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Paper 34
Entered: November 17, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner

IPR2024-01157
Patent 11,697,011 B2

Record of Oral Hearing
Held: October 29, 2025

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

Imperative Care v. Inari Medical
IPR2026-00169
Imperative Care Ex. 1042

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The above-entitled matter came on for hearing on October 29, 2025, commencing at 9:00 a.m., via video teleconference.

1 P R O C E E D I N G S
2 - - - - -
3 JUDGE MAJORS: All right. Everyone, good morning. This is
4 Judge Majors. With me are Judges Fredman and Jeschke. This is the final
5 oral hearing in this proceeding, IPR2024-01157, and this relates to Patent
6 Number 11,697,011.
7 Petitioner is Imperative Care, Inc., and the Patent Owner is Inari
8 Medical, Inc. The court reporter is present, and the Board will issue a
9 transcript, which will become part of the record in due course. Counsel for
10 Petitioner, would you please identify yourself and let us know who's going
11 to be doing the speaking today.
12 MR. STOWELL: Good morning, Your Honor. Joshua Stowell of
13 Knobbe Martens on behalf of the Petitioner, Imperative Care. I will be
14 conducting the oral argument this morning. I am joined at counsel's table by
15 my colleague, Brian Barnes.
16 JUDGE MAJORS: All right. Welcome. And for Patent Owner,
17 who is appearing today and who will be doing the speaking?
18 MR. HAMILTON: Good morning, Your Honor. Joseph Hamilton
19 from Perkins Coie on behalf of Patent Owner, Inari. With me at counsel
20 table is Matt Williams, also from Perkins Coie. And it's my understanding
21 that on the public line there are representatives from Stryker Corp., one of
22 the real parties of interest and including Merle Elliott, IP counsel of Stryker.
23 JUDGE MAJORS: Okay. Welcome everyone. As set forth in our
24 September 16th, 2025, order, each side has 60 minutes to present its
25 argument in this case. The Panel will do our best to keep track of time, but I

1 would suggest that the parties do the same. Petitioner has the burden of
2 proof and will present its arguments first.
3 Counsel for the Petitioner, would you like to reserve any time for
4 rebuttal?
5 MR. STOWELL: Yes, Your Honor. Petitioner would like to
6 reserve ten minutes for rebuttal.
7 JUDGE MAJORS: Okay. And Patent Owner, would you like to
8 reserve any rebuttal time?
9 MR. HAMILTON: Yes, Your Honor. Patent Owner would like to
10 reserve 20 minutes.
11 JUDGE MAJORS: As I think everyone has said, this hearing is
12 open to the public, and there's a public line that's open. The panel has access
13 to the entire record, including the parties' demonstratives.
14 It would help us if, when you're going through and referring to
15 your demonstratives, if you could refer to the page number and then just
16 give us a second or two to catch up to you.
17 Our expectations are that the parties will not interrupt the other's
18 presentations today unless absolutely necessary. And, if during your
19 presentations today, you see some sort of technical issue that's affecting your
20 presentation, since I'm appearing by video, if you see the video, for example,
21 freeze up, please let somebody there know so we can try to address that.
22 And with that, Petitioner -- Judge Fredman, do you want to put
23 -- we can put the full 60. Of course, you can go into your --
24 JUDGE FREDMAN: I put 50 up, but --
25 JUDGE MAJORS: That's fine. We'll keep track of it. But
26 obviously, you don't have to stop right at 50, if you want to keep going and

1 take a bit of your rebuttal time or all of it. Very well.
2 And with that, Mr. Stowell, you can begin whenever you're ready.
3 MR. HAMILTON: May I make one comment, Your Honor.
4 TECHNICAL SUPPORT: I'm sorry to interrupt, Judge Majors,
5 I'm to drop your call and reconnect you. You have this little delay with your
6 video and the audio. I'm going to disconnect you and call you back.
7 JUDGE MAJORS: Okay.
8 TECHNICAL SUPPORT: Hello? Can you hear us, Judge
9 Majors?
10 JUDGE MAJORS: I can. Can you hear me?
11 TECHNICAL SUPPORT: Yes, we do. Thank you for that.
12 Thank you. You should be good to go. Thank you.
13 MR. HAMILTON: Your Honor, this is --
14 JUDGE MAJORS: Whenever you're ready.
15 MR. HAMILTON: This is Counsel for Patent Owner. I have one
16 issue I'd like to raise before we start. Last night, we filed one objection to
17 one of Petitioner's demonstratives. It's my understanding you would not like
18 me to interrupt if that demonstrative comes up. I don't know if that's
19 something we should address first.
20 JUDGE FREDMAN: I'll answer that. I think, as the Board, we
21 typically don't find these things as, you know, prejudicial so that, you know,
22 even if we see it, we're not going to be prejudiced by it, so I think it's okay.
23 We'll understand that you do not want that there, but I don't think it's
24 prejudicial really, with all the evidence under consideration.
25 MR. HAMILTON: All right. Thank you.
26 JUDGE MAJORS: What's the slide number, just so I can note it

1 here.
2 MR. HAMILTON: Slide 44.
3 JUDGE FREDMAN: Okay. Yeah.
4 Are you ready to begin?
5 MR. STOWELL: I am, Your honor.
6 Good morning, everyone. And may it please the Board, Josh
7 Stowell, on behalf of the Petitioner, Imperative Care.
8 Petitioner has prepared some demonstratives that I will refer to
9 during today's oral argument. Beginning at Slide 2 of those demonstratives,
10 there's a very brief overview of how I intend to approach the oral argument
11 today. Most importantly, Petitioner intends to start by discussing the
12 Schaffer plus Hartley or Eller grounds first, and then we'll move to the
13 Schaffer only grounds.
14 Moving ahead to Slide 5 of the materials, one of the reasons it
15 makes sense to start with the Schaffer plus Hartley or Eller grounds is that
16 there's very little in dispute with respect to those grounds. The only matter
17 in dispute is whether a POSITA would have been motivated to combine
18 Schaffer with Hartley or Eller, and specifically, whether a person of skill
19 would have found it obvious to replace Schaffer's U-shaped actuating
20 members with the string that's disclosed in Hartley, or the wire member
21 that's disclosed in Eller.
22 I'll also address the Schaffer grounds today, anticipated or obvious
23 over Schaffer. That argument largely turns on the construction of filament
24 and whether Schaffer has a filament under the constructions.
25 If we turn to Slide 6 of the materials, there are a number of matters
26 that are not in dispute today. There is no dispute that Hartley and Eller,

1 those references that they do disclose a filament under either party's
2 construction. Patent Owner raises no arguments regarding whether Schaffer
3 plus Hartley or Eller meets the limitations of any of the dependent claims.
4 There are no arguments with respect to Dependent Claims 2 and 4
5 through 9 for any of the grounds. There is no dispute that Petitioner's
6 references qualify as prior art. Patent Owner has not raised any evidence of
7 secondary considerations that we need to discuss. We could also add that
8 there's no dispute that Petitioner's expert qualified as a person of ordinary
9 skill in the art from 2017.
10 On top of this case, we also have a co-pending district court
11 litigation. In that case, the court has recently ruled on Patent Owner's
12 request for a preliminary injunction. The court denied that request. We've
13 submitted that paper as Exhibit 1020 in this case.
14 The district court reviewed the Board's preliminary decision. In
15 that case, the institution decision, the court found the reasoning persuasive,
16 particularly the court found the Board's reasoning that Schaffer is likely, or
17 at least preliminarily found to anticipate the claims. The court found that
18 persuasive. The court also found arguments regarding the combination of
19 Schaffer plus Hartley persuasive.
20 The court also conducted its own analysis, and based on that
21 analysis, it found that the claims, in a related patent, the '921 patent, were
22 likely to be found unpatentable.
23 JUDGE MAJORS: Mr. Stowell, did the district court affirmatively
24 construe the claims yet in that related litigation?
25 MR. STOWELL: No, Your Honor. There's been no claim
26 construction. The court stayed the proceedings before the parties got to

1 claim construction.
2 Moving to Grounds 3 through 4, the Schaffer plus Hartley or Eller
3 grounds. I know the Board is familiar with the art here. If we could just go
4 to Slide 9, we had a comparison between the embodiments and Schaffer and
5 the '011 patent. There are obviously a lot of similarities between the
6 references. There's no dispute that Schaffer discloses buttons and springs
7 and a collapsible tubular member. The only dispute is whether Schaffer
8 discloses a filament. However, if we can go to Slide 10, there is no dispute
9 that --
10 JUDGE FREDMAN: (CROSSTALK) collapsible member isn't
11 there, somewhat? That whether the collapsible member's compliant and
12 how compliant it is?
13 MR. STOWELL: There's no dispute about the --
14 JUDGE FREDMAN: Maybe it's the Schaffer --
15 MR. STOWELL: -- the tubular member.
16 Yeah. Right. There's no dispute about that Schaffer has a
17 compliant collapse of the tubular member.
18 Hartley also discloses a hemostasis valve. And, again, it has a
19 string or a filament that wraps around a tube and chokes or constricts the
20 tube.
21 Referring to Slide 12, Eller, another reference that we rely upon
22 also discloses a filament. It has a first wire member that can be made from a
23 variety of compliant, flexible materials. The wire member wraps around a
24 tube within the valve, and it chokes or constricts the tube in this device as
25 well.
26 So, moving to Slide 14, the only dispute with respect to the

