis valve. It's not
24 simply to seal.

25 And to achieve that goal, claims 1 and 2 here require
26 a particular filament configuration in which the filament

1 conforms to the outer surface of the lumen through which
2 the instrument or tool is inserted and manipulated. Now
3 claims 3 through 9 depend from claim 2. So they include
4 the particular configuration of a filament set forth in claim
5 2.

6 Schaffer is fundamentally different from the claims.
7 Schaffer seals the lumen with an internal, highly compliant
8 sealing member that conforms to various shapes when it's
9 compressed with an external rigid compression member.
10 The claims are the opposite, requiring an external filament
11 looped around the lumen that conforms to the outer surface
12 of the lumen. Hartley and Eller employ a string or a wire in
13 a different configuration that is missing several claim
14 limitations. So that's why we are talking about the
15 combination Schaffer as opposed to anticipation by Hartley
16 or Eller. So I'm going to cover two things that show that
17 Petitioner has not met its burden to demonstrate that a
18 person of ordinary skill in the art would have combined and
19 modified Schaffer with either Hartley or Eller to arrive at
20 the particular compound filament configuration.

21 First, Petitioner has presented no evidence from the
22 perspective of a person of ordinary skill in the art that takes
23 into account the design considerations that a POSA would
24 follow to design a hemostasis valve. And what I mean by
25 that is Petitioner's expert testimony that's undisputed is from
26 the wrong perspective that does not take into account the

1 design considerations that Petitioner's expert admits would
2 be considered to design a hemostasis valve. And because of
3 that, Petitioner has not met its burden here. There is simply
4 a lack of evidence. And while Patent Owner doesn't bear
5 the burden to demonstrate patentability, when those design
6 considerations are taken into account, a person of ordinary
7 skill in the art under the correct definition would not modify
8 Schaffer to arrive at the claimed arrangement of the
9 filament in a hemostasis valve.

10 And then second, ignoring the proper perspective of a
11 person of ordinary skill in the art and Petitioner's lack of
12 any evidence or any testimony from that actual prospective,
13 Petitioner has failed to demonstrate any motivation or
14 reason that a POSA would not only combine the references
15 Schaffer and Hartley or Schaffer and Eller. So it's not
16 Schaffer, Hartley, and Eller. It's Schaffer and Hartley or
17 Schaffer and Eller, but would do so to arrive at the
18 particular claimed filament configuration. And I'm going to
19 explain what those are in claim 1, in claim 2, and because 3
20 through 9 depend from claim 2, in claims 3 through 9.

21 So let's first talk about the claims configuration. So,
22 I've put up slide -- Patent Owner slide 4. This shows claim
23 1 from the '012 Patent. You can see in this claim that the
24 patent requires a tubular body with a central lumen, a first
25 actuator, and a filament in the loop and reducing the
26 diameter of that loop to seal the valve. So a first filament

1 and a first actuator.

2 And then I want to contrast that with claim 2 of the
3 '012 Patent. Claim 2 includes all the limitations of claim 1
4 and then adds the additional limitation of a second actuator,
5 and that filament from the first claim is -- further comprises
6 a second end extending away from the loop in a second -- in
7 a different direction, and that second end portion is
8 connected to the second actuator.

9 So, jumping back to slide 4, if you look at figure 4 in
10 the upper left hand corner, you can see the configuration of
11 claim 2 is shown here. There are two actuators, that's the
12 button on top and the button down at the bottom, and there
13 is a filament that extends from one end attached to the
14 button to the other end attached to the button forming a
15 loop. That's what's claimed in claim 2.

16 Now let's talk about that purpose of a hemostasis
17 valve. The purpose of the hemostasis valve is not simply to
18 seal a lumen. The purpose, the reason hemostasis valves
19 are employed is that during a medical procedure, the valve
20 allows the introduction of tools and instruments -- or
21 instruments to perform that particular medical procedure.

22 In the '012 Patent, the medical procedure is extracting
23 a thrombosis, and you can find that in Exhibit 1001, that's
24 the '012 Patent, Column 16, Line 7 through 31 where that
25 example is provided and some other disclosures are
26 incorporated by reference. And then you can also see that

1 in figures 10 and 11, which show the procedure of
2 introducing -- the steps of introducing the tool or instrument
3 performing the procedure and then retracting the tool or
4 instrument. That is the purpose of a hemostasis valve. It's
5 not simply to seal. One skilled in the art would not place a
6 hemostasis valve -- use a hemostasis valve in a procedure
7 and procedure and not insert anything or withdraw
8 anything. The purpose is to insert these instruments into the
9 vasculature. That's why a hemostasis valve exists. So --
10 and that's in all the prior art.

11 JUDGE FREDMAN: Is there any claim limitation
12 that, or is that simply you're saying that normal use of the
13 device? It's not -- I mean it's not limiting the claim. The
14 claim doesn't say we have to insert things in it, do we?

15 MR. HAMILTON: The claim says a hemostasis
16 valve. All the prior art is directed to a hemostasis valve for
17 that very purpose, inserting a medical instrument --

18 JUDGE FREDMAN: Okay.

19 MR. HAMILTON: -- removing a medical
20 instrument. That's what a hemostasis valve is for. And so
21 the prior art --

22 JUDGE MAJORS: Can I ask you a question?

23 MR. HAMILTON: Sure.

24 JUDGE MAJORS: Yes, I agree that the prior art
25 talks about inserting tools into the hemostasis valve, but
26 isn't the point of the valve is you want an access point,

1 right, to the vasculature. You want something that if I want
2 to insert a tool, I can, and ensure that you seal around the
3 tool. Or if I extract the tool and I don't have anything
4 inserted at the moment that it's also going to seal. In other
5 words, you want the thing to seal whether there's a tool
6 inserted or not.

7 MR. HAMILTON: You absolutely want it to seal
8 whether there is a tool inserted or not. But the design
9 consideration for designing the valve is so that the tools can
10 be inserted, and the valve has to work, not simply to seal
11 when there's nothing inserted and that is your only concern
12 when designing a valve. The design considerations, and I'll
13 show this in just a minute, that both experts agree and the
14 prior art cited explain is sealing when to allow the
15 introduction and manipulation of instruments and withdraw
16 of instruments.