1 Schaffer and Hartley or Eller grounds is whether there would have been a
2 motivation to combine, and Petitioner and its expert identified a number of
3 motivations to combine Schaffer with Hartley or Eller.
4 The first motivation to combine is that Hartley suggests a solution
5 to the very problem Schaffer is trying to solve. Schaffer explains that there
6 was a gap in the art, and that prior art hemostasis valves could not seal
7 around a large number of instruments. While Hartley addresses that very
8 problem, Hartley explains that the string that's disclosed --
9 JUDGE FREDMAN: So, is Schaffer the reference that teaches
10 that there aren't really gaps because it's a highly compliant seal?
11 MR. STOWELL: Well, no. Schaffer has embodiments where
12 there is a hypercompliant seal. The embodiments that Petitioner has relied
13 upon do not use that hypercompliant seal. It is not mandatory. And we'll
14 discuss that in detail.
15 JUDGE FREDMAN: Okay.
16 MR. STOWELL: Yeah.
17 Hartley explains that its string can close over a range of diameters
18 and devices pass through the valve, or it can close down to be self-sealing.
19 So, we have Hartley suggesting a solution to the very problem that Schaffer
20 identifies.
21 If we turn to Slide 15, Eller also suggests a solution to the very
22 problem that Schaffer identifies. It also identifies this issue of sealing
23 around a large number of instruments, and it describes a wire member that
24 can conform to the instruments and seal against a large number of
25 instruments.
26 Now, there is no dispute here that Hartley and Eller both can

1 constrict around varying sized instruments. There's no dispute that Hartley
2 and Eller addressed the same problem as Schaffer, and that they describe a
3 solution to Schaffer. This particular motivation to combine is not in dispute.
4 Patent Owner has not addressed this in any of its briefing and has not
5 contested this particular motivation to combine the suggestion in Hartley or
6 Eller of the very solution to the problem identified in Schaffer.
7 If we turn to Slide 16, Petitioner identified a second motivation to
8 combine, and that was the recognition that Hartley's string or Eller's wire
9 member would better conform to instruments passed through the valve. The
10 concern being that Schaffer's U-shaped actuating members may form small
11 gaps, depending on the shape or the size of the instrument, and that the
12 ability of Hartley's string or Eller's wire member to better conform to the
13 strings would have been advantageous and would have been a desirable
14 benefit.
15 This motivation to combine is noteworthy, is consistent with all the
16 references that are discussed in this case. All the references recognize that
17 there is no perfect hemostasis seal that seals all the time. The '011 patent,
18 Schaffer, Eller, Hartley, they all recognize that gaps can form in hemostasis
19 valves in some circumstances. This argument is consistent with the art that
20 we see in this case.
21 Now, there are a few reasons why the gaps may form with the U-
22 shaped actuating members and Petitioner's expert discusses this. One is if
23 the U-shaped members are rigid, then they wouldn't conform to an oddly
24 shaped instrument or an instrument of a different size.
25 However, if we turn to Slide 17, even if the U-shaped members are
26 flexible, they are anchored to the buttons at a fixed distance, and so they'll

1 naturally have a curvature radius that may not match that of the instrument
2 that's inserted. So, even if the U-shaped members are flexible, gaps still may
3 occur in the operation of the device, depending on the instrument that's
4 inserted. Again, it's not able to conform as easily to the shape of the
5 instrument.
6 JUDGE MAJORS: Mr. Stowell, I have a question quickly about
7 this graphic and the one that we looked at on the former slide. Seems to be
8 an argument that these graphics envision a world where the Schaffer valve is
9 not using an extremely compliant or highly compliant central seal member.
10 Do you agree with that characterization?
11 MR. STOWELL: Correct. In this particular circumstance, it
12 would be using a, I guess, a noncompressible seal member, which is
13 described in Schaffer as one of the types of seals that Schaffer can use.
14 JUDGE MAJORS: For example, like what they use for the first or
15 the second seal member in Schaffer?
16 MR. STOWELL: Correct. Potentially, there -- Schaffer describes
17 that any of the seal members could have a variety or be made of a variety of
18 different materials.
19 JUDGE FREDMAN: Okay. Thank you.
20 MR. STOWELL: If we turn to Slide 18, Patent Owner accuses
21 Petitioner of concocting this gaps argument or manufacturing it from whole
22 cloth. Patent Owner claims that Schaffer would form a complete seal in any
23 circumstance, that it's the perfect universal valve. Obviously, this is
24 inconsistent with just the history of the development. If Schaffer truly
25 solved the problem, then we wouldn't have seen additional valves like
26 Hartley or Eller or even the '011 patent come along. So, it's inconsistent

1 with the reality of how the art has developed.
2 But also, if we look at the evidence that Patent Owner cites, we see
3 that the evidence doesn't support Patent Owner's argument. And so Patent
4 Owner has argued that the formation of gaps is contradicted by Schaffer and
5 by the statements of Petitioner and its expert. So, we should look at those
6 statements.
7 And if we go to Slide 19, we can see on the left-hand side Patent
8 Owner response. And we can see the portion of Schaffer that is cited. And
9 it says that "Schaffer valve forms a nearly fluid gas-tight seal under very
10 light compression." So, it does not say that it forms a complete seal. It's a
11 nearly fluid gas-tight seal. So, even under the portion of Schaffer cited by
12 Patent Owner, there's no recitation of forming a complete seal.
13 Now, moreover, this particular language comes from a specific
14 embodiment. And Judge Majors, you alluded to this. It's an embodiment
15 that if we look all the way back down to the bottom of paragraph 59, is for
16 illustrative purposes only, and it has a material of the third seal, is a
17 gelatinous substance, and it exhibits a self-closing nature in that it sticks
18 occlusively to itself, and it forms a nearly fluid, gas-tight seal. So, this is a
19 very specific embodiment of the valve that uses third central seal member
20 165.
21 JUDGE MAJORS: I have a follow up to that --
22 MR. STOWELL: Sure.
23 JUDGE MAJORS: -- issue. At times, it seems like the parties are
24 using the -- for lack of a better description, I'll call it the sticky gelatinous
25 material, using that differently than the third central seal member material of
26 a highly compliant nature that's described elsewhere in Schaffer.

1 My question is are these really the same thing that we're talking
2 about here, or are they, in fact, different?
3 MR. STOWELL: Well, my understanding of Patent Owner's
4 argument is that, well, every time the third seal member is described, it
5 needs to be this sticky, gelatinous material. Petitioner disagrees with that.
6 There is a wide variety of seal materials disclosed in the patent that could be
7 used for the third seal member or any other seal member.
8 If we look at page 20 of the slides, Petitioner has relied on the
9 embodiments in Figures 30 to 34 and paragraph 75 of Schaffer introduces
10 that embodiment, and it requires a seal module 100, and it broadly describes
11 the seal module. It says the seal module may have one or more seal
12 members. It says the seal module 100 and or any of its respective seal
13 members can be formed of one or more materials. So, it broadly describes
14 what the seal module is made from.
15 It then goes on, in paragraphs 76 and 77, to describe additional
16 options or additional embodiments. And what we see Patent Owner trying
17 to do is limit the disclosure about Figures 30 and 34 to just the description in
18 paragraph 77 that mentions third seal member.
19 But again, that's just an embodiment. The description of Schaffer
20 is much broader, and it describes many more materials. If, for example, we
21 look at Slide 21, we can see one of the descriptions in Schaffer of the
22 different materials that the valve can be made of. It can be made from a
23 high-durometer material, self-lubricating lubricious or coated materials,
24 specialty silicones, natural latex, synthetic rubbers. And Mr. Thornton has
25 testified that many of these materials would not be sticky or gelatinous.
26 Notably, many of these materials overlap with the materials that are

1 described in the '011 patent, which of course doesn't say that any of these
2 materials are sticky or gelatinous either.
3 If we turn to Slide 22, we have a couple of the figures here, Figures
4 32 and 33. Petitioner's argument is that Schaffer's valve in these figures
5 always requires third seal member 165, and yet we don't see 165 in any of
6 the figures. One would think that if it were a required element of the
7 embodiment, it would be included within the figures.
8 If we turn to Slide 23, we also have testimony that this particular
9 embodiment that's self-closing or sticky valve would not work well for
10 Figures 30 to 34. The way that Figures 30 to 34 embodiment works is that
11 pressure is applied to the tube and it closes the tube by the U-shaped
12 actuating members. When a user presses the buttons, that tension is released
13 and the tube member expands back to its shape on its own. Well, if the
14 valves stick to itself, that would inhibit the valve's ability to return to its
15 shape. And even Patent Owner's expert, Dr. Zalesky, agrees that a sticky
16 valve wouldn't be optimal for Figures 30 to 34, and that's at Exhibit 1015 of
17 page 164, line 7 to 17. So, Schaffer does not support Patent Owner's
18 arguments that no gaps would form.
19 If we go to Slide 24, we can look at the alleged contradictory
20 statements made by Petitioner and its expert. This particular statement on
21 Slide 24 is something that Patent Owner has repeatedly cited, but it doesn't
22 contradict Mr. Thornton's positions. Mr. Thornton was asked if Schaffer's
23 U-shaped members formed a complete seal, would there be any reason to
24 modify Schaffer? And he said, well, if it worked perfectly, no. But Mr.
25 Thornton is on record throughout this IPR of explaining that Schaffer would
26 result in gaps depending on the size of the instrument inserted through the

1 device. So, again, the testimony does not contradict Mr. Thornton's
2 statements.
3 If we move to Slide 25, Patent Owner has also made some
4 arguments about how using Hartley's string or Eller's wire would not work
5 as well if two instruments were inserted through Schaffer's valve. This
6 argument is not probative for several reasons.
7 First, if we go to Slide 26, this discussion of inserting two or more
8 instruments, again, is with respect to a very specific embodiment. This is an
9 embodiment that is described in Figures 12 to 15 that does not use actuating
10 members to close the valve. This is a passive seal that relies on back
11 pressure from the fluid to seal the valve. So, it's a very different member. It
12 does require the third central seal member, unlike Figures 30 to 34. And it
13 explains that the material of the third central seal member is so compliant
14 that he forms a seal around the instruments.
15 So, if we turn to Slide 27, we see an issue with the demonstrative
16 that was prepared by Patent Owner because the seal, the green item in the
17 figure, is not so compliant that it seals around two instruments. We see that
18 it is a noncompressible seal member that wraps around. And as Mr.
19 Thornton points out, the figure on the right would look the same regardless
20 of whether you used Hartley's string or Eller's wire member or the U-shaped
21 actuating members.
22 If we move to Slide 28, Petitioner has identified a third motivation
23 to combine Schaffer with Hartley and Eller, and the motivation is that the
24 combination involves a simple substitution of one known element, which is
25 Hartley string for another.
26 JUDGE FREDMAN: How many different ways of closing this

1 would be possible?
2 MR. STOWELL: When you're talking about closing the tubular
3 member and the hemostasis valve?
4 JUDGE FREDMAN: Exactly.
5 MR. STOWELL: Yeah. So, in this particular case, there are three
6 ways that have been identified to constrict the tubular member: Schaffer,
7 Hartley and Eller.
8 JUDGE FREDMAN: There are no other ones that are known in
9 the art?
10 MR. STOWELL: Well, Patent Owner has argued that methods of
11 compressing, so pinching the valve, should also be counted. And so there
12 would be a fourth method of closing the valve if you include pinching or
13 clamping the valve. So, there are four ways to close the valve that have been
14 identified in this case.
15 So, on this third motivation to combine in this simple substitution,
16 if we turn to Slide 29. Hartley describes a very simple way of attaching its
17 string to its actuators. You put a little hole in the actuator, and you tie the
18 string off on the other side, and Mr. Thornton explains that the same method
19 could be used to incorporate Hartley's string into Schaffer's valve. You
20 would drill a little hole on the button, and you would tie the string off on the
21 other side. There is no dispute in this case that drilling a hole and tying off a
22 string would have been beyond the knowledge of a POSITA, so that issue is
23 undisputed.
24 If we turn to Slide 30, Eller also describes simple methods of
25 attaching its wire member to its actuator. It describes using adhesives,
26 welding, fusing. And again, Mr. Thornton has testified that those same

1 simple methods could be used to incorporate the wire into Schaffer's valve.
2 And again, there's no dispute from Patent Owner that a person of ordinary
3 skill in the art would have possessed the knowledge and the skill to use an
4 adhesive or to weld or to fuse the wire member to Schaffer's buttons.
5 If we turn to Slide 31, Patent Owner has argued that this
6 combination would not have been simple, and we see what is the sum total
7 of their response, that it would increase the complexity and variability of
8 Schaffer's valve. And if we go to the cited paragraph of Dr. Zalesky's
9 supplemental declaration, we see the exact same statement.
10 There's never an explanation for why this combination would
11 increase the complexity or the variability. These type of conclusory
12 statement certainly isn't enough to rebut Mr. Thornton's testimony that doing
13 simple things like drilling a hole and tying off a string on one end of the hole
14 or gluing or welding would have been outside the scope of a person of
15 ordinary skill's knowledge and experience.
16 If we move to Slide 32, Petitioner identified yet a fourth reason
17 why a person of ordinary skill in the art would have been motivated to
18 combine Schaffer with Hartley and Eller.
19 And Judge Fredman, I think this one gets to the question that you
20 asked earlier, how many ways could this be done? And Mr. Thornton
21 testified that there would be a finite number of ways to compress that
22 resilient material in a hemostasis valve.
23 Now, Patent Owner did not address this argument in its POR. In
24 our reply to the POR, we pointed that out and said it's unrebutted that there's
25 a finite number of options.
26 Patent Owner then came back in its surreply and tried to address

1 this for the first time. Patent Owner was obviously warned in the scheduling
2 order that arguments not raised in the POR would be waived. So, Petitioner
3 believes that this argument has been waived by Patent Owner. However, I'll
4 also substantively address the issue.
5 If we look at Slide 33, Patent Owner has no evidence from its own
6 expert to support its positions here because it did not address this argument
7 in the POR. So, what it tries to do is suggest that Petitioner's expert
8 admitted that there were more than three ways to constrict a tubular member
9 in a hemostasis valve.
10 And if we go to Slide 34, we can see that that's not correct. And
11 what Mr. Thornton was asked about during his deposition was pinched
12 valves.
13 So, Judge Fredman, as you alluded to earlier, this idea of
14 collapsing a valve from two different -- just two different sides, as opposed
15 to circumferentially constricting the valve, like we see in Schaffer and
16 Hartley and Eller. And Mr. Thornton explained that that's really a different
17 mechanism of action, pinching versus the circumferential constriction, and
18 he was consistent about that.
19 So, the evidence is clear that in terms of constricting a tube in a
20 hemostasis valve, there are three available and finite options: Schaffer,
21 Hartley, Eller.
22 If we move to Slide 35, even if we were to include pinch valves
23 within the universe of the solutions, there are still a finite number of ways to
24 compress the resilient material in a hemostasis valve. And Mr. Thornton
25 tried to articulate this as best he could on the fly during his deposition. And
26 again, we didn't have an opportunity to present evidence from Mr. Thornton

1 in rebuttal because this argument wasn't contested until the surreply. But he
2 explains that there are still a finite number of ways to compress the resilient
3 material in a hemostasis valve. And that's true. Even if we add the pinch
4 valves, we're up to four. Four is still finite.
5 JUDGE MAJORS: What, Mr. Stowell, what do you make of this
6 testimony that Patent Owner cites -- or Mr. Thornton said, in effect, well, I
7 don't know how many different ways there are to compress a tube?
8 MR. STOWELL: Yeah. So, I'll be honest, the questioning in
9 testimony there is a little bit muddled. He was asked generically, how many
10 ways are there to compress a tube? And he said he wasn't sure. But I think
11 if we look at the evidence that's submitted in this case, he has identified
12 three ways to constrict a tube: Schaffer, Hartley, and Eller. And if we
13 include the pinch valves, that's a fourth way.
14 Patent Owner has not come forward with any other explanation of
15 any prior art that differs from those methods here. And so I think while, you
16 know, in the abstract, could there be potentially another way? Sure, maybe.
17 But the evidence here shows that there's four ways at a maximum: pinching,
18 Schaffer, Hartley, and Eller. And it's a finite number. We don't have any
19 evidence of another means of constricting the tube.
20 JUDGE MAJORS: When we say or when you say, "pinch valves,"
21 are we talking about -- and I will confess it's a little bit hard to keep some of
22 the records in these various related cases clear, but perhaps it's in this case
23 and perhaps it's another, but Wong and Keyes (PHONETIC), which were a
24 couple references that were in the prosecution of some of these patents. Is
25 that what we're talking about when we say a "pinched valve"?
26 MR. STOWELL: Right. So, those are examples of a valve that

1 would be pinched from two sides by the sliding mechanism, or the
2 mechanism of Keyes.
3 But again, those haven't been substantively discussed by either
4 party in this IPR. Again, Patent Owner didn't address this in its POR. It's
5 strictly relying on this deposition testimony from Mr. Thornton. So, those
6 have not really been put at issue in terms of how exactly they operate, how
7 the function is, whether it's a pinch valve. It's really outside the scope of this
8 petition, to be honest.
9 If we go to Slide 36, Patent Owners also argue that replacing the
10 U-shaped actuating members with Schaffer or with Hartley's string or Eller's
11 wire member would somehow change the principles of operation. And Mr.
12 Thorton addresses this in paragraph 39 and as well at other parts of his
13 declaration, and he explains that the valve is going to work the same way,
14 regardless of whether you have the U-shaped actuating members or a string
15 or wire member. When the user presses the buttons, tension on the string or
16 U-shaped actuating members is released and the central tubular member
17 expands. When you release tension on the spring-loaded buttons, the force
18 is reapplied to the tubular member, and the tubular member is sealed. So, it
19 works the same, regardless.
20 JUDGE FREDMAN: So, when you release the tension on
21 Schaffer, and you have this sort of special compliance, will that also spring
22 back or that not expected to spring back?
23 MR. STOWELL: Yeah. So, that's one of the issues with the
24 gelatinous sticky material that's described as one embodiment in Schaffer. It
25 wouldn't really work with the embodiments in Figures 30 to 34 because it
26 wouldn't spring back. It says it sticks to itself. And so you wouldn't get that

1 springy compliance that you need. And that's one of the reasons why Patent
2 Owner's argument that third seal member 165 is required by Figures 30 to 34
3 is just not accurate.
4 If we turn to Slide 37, there's a very brief discussion in Schaffer.
5 In fact, just one sentence about how when the buttons are pushed, the
6 actuating members are able to forcibly disengage the walls of the sealed
7 module. And Patent Owner has argued that this one sentence that this is the
8 principle of operation of Schaffer, and that this forcible disengagement
9 somehow means that the actuating members come out of contact with the
10 outer walls of the seal module and somehow operate differently than a
11 filament would operate.
12 That's simply not true. The forcible disengagement is the same
13 regardless of whether we are using the actuating members or a string.
14 Again, when the buttons are pushed, the central seal member expands.
15 When the buttons are released, the central seal member is constricted.
16 If we look at Slide 38, Patent Owner has also argued that the string
17 or wire would compromise the ease of manufacturing. The argument here is
18 that a person of skill in the art, with all of this experience, wouldn't be able
19 to figure out how to slide a tube through a string. It's simply not creditable
20 based on the amount of training that the person of ordinary skill in the art
21 has had.
22 It also relies on just one example of manufacturing that's spelled
23 out in Schaffer. Both parties' experts agree that there would be other modes
24 of manufacturing that could be used, it's not disputed, to alleviate any issues
25 that might be caused by using a string.
26 If we turn to Slide 39, Patent Owner also argue that using the string