17 So, the design consideration is not I'm going to
18 design a valve that can seal everything else. You know, we
19 can forget about any other use of the valve. The use of the
20 valve is to insert these medical instruments. That has to be
21 taken into account. And a person of ordinary --

22 JUDGE MAJORS: Go ahead, finish your point.

23 MR. HAMILTON: And a person of ordinary skill in
24 the art would consider all those design considerations when
25 designing a hemostasis valve. And in a minute I'm going to
26 show you why that matters and why, if a person of ordinary

1 skill in the art that understands those design considerations
2 that are unconverted, both experts agree that these are the
3 design considerations in designing a hemostasis valve,
4 would not modify Schaffer.

5 Now, Petitioner's expert provided an opinion
6 without -- of an individual with no medical device
7 experience, and the only consideration of Petitioner's expert
8 is to seal a valve. That's the only consideration. Now, of
9 course, an automotive engineer, if they were asked to seal a
10 lumen -- to seal something, you could take a string and
11 crank it down as hard as you want. That completely ignores
12 the fundamental purpose of the hemostasis valve, which is
13 to insert an instrument, manipulate that instrument, and
14 withdraw the instrument, and at the same time, maintaining
15 a seal. And that's exactly what Schaffer describes in its
16 background section.

17 JUDGE MAJORS: So can I ask my question now?

18 MR. HAMILTON: Sure.

19 JUDGE MAJORS: So how can that be Patent
20 Owner's position that Mr. Thornton didn't take the insertion
21 of tools into consideration? He's got an entire rationale
22 based on formation of gaps around tools. So I guess I'm
23 pushing back on the premise that he didn't consider design
24 considerations or the use of these hemostasis valves in the
25 presence of a tool in forming his opinions on the issue of
26 obviousness.

1 MR. HAMILTON: So the only consideration that
2 Mr. Thornton took into account from this perspective of an
3 individual that could be an automotive engineer or some
4 other training, having no understanding of medical devices
5 and why hemostasis valves -- what the purpose of a
6 hemostasis valve is, admits what's shown, and I've put up
7 now Patent Owner's demonstrative, slide 16. This is an
8 excerpt from Schaffer on the right, Paragraph 7.

9 The problems in designing a valve are complex and
10 involve a balance of closing force, opening force, friction,
11 compression, and durability. There's all these factors that
12 must be taken into account to design a hemostasis valve that
13 includes the ability to insert a tool, manipulate the tool, and
14 withdraw the tool. So simply sealing is not the primary
15 concern in a hemostasis valve. Yes, it has to seal, but it has
16 to be able to do these things. And what Petitioner's
17 expert -- so Patent Owner's expert explain this, Dr. Zalesky,
18 Exhibit 2008, Paragraph 59. That's in the Patent Owner
19 response in the intro.

20 Petitioner's expert agreed. So, Exhibit 2013, Page 60,
21 starting at Line 20, Petitioner's expert explained that a
22 physician would move the devices back and forth. There'd
23 be manipulation. This goes right to these factors set forth in
24 Schaffer, opening force, closing force, this balance, friction,
25 etc. Petitioner's expert explained a key design consideration
26 is manipulating the tool, getting feedback to the tool when

1 it's inserted into the patient. And if the only concern is
2 simply sealing and you crank it down, you've ignored all
3 those considerations.

4 And Petitioner's -- excuse me. Petitioner's expert's
5 testimony, which is admitted to be from a perspective of an
6 individual that has no medical device experience
7 whatsoever, no consideration of this balance of closing
8 force, opening force, friction, and compression to achieve
9 the purpose of the valve, and that's inserting and
10 manipulating an instrument, giving the physician feedback.
11 If a person -- if the actual person of ordinary skill in the art
12 with those considerations in mind, that person would not
13 simply take a string, put it into Schaffer, and crank it down
14 as hard as possible and only consider the sealing aspect of
15 the design of a hemostasis valve.

16 JUDGE MAJORS: Mr. Hamilton?

17 MR. HAMILTON: Yes.

18 JUDGE MAJORS: Mr. Hamilton. Now, would you
19 agree that those same considerations as you've articulated
20 them would have been in play or would have been
21 considered in the design and use of the Hartley and the Eller
22 valves?

23 MR. HAMILTON: Yes. Yes.

24 JUDGE MAJORS: And --

25 MR. HAMILTON: Yes, Hartley and Eller -- so
26 sorry. Please.

1 JUDGE MAJORS: And those two hemostasis valves
2 as described in those references both use a string and a wire,
3 correct?

4 MR. HAMILTON: They do, Your Honor.

5 JUDGE MAJORS: And so you're not disputing that
6 skilled artisans knew how to use either a string or wire in a
7 hemostasis valve, including how to use it in conformance
8 with the considerations that you just articulated, right?

9 MR. HAMILTON: They knew how to use it in the
10 design and the filament configuration of Hartley and Eller,
11 and Hartley and Eller have different mechanisms for
12 meeting those limitations. And the issue this goes to is why
13 is one modifying Schaffer? Schaffer achieves that balance
14 through a particular arrangement, and a rigid external
15 member and this internal, highly compliant sealing member
16 that allows -- that can seal under very light compression so
17 that, as Schaffer says, right here in Paragraph 7, you don't
18 damage your instruments. And as Petitioner's expert
19 explained at that Exhibit 2013, Page 60, you can manipulate
20 the devices.

21 And then again, I just want to point out Exhibit 2006,
22 Page 7, Petitioner's expert, when presented with this
23 Paragraph 7, said these are the design considerations and
24 expands on what it's meant by feedback. That a physician
25 needs feedback when the instrument is inserted into the
26 patient. And Schaffer's principle of operation, how

1 Schaffer accomplishes that design consideration that both
2 experts agree would be taken into account is to use the
3 internal, highly compliant seal member that can be -- that
4 can seal under very light compression. You don't have to
5 crank it down. You don't have to take a string and crank it
6 down. This is what Schaffer has invented. This is
7 Schaffer's disclosure.

8 And then the question is, why would one skilled in
9 the art go change that and remove that advantage, the
10 fundamental principle of operation of Schaffer to
11 accomplish what is admitted by both experts and not
12 disputed, the design considerations of this balance between
13 closing force, opening force, friction, compression, and
14 durability? Schaffer chose a particular way to do that. Why
15 is one skilled in the art -- why would one skilled in the art --

16 Well, first, an auto engineer might do that because
17 they don't care about those considerations. Petitioner's
18 testimony -- the only testimony from Petitioner's expert is
19 from the perspective of someone who is not skilled -- a
20 person of skill in the art. It's someone that has zero medical
21 device experience. That person might do that, but if you
22 take the perspective of an actual person of skill in the art in
23 this matter that understands that the design consideration is
24 not simply sealing, it's this balance, one skilled in the art
25 would now go -- would not now go and modify Schaffer to
26 eliminate that balance in the way Schaffer has done it.