1 or wire would compromise the durability of the valve. Patent Owner's
2 expert, Dr. Zalesky, did not adopt this during his deposition. He
3 acknowledged that durable strings and durable wires were known in the art
4 as of 2017. Patent Owner also ignores that this exact same problem, this
5 supposed durability, would be an issue for the '011 patent as well, which
6 describes the filament. And yet the '011 patent never explains that it has
7 durability issues using a filament.
8 JUDGE FREDMAN: These would be devices presumably reused
9 and not one-time use devices, but if they broke, I guess you buy a new one,
10 right?
11 MR. STOWELL: Well, right. And many of them are one-time use
12 because they involve --
13 JUDGE FREDMAN: Oh, they are.
14 MR. STOWELL: -- the flow of blood. If it's a hemostasis valve
15 -- if blood flows through it, it would be a one-time or two-time just during
16 the procedure use.
17 JUDGE MAJORS: Yeah. I had a similar question. I was
18 assuming that they were disposable one-time, in which case, the durability
19 argument sort of made me wonder how -- for how long are these things
20 used? A couple hours, it seems like, and then thrown away.
21 MR. STOWELL: Yeah. And in most cases a couple hours would
22 be quite a long procedure, right? They're probably used two or three times
23 within the span of 20 minutes or 30 minutes, depending on the procedure
24 that's being used.
25 Okay. At this point, I am going to transition over to the Schaffer
26 only grounds. These are Grounds 1 to 2.

1 At Slide 41, just kind of summarize Patent Owner's arguments.
2 Patent Owners argue that the filament must be a thin and flexible length of
3 material and Patent Owner has also argued that Schaffer's actuating
4 members are rigid and therefore aren't a filament. And Patent Owner would
5 need to win on both of these issues to distinguish Schaffer from the '011
6 patent.
7 Patent Owners also argued that Schaffer's actuating members do
8 not circumferentially constrict the seal, and it argues that Schaffer's
9 actuating members do not form a loop, which is relevant to claim three only.
10 If we look at Slide 42, briefly, we can see Petitioner's construction
11 of filament. The construction was taken directly out of the '011 patent. It's
12 at least one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or
13 tapes. Turning to --
14 JUDGE MAJORS: So, I have a claim construction question. In
15 your petition -- or in Petitioner's petition, they say that there are indicators in
16 the specification of the '011 patent that tell us that they are using the term
17 "filament" more broadly than its plain and ordinary meaning. My question
18 to Petitioner is what is, in Petitioner's view, the plain and ordinary meaning
19 of the term "filament"?
20 MR. STOWELL: Yeah. And so, I think we've had a few
21 dictionary definitions that have been submitted in this case that's extrinsic
22 evidence. But it generally describes a filament as a thread-like object.
23 That's something that's found in both of the dictionary definitions. Exhibit
24 2002 and Exhibit 2003 that's been submitted by the Patent Owner.
25 As we will see, if we go to Slide 43, the '011 patent describes a
26 filament much more broadly than a thread-like object. Again, if we go down

1 to the very bottom of what's shown on Slide 43, we see that the filament is
2 -- could be a thread, a line, or cord. But also we have the ribbon, the flat
3 wire, a sheet, a tape. And those are beyond what would typically be thought
4 of as a thread-like material. And so that's why the '011 patent defines the
5 filament to be broader.
6 It also defines the filament to be made of a whole bunch of
7 materials, some of which wouldn't typically be thought of as flexible, like
8 the metal and the stainless steel. Additionally, thin and flexible are never
9 used in the specification to describe the filament. And as Mr. Thornton
10 explains in his supplemental declaration, Exhibit 1014 at paragraph 9, there
11 are no, kind of, mandatory dimensions that are described in the '011 patent
12 that would help a person of ordinary skill in the art determine whether a
13 filament is flexible or how much flexibility is required.
14 There also are no mechanical properties, like flexion, described in
15 the '011 patent that would help a person of ordinary skill in the art determine
16 how flexible a device needs to be.
17 If we turn to Slide 44, and this is the slide that my colleague
18 mentioned earlier that they have objected to. Mr. Thornton, in supporting
19 his opinion that the term "flexible" shouldn't be imported into filament, he
20 noted that Patent Owner's '384 patent, which is related to the '011 patent and
21 has the same specification, actually has claims that recite a flexible filament,
22 a first filament that is flexible and the second filament that is flexible.
23 And Mr. Thorton points out, when he reviews this, and this is in
24 his declaration in paragraph 11, that if all filaments were inherently flexible,
25 this language would be superfluous, and Patent Owner wouldn't have needed
26 to say that the filament is flexible.

1 If we turn to Slide 45, Mr. Thornton agrees with the Board's
2 institution decision that thin and flexible, importing those into the word
3 "filament," would inject ambiguity into the claim because there is no
4 information in the patent about how flexible something would need to be to
5 be a filament.
6 And when we asked Patent Owner's expert about this at his
7 deposition, and we can go to Slide 46, we asked, "How flexible does the
8 material need to be?" And he laughed and said, "The word 'very' comes to
9 mind, but I don't have a quantitative answer to that." So, we then said,
10 "Well, how would you test for flexibility?" And he said, "You would have
11 to wrap the device around whatever you were trying to conform it to and see
12 if you could wrap it around." And so we said, "Okay. Well, how compliant
13 would the material need to be?" And he laughed again and said, "Very. But
14 I think it would be more of a visual observation."
15 So, this type of vague, you know it when you see it, flexibility isn't
16 sufficient for definiteness of this patent and shouldn't be imported into the
17 term "filament."
18 Again, if we go to Slide 47, Dr. Zalesky was again asked, "Okay.
19 Well, can you tell us more about how you would test for whether a material
20 is compliant enough to be a filament?" And he said, "You know, primarily
21 trial and error." So, that clearly doesn't meet the definiteness standards that
22 would be required to inject "flexible" into the claims.
23 Now, if we go to Slide 48, even if filament requires flexibility, a
24 person of ordinary skill in the art reviewing Schaffer would understand that
25 the U-shaped actuating members must have some flexibility, and there are a
26 few reasons for that that Mr. Thornton has pointed out. First, the U-shaped

1 actuating members are significantly thinner than they are long, and if they're
2 made of the materials that are disclosed in Schaffer like plastic, then those
3 filaments would likely be flexible.
4 He also points out that the thickness of the U-shaped actuating
5 members, the relative thickness, is consistent with the relative thickness of
6 other parts of the valve that we know to be flexible, specifically the
7 compression spring. There's no dispute that the compression spring is
8 flexible. And so the thickness of those pieces of metal or plastic are
9 consistent with each other. And that's another reason why a person of skill
10 in the art reviewing Schaffer would understand that those U-shaped
11 members must have some flexibility to them. They certainly aren't rigid, as
12 Patent Owner has argued.
13 I'd also point out that Schaffer does describe other features of the
14 valve as rigid. It actually uses that term in paragraph 70, for example. It
15 identifies portions of the support members being vigilant. That same
16 description is not used for the U-shaped actuating members.
17 JUDGE MAJORS: Mr. Stowell, I have a question. We're looking
18 at the figures of Schaffer. Do you have Figure 32 handy? I don't know if
19 you have a slide or --
20 MR. STOWELL: Let me see.
21 JUDGE MAJORS: Or if you just pull it out, whatever is easier for
22 you.
23 And I'm using the figures from the 1008. I know there's a dispute
24 about that, but for purposes of the question.
25 MR. STOWELL: Is this on page 54? I believe that's Figure 32.
26 JUDGE MAJORS: No. No. I'm sorry. It's the best version of the

1 one we were just looking at.
2 JUDGE FREDMAN: I think it's on Slide 29.
3 MR. STOWELL: Okay. Slide 29. Perfect.
4 JUDGE MAJORS: I guess I was wondering, I'm looking at this,
5 and we all understand the limitations you might say of figures, but it seems
6 to me, if I'm looking at this and showing a cross section of the U-shaped
7 members, if these were, in fact, flexible as Petitioner wants us to say, why
8 wouldn't these U-shaped members be continuing to conform with the
9 exterior and the seal -- there you go. You got it right there. Continuing to
10 conform to the exterior of the seal module as it's compressed. You can kind
11 of see that they're keeping a static orientation or shape of those.
12 MR. STOWELL: Yeah. I would say that's an artifact of the
13 drafter's limitations here. And this is really the same as what we see in the
14 '011 patent, right? The Petitioner or Patent Owner has argued that the bight
15 embodiments we see in Figures 8 and 9, that those are flexible. And yet
16 when we see the cross -- when we see those devices in the, I guess we'll call
17 it the expanded and constricted configuration, they also don't change
18 orientation. They don't change shape. And so, you know, there's consistent
19 drafting that happened between Schaffer and the '011 patent and that these
20 U-shaped actuating members are kind of drawn crudely to show the concept,
21 but not precisely to show flexibility. And I think we agree that the '011 isn't
22 drawn to show the flexibility, either.
23 JUDGE MAJORS: Okay. Yeah. I guess just for my part, I would
24 say, I think, I'm sure you've seen our more recent thinking on this and some
25 of the more recent institution decisions. In reading through Schaffer, at least
26 to my eyes, we see a number of indicators that would suggest rigidity. And I