1 So what we have is Dr. Zalesky's testimony from the
2 proper perspective of a person of skill in the art that a
3 POSA would take those issues into account and would not
4 fundamentally change how Schaffer operates, how Schaffer
5 achieves that balance. In other words, not redesign Schaffer
6 to include a filament and throw out the internal sealing
7 member.

8 In contrast, Petitioner's only evidence is from the
9 perspective of an individual having no medical experience,
10 that auto engineer, and that testimony ignores and does not
11 take into account the design considerations that both experts
12 agree a POSA would actually consider when designing a
13 hemostasis valve, and that's the purpose of the valve, the
14 fundamental purpose of the valve, the ability to insert and
15 manipulate, have feedback for tools during the use of a
16 medical procedure. As Petitioner's expert said, all devices
17 are designed from the perspective of the medical procedure
18 for which the valve is going to be used.

19 So in other words, Petitioner's testimony from an
20 incorrect perspective of a POSA, excuse me, ignores the
21 very purpose of a hemostasis valve. It's not just sealing.
22 It's the balance of sealing with insertion and manipulation
23 with feedback of tools and instruments. And what I would
24 ask is that the Board should credit Dr. Zalesky's testimony
25 from that correct perspective, taking into account those
26 design considerations, the ones that both experts agree

1 would be used in designing a valve, and would not modify
2 Schaffer. And Petitioner's expert's testimony, from an
3 incorrect perspective that doesn't take into account those
4 considerations should not be credited over Dr. Zelensky's
5 testimony. Petitioner simply has a lack of evidence on the
6 correct perspective of a person of ordinary skill in the art
7 and the design considerations that a person of ordinary skill
8 in the art would employ.

9 Okay, so now let me move to the second point.
10 Throw all that out. Let's assume that an individual doesn't
11 care about any of those considerations, and the only thing
12 that matters is sealing or whatever other reason you want to
13 give. That person has decided I'm going to throw out how
14 Schaffer operates. I'm going to get rid of this internal,
15 highly compliant member that Schaffer says allows you that
16 balance between light compression and sealings you can
17 manipulate, get feedback for tools. Person of skill in the art
18 ignored -- not person of ordinary skill in the art. An
19 individual ignores all of that and decides I'm going to get
20 rid of that internal member. And instead of using Schaffer's
21 rigid U-shape members, I'm going to include a string, like
22 Hartley or Eller. In other words, that person's decided to
23 fundamentally redesign Schaffer from its design and its
24 balance of those factors into something else, and instead
25 replace those rigid compression members with strings of
26 wires. That's not enough.

1 What Petitioner has to demonstrate is someone
2 skilled in the art would do so in the particular claimed
3 configuration and filament arrangement. So how does
4 Petitioner arrive at the particular claimed arrangement and
5 configuration? One way, impermissible hindsight using the
6 claimed arrangement and configuration as a roadmap to
7 arrive at the claims. And how do we know this?
8 Petitioner's expert told us as much at deposition.

9 So first, when asked about simply replacing the
10 U-shaped members with a string, a different configuration
11 that Petitioner and Petitioner's expert proposed, he testified,
12 and I'm quoting and this is from Exhibit 2014, Page 37,
13 starting at Line 23, I think there are many different options
14 that a person of skill in the art could attempt. There are
15 many options, not just one. So, why does a person of
16 ordinary skill in the art choose the option that's claimed, and
17 expressly claimed in claim 2, as I showed you earlier, as
18 opposed to any of these other options?

19 Now, what first Petitioner, unsolicited, said there are
20 many options. Petitioner's -- excuse me. Petitioner's expert
21 quickly realized that's a problem and then said, well, I don't
22 know if there are other options. This is immediately
23 following at Page 41 starting at Line 9. So there are many
24 options. That's his unsolicited --

25 JUDGE FREDMAN: If we go back to Page 37,
26 Line 25, which is the sentence immediately following the

1 one you just quoted, it says a very simple one would be a
2 single filament wrapping around -- one time around the
3 opposing buttons. So he didn't very quickly. He
4 immediately stated that.

5 MR. HAMILTON: He said that is one option. That's
6 right. And then --

7 JUDGE FREDMAN: But that was the -- that was for
8 the immediate option that came forward.

9 MR. HAMILTON: And then the next sentence, if
10 you continue reading, is other designs could be attempted of
11 course.

12 JUDGE FREDMAN: Which is the Pro Mold. I
13 mean, you can always -- Pro Mold is a case -- an old case
14 that says you can always improve things. Yes. That's
15 always the case.

16 MR. HAMILTON: So, there are many different
17 options of configuring a filament in -- if one skilled in the
18 art was going to take a filament and replace Schaffer's U-
19 shaped members with that filament, there are many
20 different configurations on how to do so.

21 JUDGE FREDMAN: There's at least two, I guess.
22 Yeah.

23 MR. HAMILTON: Well that's two, and actually later
24 he said he doesn't know how many options there are. That's
25 Exhibit 2014 at 41. And then later when presented with the
26 option of simply substituting the string for each U-shaped

1 member, so two U-shaped strings, he said he did not
2 consider that option when presented with the other option,
3 and that's exactly what's shown in all three references. A
4 single actuating member, so a U-shaped member or a string,
5 that's attached to one actuator, one button, one rotating
6 member. That is what's shown. Uncontroverted, every
7 reference, that's what's shown. So why is one skilled in the
8 art jumping to a different configuration when there are
9 many options? And then he was presented with another
10 option, taking the string from one button, wrapping it
11 around the lumen, and going back to the same button. He
12 said he didn't consider that option either. In fact --

13 JUDGE MAJORS: Mr. Hamilton, how would those
14 options though -- let me take a step back. Do you agree that
15 Hartley and Eller describe using a string or a wire for
16 purposes of a sort of a cinching effect?

17 MR. HAMILTON: So, let's talk about each one
18 individually. Eller uses a wire that is attached on one end,
19 in every single embodiment on one end to a single rotary
20 actuator. That's what Eller discloses. You don't even attach
21 the second end to it actuator in Eller. So the combination of
22 Schaffer with Eller doesn't give you a string attached on
23 two ends at all to an actuator.

24 JUDGE MAJORS: I understand the distinction that
25 you're raising. You can come back to it. I'm simply saying
26 do you agree that those references stand for the proposition

1 that if you pull two ends of the string in a hemostasis valve
2 or wire, you're going to get this cinching effect?

3 MR. HAMILTON: Well, they certainly stand for the
4 proposition if you pull two ends of a string by a single
5 actuator, you will get that effect. That's what they disclose.
6 Both references and that's what Schaffer discloses as well.
7 A single U-shaped member attached to a single actuator.
8 That's in every reference.

9 JUDGE MAJORS: Okay.

10 MR. HAMILTON: So yes, it does stand for that
11 proposition.

12 JUDGE MAJORS: And the configurations that
13 you're suggesting were not considered. It seems to me that
14 none of those is going to give you a cinching effect where
15 you're going to get this constriction around the entire
16 circumference of a tube. You might be able to pull one side
17 of that one direction, but you're still not going to get this
18 effect where it's sort of being, you know, cinched, for lack
19 of a better description, or I know Patent Owner's used the
20 term garrote in its patent.

21 But I'm still not understanding why Mr. Thornton's
22 analysis is deficient by virtue of -- I don't think he's
23 required to line up and knock down every hypothetical
24 possible change that might be made to the prior art. He's
25 saying here's one approach that has worked in these two
26 other hemostasis valves, and it would have been obvious to

1 use that approach in the Schaffer valve. And I know that
2 Patent Owner's position is well, those are connected
3 differently or they're configured differently in Schaffer and
4 Hartley, but again, I understand his testimony to be that it
5 was known that if you pull a string or a wire in two
6 different directions, you're going to have this cinching
7 effect that was known for hemostasis valves. Let's apply
8 that principle to Schaffer.

9 MR. HAMILTON: So first let's start with Eller.
10 Eller doesn't disclose that. Eller pulls on one end and never
11 pulls on both ends. So, that's one. And Eller has many
12 different arrangements for a filament. Where the -- excuse
13 me, the wire goes in three different directions and together
14 the three wires collectively push the -- collapse the tube and
15 the member. There's another configuration that one could
16 use for attaching a filament to an actuator. In all of them
17 it's a single actuator, and in Eller, it's always the single end.
18 So, Eller and Hartley may stand that for the proposition that
19 a filament can be used in some way in a --

20 JUDGE FREDMAN: You're careful to say that Eller
21 uses one. Hartley uses two though, right?

22 MR. HAMILTON: No.

23 JUDGE FREDMAN: Never?

24 MR. HAMILTON: Well, one of what? I'm sorry.
25 Maybe I didn't understand the question.

26 JUDGE FREDMAN: Hartley doesn't have two

1 actuators?

2 MR. HAMILTON: No. Hartley has one rotatable
3 actuator.

4 JUDGE FREDMAN: And Hartley's actuator has two
5 fixed points though, right?

6 MR. HAMILTON: It is attached at two fixed points -

7 -

8 JUDGE FREDMAN: Okay. That's what you're --

9 MR. HAMILTON: -- to that actuator.

10 JUDGE FREDMAN: That's what you're -- that's the
11 distinction you were trying to make before?

12 MR. HAMILTON: Yes. That's right. That's right.

13 JUDGE FREDMAN: Because then Eller only has
14 one.

15 MR. HAMILTON: Eller only has one. That's right.
16 One end.

17 JUDGE FREDMAN: But Hartley does have two.

18 MR. HAMILTON: Hartley does have two, and that's
19 exactly what's disclosed in Schaffer. Both ends attached to
20 the same actuator button. They're the same in that regard.
21 There is no reference that takes something that's flexible
22 like a filament and attaches it to two independently moving
23 actuators, which is expressly claimed in claim two.

24 JUDGE FREDMAN: There's no anticipation
25 reference as we understand that.

26 MR. HAMILTON: Well, there --

1 JUDGE FREDMAN: If there was, that would be --

2 MR. HAMILTON: There would be lots of other
3 features. So anticipation or not, there's no reference that
4 discloses this method of -- this configuration of a filament.

5 JUDGE FREDMAN: Okay.

6 MR. HAMILTON: And there -- as Petitioner's expert
7 admits, there are many configurations that could be used.
8 And what Petitioner's expert does, the only one Petitioner's
9 expert considers is the claim configuration. Admitted at
10 deposition, Petitioner's expert went straight to the claim
11 configuration, said that's what someone would do. That is
12 textbook impermissible hindsight starting with the claim
13 configuration and then saying that -- and then using that for
14 that is the one of the many substitutions that one skilled in
15 the art would employ for his obviousness analysis.

16 Now, what I want to point out is Petitioner's expert
17 has flip flopped on that position throughout the series of
18 IPRs. So, in the '011 IPR, and this is a citation to the
19 petition. This is what Petitioner said too in the '011, and it's
20 citing to the Petitioner's expert. Same expert here, Exhibit
21 1003, that one skilled in the art would simply replace each
22 U-shape member with a string, two U-shaped strings. That
23 was Petitioner's position in that IPR. Now all of a sudden
24 the claim says you must attach each to a different actuator
25 that moves independently, and Petitioner's expert says, oh,
26 no. One wouldn't do that because the claim says this is

1 exactly what one skilled in the art would do.

2 So, here we've got two different configurations. In
3 one IPR, Petitioner's expert says one skilled in the art would
4 simply replace each U-shaped member with a different
5 string to get two U-shaped strings. And then --

6 JUDGE MAJORS: Mr. Hamilton, how was that a
7 flip flop? I think he's offering alternative theories. You're
8 correct in the '011 IPR, there was a position based on
9 Schaffer alone that said the replace the two U-shaped
10 actuating members with a flexible ribbon. We rejected that.
11 And then they have a separate set of -- one of three
12 challenges that proposed that the Hartley or Eller
13 substitutes. I don't see that as a flip flop. That's just
14 alternative obviousness theories as is common in IPRs.