1 know you may say, well, those are embodiments, but it seemed to me, when
2 they talk about making these things, these actuators out of machined
3 aluminum or machined plastic, and they're -- want to slide along the exterior
4 of the housing, it all seems to point to more of a rigid structure than anything
5 that would be flexible.
6 Put aside the question of, well, could you make them flexible, or
7 would you want to make them flexible? But just looking at Schaffer itself,
8 I'm not really finding anything in the reference where we can say, okay.
9 This is an indication that the thing -- that these things are, in fact, flexible.
10 MR. STOWELL: Yeah. Well, certainly the materials, right? And
11 the relative dimension of the devices. If these were plastic, it's very hard to
12 envision. And Mr. Thornton explains this, and plastic is one of the materials
13 that's identified for the U-shaped actuating members, how that would be
14 rigid. There would certainly be some flex to a plastic piece.
15 And so, then we're getting into this debate about, okay. Well, how
16 rigid is rigid? It's certainly not completely rigid. Nothing is completely
17 rigid. How rigid is rigid? How flexible does it need to be? And that's
18 where we get into this difficulty that there's no disclosure of flexibility in the
19 '011 patent. It doesn't provide any context that we could rely upon to figure
20 out how flexible the filament needs to be to meet the limitations of the
21 patent. I will just briefly address the machining.
22 If we go to Slide 49, Brian.
23 There is testimony on this. And of course, simply machining a
24 device or a component doesn't mean that it's rigid. And Mr. Thornton
25 explains that if you remove enough material during machining, you
26 obviously end up with flexible part.

1 Both of the experts also agree that there are other ways to make
2 this -- these components, the U-shaped actuating members, including
3 extrusion, that would certainly result in flexible parts. So, there's really no
4 dispute that this example alone doesn't result in a rigid piece, but also that
5 there would be other known manufacturing methods that would be added to
6 this exemplary method that would result in flexible pieces.
7 JUDGE FREDMAN: Standard of (INDISCERNIBLE), I think it's
8 a little careful. In re: Buzzard is a case that one of my colleagues read a long
9 time ago, with a guy that got slammed for trying to make something flexible
10 that really wasn't.
11 MR. STOWELL: If we turn to Slide 51, briefly, the Patent Owner
12 has argued that Schaffer's actuating members -- Slide 51. That Schaffer's
13 actuating members don't circumferentially constrict. But that's not
14 consistent with the description and the '011 patent. The '011 patent explains
15 that a filament can be made of more than one filament.
16 In the embodiment that's shown on Slide 51, we have two sub
17 filaments. If we go to Slide 52, the patent describes that those two sub
18 filaments create an encircled area, and that when you decrease the size of the
19 encircled area, it constricts, collapse, and/or seals the elongate member. So,
20 when we have two U-shaped members, we form an encircled area or a
21 circumference, and we constrict the valve.
22 JUDGE FREDMAN: But your area is different. I mean, in -- the
23 bight of Schaffer is different than what's actually shown in this patent, right.
24 In Slide 51, because there there's interlocking; right? And you actually are
25 adjacent.
26 MR. STOWELL: Well --

1 JUDGE FREDMAN: So, slightly different in that case.
2 MR. STOWELL: It's different than what's shown in the body, but
3 not what's described in Schaffer or in the '011 patent. The '011 patent
4 specifically states that the U-shaped bights can interlock or can be non-
5 interlocking.
6 JUDGE FREDMAN: Yeah.
7 MR. STOWELL: And then it goes on to talk about when they
8 overlap, so when they're non-interlocking, they form an encircled area.
9 JUDGE MAJORS: Mr. Stowell, I have a question. You have two
10 -- hypothetical I'm going to give you. You have two opposing bights that
11 circumferentially constrict, at least under Petitioner's interpretation. Does
12 that necessarily form a loop?
13 MR. STOWELL: That would form a loop, yes.
14 JUDGE MAJORS: Okay. So, then my follow up to that is going
15 to be, those limitations are in Claim 1. What does Claim 3 of the '011 patent
16 add, which recites specifically a loop?
17 MR. STOWELL: Yeah. I think it doesn't add anything beyond
18 circumferentially constricting. I think it's really duplicative and would be an
19 improper dependent claim. Obviously, that's not a basis that we can
20 challenge in an IPR. But I believe it would be an improper dependent claim
21 because the independent claim also already says that there's circumferential
22 constriction by the filament.
23 I'm going to just jump ahead briefly --
24 JUDGE FREDMAN: Hold on, I think three is actually different.
25 I'm going to make one more little comment here because it does say, a first
26 portion of the filament extends in a loop completely around. The

1 implication is a single element? Not two elements joined together; right?
2 MR. STOWELL: It does refer to a single portion of the filament.
3 But again, filament is defined in the '011 patent to be one or more filaments.
4 And so --
5 JUDGE FREDMAN: Right, but this is further limiting; right?
6 That other -- that sort of -- you made the argument that it wasn't further
7 limiting, but if it's not -- if it was understood to be further limiting it would
8 have to mean something. A single portion would be different.
9 MR. STOWELL: Well, I think under the way Patent Owner has
10 been arguing it, they're trying to get the Board to inject a limitation that a
11 loop is made of a single filament; right? They want to inject this additional
12 limitation, single filament, in there, which simply doesn't appear in the
13 claim. They certainly could have written the claim to require a single
14 filament to create the loop. That's not what's written. It says, a filament and
15 a portion of that filament, which can be the two bight elements creates the
16 loop.
17 JUDGE FREDMAN: Okay.
18 JUDGE MAJORS: I have one more question still before we get
19 too far off the filament issue.
20 MR. STOWELL: Sure.
21 JUDGE MAJORS: Is there any evidence in the record that
22 affirmatively or expressly characterizes a filament as being inflexible or
23 rigid? I mean, we know, I think, that if you look at the patent, at least
24 Figures 6 and 7, I hope you would agree with me, those would require
25 necessarily flexibility. So -- but I'm just trying to probe. Is there anything in
26 the record where we can say, either intrinsic or extrinsic, or we can say

1 expressly, this is referring to a filament, and it's telling us that the thing can
2 be rigid?
3 MR. STOWELL: Well, I think that there's probably two areas that
4 I would point you to. One is the description of the filament as being
5 potentially made of metal and stainless steel. That certainly suggests some
6 level of rigidity for a stainless-steel filament. The other thing I would point
7 to is that, to the extent the Board is going to limit Schaffer to rigid U-shaped
8 actuating members simply based on the drawings, then that same argument
9 should apply to Figures 8 and 9 of the '011 patent, where the shape of the U-
10 shaped actuating members doesn't change between the expanded
11 configuration and the contracted configuration. So, those are two of the
12 areas of the patent that I would point to for the rigidity.
13 JUDGE FREDMAN: Do you want to keep going on? Because
14 you're pretty much out of time.
15 MR. STOWELL: I'll just briefly discuss the definition of
16 POSITA, because that's come up in this case. If we turn to Slide 57, Mr.
17 Thornton based his definition of POSITA based on his own experience in
18 the industry. He actually designed hemostasis valves at the relevant time
19 period and catheter based projects, and he hired individuals with the
20 experience in paragraph 35.
21 If we look at Slide 58, Patent Owner has disputed this. But there
22 are several problems with this. First, the Patent Owner's expert has not
23 adopted this experience designing medical devices. If we look at Slide 59,
24 he specifically says that the person of skill in the art wouldn't need that
25 experience.
26 But going back to Slide 58, I think Patent Owner's argument also

1 ignores that we're talking about a very simple device here. The claim device
2 is a valve, not even a hemostasis valve, a valve that has springs, a button, a
3 tube, and a filament. Patent Owner has pointed to no specific claim
4 language or any material in the patent that would require experience
5 designing medical devices or hemostasis valves to understand such a simple
6 technology. And with that, I will rest.
7 JUDGE MAJORS: Okay. By my account, you have about seven
8 minutes left.
9 (Pause)
10 MR. HAMILTON: Good morning, Your Honors.
11 As Petitioner explained and the Board recognized and the panel is
12 aware, there are several related IPR petitions that have been assigned to this
13 same panel. Institution decisions for those IPRs have come out over the last
14 several months, involving some of the same issues here. For example,
15 whether the term filament requires flexibility, whether Schaffer discloses a
16 filament under that claim construction, and whether a person of ordinary
17 skill in the art would have combined Schaffer with Hartley or Eller, as
18 Petitioner proposes here.
19 In this institution decision the Board stated that a more full record
20 was needed on some of those issues, like claim construction. In the most
21 recent institution, which was last week, that's in IPR2025-00989 with the
22 same panel, Paper 10. That record was more fully developed and submitted
23 in the pre-institution phase. And in that institution decision, the panel found
24 that the term filament requires flexibility that Schaffer does not disclose a
25 filament under that construction.
26 For the reasons set forth in that decision and in the briefing,

1 Grounds 1 and 2 fell. Anticipation by Schaffer or obviousness over Schaffer
2 alone is not met. In addition here, the claims require that the filament
3 circumferentially constrict to form the seal. Regardless of the meaning of
4 the term filament, Schaffer's side by side U-shaped members do not form a
5 circumference and thus cannot circumferentially constrict.
6 I'll just note, also, Petitioner didn't argue Ground 5 in its reply, or
7 here today. That ground also fell for the reasons in the briefing, and in the
8 institution decision here.
9 There are a few points that I want to come back to with respect to
10 Grounds 1 and 2, but today I want to focus on Grounds 3 and 4, which are
11 essentially the same issue, would a person of ordinary skill in the art be
12 motivated to modify Schaffer with a string or wire in the claimed
13 configuration?
14 I'm going to cover a few things. First, that definition of a person of
15 ordinary skill in the art, that is important in this proceeding. Second, that
16 there is no motivation to modify Schaffer. Specifically, Schaffer seals with
17 a seal member 165 that is highly compliant and deformable in every
18 embodiment. That's how Schaffer operates. Petitioner has said its proposed
19 combination does not include that seal member 165.
20 Patent Owner has pointed out that if the seal member -- excuse me,
21 if the proposed combination doesn't include the seal member, Petitioner's
22 proposed combination would not form a seal in the very purpose of the
23 Schaffer reference sealing around multiple instruments.
24 And Petitioner's expert in response criticizes Patent Owner's
25 assertion because Patent Owner excluded the seal member 165. Of course,
26 to meet Schaffer's purpose of sealing around multiple instruments, seal

1 member 165 must be included.
2 JUDGE FREDMAN: Is Schaffer limited to sealing in multiple
3 instruments, or can it seal around the single instrument?
4 MR. HAMILTON: Schaffer can do -- what Schaffer says in the
5 background, and let's just jump to Slide 17. This is the background of
6 Schaffer. What Schaffer says is, existing devices do not perform a complete
7 seal against leakage in the presence of a wide range of instruments or in the
8 presence of multiple instruments. Schaffer is trying to provide a device that
9 will seal in all those circumstances, and that wide range of instruments is
10 different sizes, different shapes, different diameters. And I'll get to this in a
11 minute. But in contrast, both Hartley and Eller purport to provide a seal that
12 --
13 JUDGE FREDMAN: I mean Schaffer identifies a number of
14 problems, doesn't it? You're sort of constraining it only to that problem. But
15 paragraph 5 of Schaffer, for example, talks about manually opening and
16 closing the valve. It's another problem he's addressing. So technically, this
17 is one of the problems he addresses doesn't mean it's the only problem he
18 addresses. And, indeed, it might mean that different devices where it's one
19 -- you want an automatic device, and you maybe also want a device that is
20 fully compliant on two instruments. So, it seems like you're trying to
21 conflate everything into a single device, which Schaffer doesn't necessarily
22 say you have to do and it's figures don't all show.
23 MR. HAMILTON: That is correct. Schaffer discloses many
24 problems. And in the very next paragraph, paragraph 7, Schaffer says, the
25 design considerations for a valve are complex. It involves the balance of
26 closing force, opening force, friction, compression, and durability. There are

1 lots of issues that go into why a hemostasis valve is designed in a particular
2 manner.
3 JUDGE FREDMAN: But, it sort of, then that same paragraph
4 says, they may not allow the insertion of soft flexible instrumentation, such
5 as, A, floppy head wire, laser fiber, or a soft tip catheter, suggesting that
6 those are individually added, put in. But anyway, go on.
7 MR. HAMILTON: I'm sorry, I didn't quite understand. The --
8 JUDGE FREDMAN: The point being, that they're single
9 elements. They're not -- he's not in that point talking about two things at
10 once.
11 MR. HAMILTON: That is correct. Schaffer is saying there's
12 many uses for a valve.
13 JUDGE FREDMAN: Yeah.
14 MR. HAMILTON: And one skilled in the art would do different
15 things. But what Schaffer is also saying is that the current valves solve some
16 of those issues. They don't solve all those issues. That is the point of
17 Schaffer, is we have a valve that you can use in these circumstances. You
18 don't have to go swap it out depending on what you want to do for a
19 different procedure.
20 Now here's why that definition of a POSA is important. So, I've
21 got Slide 8 up now. This is, shows the parties' proposed definitions of a
22 person of skill in the art. As shown on Slide 8, the parties agree, the person
23 of skill in the art would have an undergraduate degree in mechanical
24 engineering or related engineering discipline and two to four years of
25 product design or engineering experience. That's where Petitioner's
26 definition stops and Patent Owner's definition continues, designing medical

1 devices in the field of the '011 patent.
2 So, Petitioner's definition is unrelated to the field of the '011
3 patent. That can't be the proper definition. And in fact, on the next slide,
4 there's no disagreement on what the field is. This is Slide 10 -- excuse me,
5 Slide 9. On the left is a quote from Petitioner's expert, Expert's declaration
6 what the field is. Hemostasis valves for use during intervascular procedures.
7 And Petitioner's expert confirmed, when anyone is designing a hemostasis
8 valve, they have to consider the needs of the physician, the needs of the
9 procedure, and the needs of the patient.
10 Petitioner's person of ordinary skill in the art would have no
11 understanding of any of those needs, and not take into account why Schaffer
12 is designed in the way it's designed, why Schaffer includes, for example, a
13 rigid actuating member and an internal sealing member, highly compliant
14 sealing member. Petitioner's person of ordinary skill in the art would have
15 no understanding of those requirements.
16 Back on Slide 17, the complex issues involved in designing a
17 hemostasis valve, the balance of these forces, friction, etc.
18 Petitioner's expert also at --
19 JUDGE MAJORS: Mr. Hamilton, can I interrupt you for a
20 second?
21 MR. HAMILTON: Sure.
22 JUDGE MAJORS: Does Patent Owner disagree with the Board's
23 articulation of the POSA standard in the two most recent institution
24 decisions in the '728 and '989 case?
25 MR. HAMILTON: Your Honor, I don't have it in my head exactly
26 right now, but it is pretty, pretty close. So, if we do have an agreement, it's

1 probably minor. But it is --
2 JUDGE MAJORS: Okay. I appreciate that, that it's not in front of
3 you. I mean, I think the distinction was we said there, well, they have to
4 have some experience in products within the field of the invention, although,
5 not design per se. It could be bench testing, for example, and other things.
6 But it couldn't just be, you know, having some engineering experience with
7 any product whatsoever out there in the universe.
8 MR. HAMILTON: And what Patent Owner's expert said at depo
9 was not that one would not need any experience in medical devices. What
10 Patent Owner's expert said is, one wouldn't have actually had to have
11 designed a hemostasis valve. But Patent Owner's expert further explained
12 that one would have to have an understanding of medical procedures,
13 medical devices, in general, the -- what's used with the hemostasis valves, so
14 catheters, et cetera. They'd have to understand what the device is going to
15 be used for and how it's going to operate.
16 JUDGE FREDMAN: So, can you direct me to how that call
17 -- how that change changes the analysis. How does it matter?
18 MR. HAMILTON: Why does it matter? Okay. So, the issue is, in
19 this case, and it's -- or one of the primary issues for these grounds is,
20 Petitioner has to show that a skilled artisan would have to have been
21 motivated to combine the teachings of the prior references to achieve the
22 claimed invention, and that the skilled artisan would have to have had a
23 reasonable expectation of success in doing so. And I'm quoting from one of
24 the cases cited in our brief, RJR. That's non-controversial.
25 But there's a couple things there. One is, the motivation has to be,
26 not just to combine the references, but to combine the references in the

1 claimed manner. And two, there has to be a reasonable expectation of
2 success. A person of ordinary skill in the art, having no understanding of
3 medical devices, what the hemostasis valves are used for, what are the
4 design considerations in a hemostasis valve that are articulated in Schaffer
5 would have discounted many of the aspects of Schaffer that would cause one
6 of skill in the art not to modify Schaffer, to eliminate the rigid U-shaped
7 members, and eliminate the internal seal member that Schaffer says forms
8 the seal, and then take a string from another reference and include that in
9 Schaffer in a manner that's not disclosed in any of the references.
10 So, for example, an auto engineer, if they want to seal a tube, take
11 a string and crank, crank, crank the heck out of that string and seal that tube,
12 you don't care about all these complex balancing of factors that Schaffer
13 itself articulates.
14 JUDGE FREDMAN: But the other prior arts are in the same field
15 of endeavor, right? We're not talking about an auto engineer. So, I'm not
16 -- it almost seems like you're saying that, a highly skilled person would, who
17 is the -- pretty much, if you're saying the person is highly skilled, they would
18 be able to make this change even more easily, not less easily?
19 MR. HAMILTON: So, it depends on what -- why you're making
20 the change. So, Petitioner has characterized, actually, maybe a couple
21 different problems, but the simple thing is sealing. That's not the only
22 consideration for a hemostasis valve and a person of skill in the art, with that
23 higher level of skill that understands what else needs to go into a hemostasis
24 valve, would understand why Schaffer includes these features and why
25 they're important to Schaffer, and that would be a reason why they wouldn't
26 delete those features and create a valve that might seal in an auto engine, but

1 it wouldn't be useful in a hemostasis valve for a medical procedure.
2 JUDGE FREDMAN: But the, Hartley is a medical device coming
3 into the body and Eller is a device also going into the body. I'm not entirely
4 clear why the auto valve matters. That's seems an odd choice.
5 MR. HAMILTON: Well, I'll just put it simply. Petitioner's person
6 of skill in the art would overvalue sealing at the cost of every other factor in
7 --
8 JUDGE FREDMAN: Okay. I understand your argument.
9 MR. HAMILTON: Okay.
10 JUDGE FREDMAN: Move on.
11 MR. HAMILTON: Now, even if that were the case, the proposed
12 modification does not seal better. There is no motivation to make that
13 modification.
14 I want to point out one thing first. So, Petitioner is briefing in the
15 presentation here, talked about how simple this is, and that this can be done.
16 The test for obviousness is not that it can be done, no matter how simple it
17 is. The test for obviousness is there must be a motivation to make the
18 modification and not just combine the references, but the modification as
19 claimed.
20 So, let's talk about no motivation in Schaffer. I'm still on Slide 17.
21 JUDGE FREDMAN: I mean, I hate to go to case law because it's
22 -- I mean, we're trying to argue facts. But, I mean, KSR says, the person of
23 ordinary skill has good reason to pursue the known options within their -- his
24 technical grasp, or her technical grasp, and express substitution to substitute
25 one equivalent for another and -- this is not in KSR this is in in re: Fout,
26 express substitution is not necessarily present to make a substitution