15 MR. HAMILTON: So it's an alternative obviousness
16 theory that provides no reason why one would pick one
17 configuration or the other. Petitioner's expert simply says,
18 this is what one would do without any basis for picking that
19 particular configuration. In the '011 Patent IPR, Petitioner's
20 expert said you would pick something else, and I just want
21 to point out in the 921 --

22 JUDGE MAJORS: But --

23 MR. HAMILTON: I'm sorry.

24 JUDGE MAJORS: Let me push back on that real
25 quickly. But that's not what he said. He said the reason we
26 do that in part was because of this uniform compression or

1 constriction around the exterior of the tube. So I don't see
2 how he proposed that modification without any rationale.
3 In other words, to eliminate gaps and the well, I won't recite
4 the whole theory, but you're aware of it.

5 MR. HAMILTON: So, now I'm back to what was
6 originally said in the '011. Petitioner's expert and Petitioner
7 said just changing the U-shaped members to strings so you
8 got two U-shaped strings would more closely conform to
9 the seal module. That's the exact same motivation in -- that
10 Petitioner later on replied for the first time in the '011 and
11 then submits that same direct declaration in this IPR that
12 the -- I'll digress for a minute, doesn't address the actual
13 claims in this IPR at all. So that second declaration
14 submitted to this IPR is directed to different claims.

15 But the same reason -- Petitioner uses the exact same
16 reason for both. That it would more closely conform to the
17 outer surface. And it's only after Patent Owner points out
18 and the Patent Owner responds that there's no reason
19 because Petitioner said initially that to more closely
20 conform, one would simply replace each U-shaped member
21 with a string. It's only after the Patent Owner points out
22 that there is no reason to choose this other configuration
23 that Petitioner comes on reply in the '011 and submits a
24 declaration that says, oh, forget what we said. One wouldn't
25 do that because that doesn't actually seal. What one would
26 do is get that better conforming by using a configuration,

1 again, of a single string attached to two independent
2 actuators. That's not shown anywhere. That only comes on
3 reply.

4 And I just want to point out this is going on in many
5 of the different IPRs. So, this is IPR2025-00728, the '921.
6 Here the simple substitution is to replace Schaffer's U-
7 shaped member, each of Schaffer's U-shaped members with
8 a separate string or wire. And same thing for Eller that's
9 shown on slide 35 of Patent Owner's demonstratives.
10 Petitioner's position of what one skilled in the art will do
11 changes depending on what the claims say, and that's
12 because Petitioner's expert doesn't consider the other
13 options when looking at a patent. He starts with what the
14 claims say. This particular configuration would be obvious
15 because that's what the claims say. That's how -- that's why
16 one would arrive at that particular configuration.

17 And I'll just point out one more. This is slide 36.
18 This is a much more recent filed IPR2025-01562. In this
19 one, Petitioner's got yet another configuration of including a
20 string or a wire. That is the simple substitution again. And
21 this one is you wouldn't just put one, you put two in there.
22 Petitioner's -- and each of those is -- each of these is based
23 on what Petitioner originally said was the reason one would
24 replace each U-shaped member with a string because it
25 would better conform. And now -- and throughout the
26 course of these IPRs, Petitioner's and Petitioner's expert

1 position changes depending on what the claims say.

2 And so, I just wanted to make sure that the point I
3 made a moment ago wasn't lost. So in the '011 Patent IPR,
4 Petitioner originally said one would simply replace each U-
5 shaped member with a string. And then only on reply came
6 back with a new declaration that said oh, you wouldn't do
7 that. What you would actually do is replace both U-shaped
8 members with a single string and include it in a different
9 arrangement.

10 And I just want to point out, and this is from that
11 second declaration. This is where Petitioner said that. If
12 the highly compliant member is included in Schaffer, which
13 is Schaffer's fundamental principle of operation, that's how
14 Schaffer works, to achieve that balance that a person of
15 ordinary skill in the art would -- uncontroversially, would
16 take into account in designing a hemostasis valve, these
17 gaps would be filled. This would not be an issue. You
18 wouldn't get -- there's no motivation to get or no reason to
19 get anywhere near including a string. Now, in this IPR,
20 Petitioner did not submit any new declaration on reply.

21 JUDGE FREDMAN: You're going into your rebuttal
22 time, if you want. It's up to you.

23 MR. HAMILTON: Yeah, let me just finish this
24 point. Petitioner didn't submit any new declaration or reply.
25 What Petitioner submitted was the declaration from the '011
26 Patent that is directed to different claims that have different

1 limitations. So that declaration cannot, again, be credited
2 over Dr. Zalesky's testimony about the actual claims in this
3 case from the proper perspective of a person of ordinary
4 skill in the art.

5 So I just want to sum up, I think I made two points
6 here. One, that person of ordinary skill in the art and that
7 perspective is important. Petitioner's expert applied the
8 wrong definition, applied the wrong standard, didn't take
9 into account what both experts agree would be the key
10 considerations in designing the limitations now.

11 And second, ignoring all that, let's say a person of
12 interest in the art is going to throw out how Schaffer
13 actually discloses that the valve is sealed and how Schaffer
14 achieves that balance with this highly compliant internal
15 seal and an external rigid compression member and all the
16 advantages that Schaffer says, throws out the only way
17 Schaffer says to manufacture those U-shaped members, the
18 only way Schaffer says to assemble the device, ignores all
19 of that disclosure of Schaffer, and decides they want to put
20 in a flexible member, so a wire or string into Schaffer. Why
21 does one skilled in the art choose the particular claimed
22 arrangement? Petitioner's expert considered one option, the
23 claimed option. Petitioner's expert -- that demonstrates the
24 impermissible hindsight of starting with the claims and then
25 coming up with a motivation to arrive at the claims.

26 Now, one other point I want to make before I sit

1 down. Petitioner's expert, who purportedly has 35 years of
2 experience in this field of hemostasis valves, admitted in his
3 deposition that until this case, until he saw the '012 Patent
4 or its related patents, he had never seen a hemostasis valve
5 in the market that included a filament. Not one. Not one.
6 And even to this day, he has never actually tested or
7 observed or handled a hemostasis valve that includes a
8 filament. And yet his testimony from this incorrect
9 perspective of a person of ordinary skill in the art is that a
10 person of ordinary skill in the art, that these things are
11 simple substitutions, that they're interchangeable in this
12 particular configuration that's not in any reference, and that
13 one skilled in the art would know that would work.