1 obvious.
2 I mean, I think the main argument here, the one that maybe I'd
3 most like you to address is the direct substitution argument, not the
4 motivation argument.
5 Can you explain why there's not -- why this isn't just a substitution
6 of one of the four, we'll say the pinching as one of the four, one of the four
7 ways of closing for another one of the ways of closing.
8 MR. HAMILTON: Okay. So, there's a couple things there. I'll
9 come back to the four ways. There are many ways to seal a valve to
10 compress a --
11 JUDGE FREDMAN: Do you have evidence of other ways?
12 MR. HAMILTON: Petitioner's expert explained all those other
13 ways. They went through -- in Schaffer, there are many ways. So, if you
14 could say pinching. Essentially, all of these are pinching. That's what these
15 do. They squeeze the valve.
16 Now, how does one pinch the valve to seal the valve? You can do
17 it with a clamp. You can do it with -- in Schaffer, I think every embodiment
18 has a different configuration to achieve that. One of them are these rigid U-
19 shaped members. So, there are many ways just in Schaffer alone. At the
20 deposition, and this is Wang and the other reference is escaping me, but it's
21 in our briefing. They'll show other ways.
22 I went through those with Petitioner's expert at depo, and at the end
23 he said, yes, there are many other ways. They're all pinching. And he didn't
24 know how many other ways there were.
25 JUDGE FREDMAN: So, why wouldn't it be obvious to substitute
26 any of these known ways? But what does matter?

1 MR. HAMILTON: Because those known ways have different
2 considerations, and the way that Petitioner proposes to make the
3 combination actually decreases how well Schaffer's valve seals. A person of
4 skill in the art would look at it and say, why am I -- why would I get rid of
5 the method of sealing in Schaffer, this highly compliant seal module,
6 whether it's an embodiment or not, Schaffer says, this is how you seal.
7 Why would I get rid of that, take something from another
8 reference, a string that won't seal, in all these situations where Schaffer says
9 it will seal, and, in fact, in those situations, it seals even worse?
10 JUDGE FREDMAN: Okay.
11 MR HAMILTON: Okay. So, let's just talk about this idea of what
12 Schaffer discloses in terms of the seal member. I'm going to jump to Slide
13 18. So, here are some of those other ways to compress a tube. These are
14 other embodiments in Schaffer itself, and in many other references there are
15 many, many other ways, and as Petitioner's expert said he doesn't know how
16 many ways there are to seal a tube, to compress a tube to seal it.
17 In every embodiment in Schaffer, and they are embodiments, the
18 seal member is the portion of the tube that interacts with the external rigid
19 member to form the seal. And in that way, Schaffer discloses that its device
20 can seal in all these situations, different shaped instruments, different size
21 instruments, no instrument at all, or multiple instruments. That's the
22 advantage of Schaffer. And one skilled in the art would not look at Schaffer
23 and say, okay. Let's get rid of all those advantages and go and include a
24 string or a wire, because it's used in some other device that will seal worse in
25 most of those situations.
26 Let's talk for a minute. Now I'm on Slide 19. Petitioner's expert

1 admitted that Figures 30 through 34 includes seal member 165. That's in his
2 depo, Exhibit 2010, 73, 13 through 77, 3. So, Petitioners argue two things in
3 response, that Schaffer discloses other materials for the seal member than
4 seal member 165 that are not highly compliant, so you don't need this
5 internal seal member. That was the first argument.
6 And the second one is, Schaffer's embodiment, Figures 30 through
7 34, could not be used with a sticky, gelatinous material. So, two things,
8 Patent Owner's arguments don't require that the sticky gelatinous material is
9 used. The issue is the internal material has to be compliant such that the
10 rigid member deforms that material, it fills gaps and seals in these situations.
11 JUDGE FREDMAN: You're saying -- you're effectively arguing it
12 has to seal just because it has to do two instruments that are inside? Because
13 a single instrument, presumably, wouldn't necessarily have the struggle?
14 MR. HAMILTON: Well, it would in Petitioner's proposed
15 motivation. If you don't have that seal member, and let's just jump to that
16 slide. I'm on Slide 29, top left. This is the only motivation in the petition.
17 What Petitioner says is -- excuse me, only description of a motivation based
18 on that Schaffer would not seal. And this is top left, petition at 36. This is a
19 figure that shows the rigid actuating members of Schaffer, alumin, and then
20 a one instrument inserted in Schaffer that is essentially the same shape as the
21 rigid U-shaped actuating members, and is essentially the same size, just
22 slightly smaller.
23 And what Petitioner says is, one skilled in the art would look at
24 Schaffer and realize it wouldn't seal in even this simple situation. And that
25 -- one skilled in the art is not so unreasonable. One skilled in the art would
26 know, Schaffer -- the only method in Schaffer of sealing with the interaction

1 of something from the outside providing compression is to have an internal,
2 highly compliant member.
3 So, in Petitioner's own -- so, a person of skill in the art would look
4 at that and immediately, the simple substitution, would be to include
5 Schaffer's member, and that would provide all these other advantages.
6 JUDGE FREDMAN: And would -- if you're using Schaffer,
7 remember and you chose to use Eller's, you know, string, why wouldn't that
8 work?
9 MR. HAMILTON: That's a great question. And let me jump to
10 that, because number one, Petitioner bears the burden in this case. Petitioner
11 has never argued or provided any evidence that Schaffer would seal better if
12 you used a string and the internal member.
13 JUDGE FREDMAN: I didn't say better. It's equivalent.
14 MR. HAMILTON: Or the same. Or the same. There's no
15 evidence of either one in this case, because Petitioner says person of skill in
16 the art would not include the sealing member. So, it --
17 JUDGE MAJORS: Mr. Hamilton, can I push back on that just for
18 a moment?
19 MR. STOWELL: Sure.
20 JUDGE MAJORS: Imagine we have a situation where it's just a
21 single circular, large port catheter that is being used as the tool, and we have
22 this depiction here on the copy of Slide 29, which allegedly is using the U-
23 shaped members of Schaffer. If we swap out a flexible string for that, how
24 is that going to perform any differently, to Judge Fredman's question than
25 the U-shaped members? And one further point I would make is they do,
26 Petitioner does cite, I think it's paragraph 37 of Harley that says that the

1 string can close down, can be self-sealing, or close down completely around
2 instruments or even if they're -- sorry, in the case of even no instruments.
3 So, anyway, that's a long question, but I'm just trying to explore
4 this issue of, how is the string going to work any differently in this situation
5 if you just take them out and use the string instead?
6 MR. HAMILTON: So, if I understand right, if you remove the
7 seal member 165, is that correct?
8 JUDGE FREDMAN: No, the bights. The -- if you replace the
9 bights with the string I think is what he is saying.
10 MR. HAMILTON: Replace the bights and include the seal
11 member?
12 JUDGE FREDMAN: Sure.
13 JUDGE MAJORS: Sure. Either keep the seal member or don't, or
14 take the highly compliant seal member out. In either situation, how is it
15 going to perform any differently with the string?
16 MR. HAMILTON: So, this paragraph -- first of all, I'll go to the
17 paragraph that cited, 37 of Hartley, doesn't say the string allows the seal
18 around multiple shaped instruments. What it says is, herein is provided a
19 valve that provides the seal. And Hartley's valve is a string connected to a
20 single actuator. It is controlled on both sides in the exact same manner to
21 ensure controlled and predictable movement of what happens with that
22 string.
23 So, that paragraph 37 doesn't say, string is what does everything in
24 our device. It says, our valve does this. That paragraph doesn't support
25 Petitioner's position. But let me --
26 JUDGE FREDMAN: But it doesn't, in combination with the

1 flexible material that's being, presumably, that's the tube; right? The flexible
2 material, like the one disclosed in Schaffer. In any case it discloses that
3 idea.
4 MR. HAMILTON: The flexible --
5 JUDGE FREDMAN: I mean, how is it -- if it, if the string is not
6 by itself doing it, then it has to be the material of the tube that's helping it;
7 right?
8 MR. HAMILTON: The combination of the material of the tube,
9 the string, the way the string is moved in Hartley?
10 JUDGE FREDMAN: I mean, the way that the string is moved is
11 to pull it tight. I don't think that's --
12 MR. HAMILTON: By a single actuator.
13 JUDGE FREDMAN: All right.
14 MR. HAMILTON: And the proposed combination has two. But
15 let me just show you why --
16 JUDGE FREDMAN: Go ahead.
17 MR. HAMILTON: Let me just show you why the proposed
18 combination is not the same and it's actually worse. So, as I said, Petitioner
19 bears the burden. There's been no evidence on if you include the internal
20 sealing member. But what the Petitioner's expert did testify to is technical
21 facts that show why Schaffer's member works the way it does and why it
22 would work better than a string.
23 So, Petitioner's expert explained that a harder material, and this is
24 on Slide 36, top right, a harder material would be able to deform a softer
25 material more readily. So, a harder material works better to deform and
26 form the seal. Well understood.