14 Well, Petitioner did not -- Petitioner's expert -- that's
15 based on, again, starting with the '012 Patent. That's
16 impermissible hindsight. You cannot use the '012 Patent's
17 disclosure that this is going to work or that this particular
18 configuration is out there and then use that to backdoor
19 come in to arrive at the claimed configuration.

20 So, back to what Petitioner said at the beginning.
21 There's no dispute regarding motivation. Of course, there's
22 a dispute regarding motivation. And Petitioner needs to
23 show more motivation to arrive at the particular claim
24 configuration. Claim 2 has two actuators, a single filament
25 looped around a lumen between those two actuators.
26 Petitioners provided no basis to arrive at that configuration,

1 as opposed to any other configuration because Petitioner's
2 expert started at the claim configuration.

3 And then Petitioner's expert's testimony that first one
4 would simply replace the U shape members and then
5 later no, one wouldn't do that because, for the same reason,
6 conforming to the outer surface, one would simply take a
7 single string and wrap it around a lumen demonstrates from
8 a perspective of -- that is not a person of ordinary skill in
9 the art should not be credited over Dr. Zalesky's testimony
10 from the proper perspective that takes the actual design
11 considerations into account. Thank you.

12 JUDGE MAJORS: Mr. Hamilton, before you sit
13 down, does the '012 Patent, does that patent anywhere
14 describe special challenges or difficulties in using the
15 filament for purposes of constricting a lumen?

16 MR. HAMILTON: Difficulties or challenges?

17 JUDGE MAJORS: Yes.

18 MR. HAMILTON: Well, yeah. It describes that the
19 configuration has not been found in the prior art. It
20 certainly does that, and I'm not sure -- as I sit here, I can't
21 say any -- although I'll point to one. One that Petitioner's
22 expert has said is a challenge. A filament moves when it's
23 in a device like this. The devices are held in all different
24 directions, and the filament can slide around and not stay in
25 its position, and you don't know if it's going to do what it's
26 supposed to do when you need it to do it. Critical, critical

1 in a medical procedure. A person of ordinary skill in the art
2 would take that into account. That's a challenge that is
3 addressed in the asserted patents and is admitted to be an
4 issue when designing a hemostasis valve using a filament
5 and not taken into account by Petitioner's expert from this
6 incorrect perspective of a person of ordinary skill in the art.

7 JUDGE MAJORS: Okay. Thank you.

8 MR. STOWELL: Thank you, Your Honors. Joshua
9 Stowell on behalf of Petitioner again. Critically during,
10 presentation by Patent Owner, I did not hear Patent Owner
11 identify or dispute any issues that were not resolved by the
12 Board in the '011 final written decision. Critically, Patent
13 Owner did not dispute that Hartley and Eller each disclose a
14 filament formed into a loop.

15 I'm going to start here with Patent Owner's
16 demonstrative 16. I don't know how Patent Owner can
17 argue that Mr. Thornton did not consider or address closing
18 force, opening force, friction, compression, and durability.
19 The record is ripe with statements by Mr. Thornton opining
20 on these topics and considering these topics. If we go to
21 Patent Owner's slide 38 real quick. Here we have an
22 example where Patent Owner is relying on testimony from
23 Mr. Thornton about how the devices would behave, that
24 harder materials may deform more than softer materials.
25 Clearly, he's considered the forces and the materials that are
26 used in operating these valves.

1 If we go to Petitioner's slide 16, we have testimony
2 from Mr. Thornton about how a person of ordinary skill in
3 the art would have been motivated by Hartley's disclosure
4 that it can close over a range of diameters and devices. I
5 just heard Mr. Hamilton argue that this was something that
6 Mr. Thornton didn't consider, that devices needed to go in
7 and out of these valves. Clearly, he did consider it. He has
8 a number of opinions on this issue.

9 If we go to Petitioner slide 38, again, Mr. Thornton,
10 opining on the principles of operation and how the devices
11 operate and how the forces interact with the strings to
12 compress the tubular member. Clearly, Mr. Thornton
13 discussed the opening and closing forces and considered
14 those forces and consider devices going in and out of the
15 valve. That can't really be in dispute.

16 I'm also going to just briefly discuss Patent Owner's
17 arguments about the person of ordinary skill in the art. The
18 Board considered this same argument in the '011 final
19 written decision at Pages 12 to 14. It defined the person of
20 ordinary skill in the art. The Board found that both parties
21 declarants qualified as a person of ordinary skill in the art,
22 and the Board provided a specific definition for the level of
23 skill that person would have. Neither parties' experts in
24 their declarations apply that specific definition of a person
25 of ordinary skill in the art.

26 If we look at slide 76 of Petitioner's slides, we see

1 Patent Owner's expert's definition of a person of ordinary
2 skill in the art, and it is not exactly the same as the Board
3 defined it in the '011 final written decision. So neither
4 parties' expert applied the exact definition. However,
5 clearly Mr. Thornton has considered all of the elements that
6 relate to the operation of the valves in this case.

7 Additionally, you know, Mr. Hamilton spent a lot of
8 time talking about the purpose of hemostasis valves.
9 There's no dispute in this case. All the references that we're
10 relying on have hemostasis valves. There's no automotive
11 valves like Mr. Hamilton was talking about. Nobody's
12 relying on valves outside the scope of the art. So, that's not
13 an issue in this case.

14 It also seems like Mr. Hamilton's argument is that
15 there can only be one obvious way to improve a hemostasis
16 valve. That's simply not the law. The fact that there might
17 be multiple obvious ways to improve a hemostasis valve
18 does not make any one of those obvious solutions less
19 obvious. What Mr. Thornton did in this case is he assessed
20 the prior art. He looked at the Hartley reference, which
21 undisputedly has a filament that forms a loop. Force is
22 applied to both ends of that filament to close the lumen.
23 The fact that it's attached to a housing at one end and an
24 actuator on another end, force is applied to the end of both
25 ends of that filament to cinch the valve.

26 JUDGE FREDMAN: So how do you respond to the

1 argument that Mr. Hamilton made that hindsight is
2 essentially occurring because the expert is responding to the
3 claims in each particular case?

4 MR. STOWELL: Yeah. There's no -- I noticed Mr.
5 Hamilton didn't put up any testimony where Mr. Thornton
6 said he started with the claims and went out and found the
7 prior art. What he did was he looked at the prior art that
8 was out there. He recognized that it was well known in the
9 art to use a filament to cinch a tube within a hemostasis
10 valve. It was well known to use buttons that were spring
11 loaded to apply tension to filaments and actuating members
12 within a hemostasis valve. And because the sealing may be
13 superior or would be superior in some cases with the
14 filament, he found that it would be obvious to apply that.

15 And as the Board stated in its opinion on the final
16 written decision of the '011 Patent, the solution that is
17 obvious doesn't need to be the best solution. It just needs to
18 be a solution where there would be a motivation to
19 combine. And so Mr. Thornton walked through for
20 different reasons why there would have been a motivation
21 to combine the references in the way. There is no testimony
22 that he started with the claims, and that's the only place he
23 looked.

24 And then, just briefly discussed this whole flip flop
25 argument. Judge Majors, you are exactly correct.
26 Petitioner has been consistent throughout this IPR and the

1 following IPRs that it would have been obvious to combine
2 Hartley's string or Eller's wire with Schaffer's valve that
3 was in the original petition on the '011 Patent. We have
4 been consistent. The fact that there may be other obvious
5 solutions to the problem does not undermine that one
6 obvious solution.

7 Lastly, Mr. Hamilton stressed that Mr. Thornton
8 hadn't seen a valve exactly like the valve described in the
9 '012 Patent in the market, but he explained that he saw
10 valves like that in the prior art. The '011 or the Hartley
11 reference, the Eller reference, they both used strings. All
12 the components that are claimed in the '012 Patent claims
13 are found in the prior art. Mr. Hamilton tried to suggest that
14 Mr. Thornton was wrong for not having tested the valve.
15 There's no evidence that Dr. Zalesky tested the valve either.
16 It appears that Mr. Hamilton is trying to apply a double
17 standard to the experts in this case, which would be unfair.

18 Mr. Thornton qualifies as a person of ordinary skill in
19 the art. He considered all the relevant factors. He walks
20 through all the motivations to combine, which this Board
21 has found were supported in the final written decision of the
22 '011 Patent. And for that reason, the claims of the '012
23 Patent should also be invalid based on Schaffer plus Hartley
24 or Schaffer plus Eller at least. If there are no questions, I
25 will rest.

26 JUDGE FREDMAN: No further questions, but thank

1 you.

2 MR. STOWELL: Thank you.

3 JUDGE MAJORS: Thank you, counsel.

4 JUDGE FREDMAN: Thank you.

5 MR. HAMILTON: So I just want to address a couple
6 of hopefully quick points. Petitioner has pointed to
7 Petitioner's expert's testimony of these different forces, and
8 what Petitioner just said is Petitioner's expert balanced
9 those forces. What Petitioner's expert did is balance those
10 forces for the sole motivation of sealing, not the insertion,
11 manipulation, the feedback required for using the tool.

12 So Petitioner, I believe, admitted that we all agree the
13 purpose of the hemostasis valve, and he didn't dispute what
14 I said was the purpose of the hemostasis valve. To insert,
15 manipulate tools, as Petitioner's expert said, to get that
16 feedback, for the use of the tool during a medical procedure.
17 Petitioner's expert's consideration of these forces for the
18 sole goal of sealing is insufficient and is not what a person
19 of ordinary skill in the art would actually take into account
20 when designing a hemostasis valve. That's why Petitioner's
21 expert's testimony should not be credited over Dr. Zalesky's
22 testimony from the correct perspective.

23 Of course, Petitioner's expert didn't admit at
24 deposition that he used hindsight and just found that the
25 claims were patentable. What Petitioner's expert has done,
26 and Petitioner throughout these cases, is start with the

1 claims and not consider any other options. Petitioner's
2 expert admitted there are many different configurations for
3 a filament in a hemostasis valve. None of those
4 configurations, Petitioner's expert admitted again, include
5 attaching each end of that filament to a separate actuator,
6 undisputed. That --

7 JUDGE FREDMAN: But Schaffer teaches that,
8 right?

9 MR. HAMILTON: Schaffer does not. Schaffer
10 absolutely does not.

11 JUDGE FREDMAN: Schaffer doesn't have two
12 actuators?

13 MR. HAMILTON: It has two actuators. It has two
14 U-shape members.

15 JUDGE FREDMAN: It doesn't have a filament. It
16 doesn't have a filament. Yes.

17 MR. HAMILTON: It doesn't have a filament at all.

18 JUDGE FREDMAN: I understand that. I'm saying
19 he has to have -- the question here sort of to me is your
20 hindsight argument is essentially saying that once
21 somebody makes something any other way, any one
22 obvious instruction, any other obvious instruction is
23 therefore necessarily hindsight. And it doesn't seem to me
24 that that can be the law. Right? If I make a chair and I say,
25 well, you know, four legs, but if I now say it's obvious to
26 use three legs or two legs or one way or 15 legs, those are

1 all unobvious simply because I made the earlier assertion
2 and I had an expert say that. It doesn't seem that that can be
3 the law.

4 MR. HAMILTON: The earlier assertion here is that
5 one would simply replace each U-shape member with a
6 string or a wire. That's the first thing that Petitioner's --

7 JUDGE FREDMAN: But more than one thing can
8 be obvious.

9 MR. HAMILTON: Yep, sure. So --

10 JUDGE FREDMAN: So the fact that the expert says
11 more than one thing is obvious can't be the only argument
12 for hindsight. That's what you're trying to rely on. It seems
13 like the only argument you're relying on.

14 MR. HAMILTON: No the hindsight is Petitioner
15 started with the claims. Petitioner only considered the
16 single configuration that's claimed. And whatever patent he
17 looked at, that's the only configuration Petitioner
18 considered. And what Petitioner has to show is that the
19 difference between the -- this is the Graham factor. You
20 assess the difference between the prior art and the claimed
21 invention. The fundamental difference is no prior art shows
22 a single filament attached to different actuators on both
23 ends. That's a fundamental difference.

24 So, what is the reason one skilled in the art would
25 arrive at that particular configuration? Initially, Patent
26 Owner's expert said one would simply replace each U-

1 shaped member with a string. So, two strings each attached
2 to the same actuating member. And then only on reply did
3 Petitioner's expert say, oh, forget that. Someone would not
4 do that. One skilled in the art wouldn't because that
5 wouldn't seal for the exact same for this reason of
6 conforming. One skilled in the art would instead use a
7 configuration that's not shown in any of those references.

8 It's Petitioner's burden to show not just motivation to
9 combine, but motivation to arrive at the claimed
10 configuration. Claim 2 and claims 3 through 9 all are clear
11 on what that configuration is. Petitioner's expert has failed
12 to provide a reason one skilled in the art would select that
13 particular configuration over any other. That's the issue.

14 And Petitioner's expert's done that with testimony
15 from a perspective that's not a person of ordinary skill in the
16 art that only takes into account sealing. That's the only
17 concern for Petitioner's expert, which is, again, I think as
18 Petitioner just admitted, not the purpose of a hemostasis
19 valve. A hemostasis valves purpose is to have the ability to
20 introduce, manipulate, and use tools and instruments during
21 a procedure. And of course, it has to seal, but it's the
22 balance of those things.

23 So when Petitioner's expert -- when Petitioner
24 testifies about balancing springs, etc., Petitioner's expert
25 doesn't say so that any of these things can happen.
26 Petitioner's expert says one could balance that so it seals.

1 That is the sole motivation from Petitioner's expert. And
2 that's why this testimony from the incorrect perspective
3 should not be credited over Dr. Zalesky.

4 I want to I want to address another issue that
5 Petitioner hasn't provided any reason or basis why this
6 Board is bound by the '011 decision. Number one, the
7 claims are different, as Petitioner showed with the claims up
8 and as I explained. This '012 Patent expressly claims two
9 buttons. They loop between the two buttons and the ends
10 attached to the different sides. So, that's, you know, a
11 fundamental difference. Petitioner has not provided a
12 reason or motivation why one skilled in the art would
13 combine the references for that particular claim
14 configuration, and that's assuming that this individual has
15 decided they're not going to use what Schaffer says seals in
16 the embodiment of figures 30 through 34.

17 And what I have up here, this is slide 25 from Patent
18 Owner's demonstratives. This is some excerpts from
19 Schaffer on the top right. It's Paragraph 75 from Schaffer.
20 And you see in the highlighted portion, the seal module 100
21 is formed of one or more seal members. And in the '011
22 decision, that section was discussed, and I believe the
23 conclusion was that highly compliant seal doesn't need to be
24 included.

25 And what I want to address here is a person of
26 ordinary skill in the art is not so unreasonable in reading

1 this passage. What Schaffer discloses is that one or more
2 seal members must be included. Petitioner admits at least
3 one has to be included. The only seal member discussed in
4 this embodiment is the internal, highly compliant seal
5 member 165. That is the only seal member that is disclosed
6 as being included in this embodiment. And in fact, let me
7 just make sure I get to the right slide. Schaffer discloses
8 that that is how this embodiment seals.

9 So a person of ordinary skill in the art would not look
10 at that passage, one or more seal members and Schaffer's
11 disclosure that -- of the only seal member that actually
12 seals, the only description of how this embodiment seals,
13 and conclude that that person would not include that highly
14 compliant seal member in this embodiment. And what that
15 would require is -- this is Petitioner's illustration of how
16 gaps are formed in Schaffer, and this is their motivation, the
17 Petitioner's motivation for why Schaffer doesn't seal.

18 And what Petitioner is asserting is that a person of
19 ordinary skill in the art. Would read that one or more and
20 say, oh, what Schaffer is disclosing is a device, and that's
21 shown in petition at Page 36, this illustration, in the
22 simplest situation to seal around an instrument. The
23 simplest situation, the instrument is essentially the same
24 shape as the U-shaped members. The instrument is
25 essentially the same size as the U-shaped members. In that
26 situation, Schaffer's disclosing a device that would not seal.

1 A person of ordinary skill in the art is not so unreasonable
2 or devoid of common sense. Schaffer discloses there's one
3 thing that seals in this embodiment, that's the internal,
4 highly compliant seal member. And the person of skill in
5 the art would understand that that is included, as it is in
6 every other embodiment of Schaffer, to achieve that balance
7 of these light external forces to create a seal -- under light
8 compression to create a seal that allows the very purpose of
9 a hemostasis valve to be achieved: inserting, manipulating,
10 allowing the physician feedback as the device is used in the
11 hemostasis valve.

12 And with that, one skilled in the art would not decide,
13 looking at Schaffer and -- let's back up for a second. One
14 skilled in the art was so unreasonable and thought, okay, I
15 don't have to include what Schaffer says is used to seal in
16 this embodiment. One skilled in the art would not then
17 think -- the plausible solution would be to do exactly what
18 Schaffer says. The plausible solution would be to include
19 that seal member if for some reason a person of ordinary
20 skill in the art was so unreasonable as to not include that
21 seal member in the first place. One would include that seal
22 member. And in that way, Schaffer's balance is achieved.

23 The only method of manufacturing the members, the
24 only method of assembling the device are preserved.
25 Schaffer's fundamental principle of operation is preserved
26 with the simple change, and this isn't pulled out of thin air.

1 This is exactly what Schaffer tells one of skill in the art to
2 do. Instead, Petitioner's expert asserts that one would be so
3 unreasonable as to exclude that member, and then instead of
4 doing exactly what Schaffer says would go and look for
5 some other way to compress from the outside, and in fact, a
6 way that's not disclosed in any other reference. It's not
7 simply a string or wire. It is a filament in a particular claim
8 configuration. Thank you.

9 JUDGE FREDMAN: Thank you.

10 JUDGE JESCHKE: Thank you.

11 JUDGE MAJORS: Thank you, Mr. Hamilton.

12 Thank you to both parties today for your attendance
13 and your presentations. Counsel, if you wouldn't mind, like
14 we did in the last hearing, just hanging around for a couple
15 of minutes to help the court reporter if there are any
16 questions about spelling. Otherwise, this matter is
17 submitted to the panel for the preparation of the final
18 written decision, and we are now adjourned. Thank you.

19 JUDGE FREDMAN: Thank you.

20 (OFF THE RECORD @ 10:40 AM)

PETITIONER:

Joshua J. Stowell
Joseph R. Re
Brian C. Barnes
KNOBBE, MARTENS, OLSON & BEAR, LLP
Joshua.Stowell@knobbe.com
Joe.Re@knobbe.com
Brian.Barnes@knobbe.com

PATENT OWNER:

Joseph Hamilton
Paul Parker
PERKINS COIE LLP
hamilton-ptab@perkinscoie.com
parker-ptab@perkinscoie.com