1 Second, Petitioner's expert explained that the U-shaped members
2 deform the seal module in the areas it's in contact with the seal module. So,
3 if you can see the comparison here between -- and that would be the same
4 for string or a wire in the proposed combination. The deformed area would
5 be where the string is or where the U-shaped members are. So, if you
6 wanted to fill in gaps with a seal module, you would be able to do that better
7 with a hard material Schaffer's rigid actuating U-shaped members and, as
8 compared to a string or a wire.
9 JUDGE FREDMAN: I think strings can close, too. If I use a
10 tourniquet in a person's body, right, if I would ever need to close their vein
11 off right is a string that you wrap around a person and then you tighten;
12 right? And that closes the vein, which is an internal structure that, you
13 know, is a tube.
14 MR. HAMILTON: So, again, if the only consideration is forming
15 a seal and you don't care about the complex balance of designing a
16 hemostasis valve, then -- and that would be someone who doesn't understand
17 medical devices or medical procedures, which Petitioner's expert said are
18 critical in designing a hemostasis valve, you have to understand these needs,
19 all these needs, which aren't recognized at all in Petitioner's expert's
20 testimony, that might be the case, but not here.
21 And now, and maybe even more importantly, the question is,
22 would a person of skill in the art -- what's the motivation to modify Schaffer
23 in the first instance, and then in the claimed manner?
24 So, that the -- if, let's say one decided, I don't want the internal
25 sealing member of Schaffer -- before I get there, also on Slide 36. If there
26 was an internal, highly compliant sealing member, the rigid U-shaped

1 actuating members would be much better equipped to deform more of that
2 material to fill in gaps than a single string or wire that would actually push
3 the material to the sides as opposed to filling in gaps.
4 Okay. So, in both those instances, let's just say, assuming a person
5 is motivated to take a string and put it in Schaffer.
6 JUDGE FREDMAN: Has a reason to or is equivalent to.
7 MR. HAMILTON: It's equivalent.
8 JUDGE FREDMAN: You don't need the word motivation here.
9 But, yeah.
10 MR. HAMILTON: Yeah. Equivalent. And what I've -- that
11 change would change Schaffer's fundamental principle of operation. Having
12 a hard material compress a soft material on the inside. That would diminish
13 all the applications that Schaffer could be used for. One of the main goals of
14 Schaffer is to provide a device that does all this. It would --
15 JUDGE JESCHKE: What is, "this," in that sense you just said?
16 MR. HAMILTON: Seal around multiple instruments, seal around
17 different sized instruments, seal with no instruments.
18 JUDGE JESCHKE: It seems to me from paragraph 6 that it says it
19 could do that, but I'm still not sure what says it has to. The principle of
20 operation of Schaffer is to seal around multiple instruments. I'm still not
21 sure. Is paragraph 6 the best place you would point for that to be the
22 principle of Schaffer's operation?
23 MR. HAMILTON: Well, no. The principle is hard material to
24 compress in an internal material.
25 JUDGE JESCHKE: But --
26 MR. HAMILTON: That's how Schaffer operates.

1 JUDGE JESCHKE: -- isn't the principle of operation the
2 functionality? What is happening is the compression. Why is it that it has to
3 be done with a hard material? To me, it doesn't matter what's done. The
4 operation is the function, the compression that is taking place. Whether it's
5 hard or a soft material doesn't seem to define the principle of the operation,
6 unless it undermines that compression, it seems to me. So, can you talk to
7 that issue?
8 MR. HAMILTON: So, the operation is compressing.
9 JUDGE JESCHKE: Okay.
10 MR. HAMILTON: And how does it compress? There are many
11 ways to compress a tube, as Petitioner's expert has said. Why would you
12 choose one way or the other? There are many different ways.
13 Schaffer's way is using a hard material to compress this highly
14 compliant material, and it has all these fantastic advantages. So, if it seals in
15 exactly the same manner, why would one skilled in the art change it, change
16 Schaffer so that it doesn't provide all those advantages? They simply
17 wouldn't. That sealing around multiple instruments, etc., sealing in a
18 different manner --
19 JUDGE FREDMAN: Is the center on multiple instruments the
20 bights, or is it the tube itself that's under pressure? What's doing that? I
21 mean, you're kind of making both arguments, and I think that's a little bit
22 confusing. I think that -- it sounds like in Schaffer what's actually making
23 the seal compliant is really the valve itself. The bights are simply pulling on
24 it. Right? They're providing the compressive force. And so, as I think
25 Judge Majors pointed out earlier, a different compressive force might be
26 expected to provide the same, you know, sealant with the same valve; right?

1 In other words, if the valve is what -- the sticky valve is what's actually
2 squeezing into -- between the places, it shouldn't matter if the compressive
3 force is provided by two bights or it's provided by a string that's also
4 circumferentially closing.
5 MR. HAMILTON: So, I just want to clarify. Schaffer doesn't use
6 the term, bight. Bight has -- it's the slack or loose part of the rope. That's in
7 the '011 patent. So, Schaffer has these U-shaped members.
8 JUDGE FREDMAN: Then U-shaped members, whatever term
9 you want to use. I'm sorry.
10 MR. HAMILTON: Okay. And if we need to, I can come back to
11 why Schaffer's U-shaped members are rigid. I think that's --
12 JUDGE FREDMAN: We're not really arguing that point. What
13 I'm saying, if you -- if we assume what you're saying is true. Right, we have
14 rigid, U-shaped members that are able, in Schaffer, to seal this, right, why
15 would then a string replacing those -- this was already asked, I guess.
16 MR. HAMILTON: Yeah. So, the question is, you have these U-
17 shaped members, you have an internal seal, they work together, they seal in
18 this great situation. You got this fantastic device. Of course, no device is
19 perfect. There are always going to be ways to improve a device.
20 But the question is, why would someone modify Schaffer to
21 remove all those benefits in a way that's not shown anywhere in the prior art
22 attaching a string to two actuators. And so, what one would have to do
23 -- and let's say, you know, they're interchangeable, whatever. They're not
24 because these are different things, but let's just assume they are. One would
25 have to look at Schaffer and say, okay, let's -- since we're going to put in a
26 string, now what else do we have to change in Schaffer? One, you have to

1 get rid of the internal compliant seal member, because a string would just
2 push it to the side as opposed to pushing it down. And that's what Petitioner
3 has argued. You wouldn't have, in their proposed combination, that internal
4 compliant seal member, and there's no evidence that you would include that
5 in this case. They haven't argued that at all.
6 But more importantly, that would eliminate Schaffer's solution for
7 that complex balance of all these forces. So, now you don't have that either.
8 So, you're -- two things that -- two reasons you wouldn't do it. Next,
9 Schaffer discloses one way to make those actuating members. It is an
10 embodiment. But now you can't use the only disclosed embodiment to make
11 the actuating members.
12 Next, Schaffer discloses one way to construct this, to assemble this
13 device. It is an embodiment again, but it's a simple way to do it. And now
14 you're going to have to change the only way Schaffer says to assemble the
15 device. So, at best, assuming it does the exact same thing, we say it doesn't,
16 but let's assume it does, now you're changing all these aspects and getting rid
17 of all these benefits of Schaffer to put in a string. And the only reason you
18 would do that is because that's what the claims say. A person of skill in the
19 art would not be motivated to do that.
20 JUDGE JESCHKE: Counsel, wouldn't the use of Hartley's string
21 in Schaffer lead to more uniform compression around the tube of Schaffer
22 and thereby eliminate some of the gaps that are -- were discussed a couple
23 slides back? Isn't that part of what Petitioner's argument is?
24 MR. HAMILTON: If the non-compliant -- or the highly-compliant
25 seal member is removed or its not included.
26 JUDGE JESCHKE: Okay.

1 MR. HAMILTON: So if someone skilled in the art decides, I'm
2 looking at Schaffer, and Schaffer says, here's how we seal, and it has all
3 these fantastic advantages, why would that person say, okay, I'm going to go
4 out and look for another way to seal, that I have to change all these different
5 things about Schaffer and actually make a device --
6 JUDGE JESCHKE: Is this --
7 MR. HAMILTON: -- that doesn't seal in some of these situations.
8 JUDGE JESCHKE: I'm sorry. I didn't mean to interrupt you
9 there.
10 MR. HAMILTON: No, please.
11 JUDGE JESCHKE: Is that element 165?
12 MR. HAMILTON: Element 165, yes.
13 JUDGE JESCHKE: Okay. So, I think Petitioner's position is that
14 that element is not actually required in Schaffer. So, I think -- is that the
15 potential disconnect here?
16 MR. HAMILTON: Okay. So, two things. One, Schaffer discloses
17 no other way to seal its device using the compression members, using some
18 rigid member on the outside. What Schaffer discloses in every embodiment
19 is that member compresses this internal seal member, highly-compliant seal
20 member 165.
21 Second, Petitioner says, well, seal member 165 doesn't have to be
22 highly compliant. It can be any material. It can -- it doesn't have to meet
23 this requirement.
24 But in fact, let's -- let me get to it. The first is -- bear with me for
25 just a minute.
26 So, I'm going to put up -- this was Petitioner's slide on that point.

1 There are many other materials that could be used for the seal module 165.
2 And if you look at this slide, there are many materials disclosed. And right
3 after that highlighting on Petitioner's side, the patent explains, the low
4 friction nature of the first and second seal members is in contrast to the
5 highly deformable and compliant nature of the third central seal member.
6 So, the fact that different materials can be provided does not mean
7 that that third seal member is not highly compliant -- highly deformable and
8 compliant. That's how Schaffer operates.
9 JUDGE FREDMAN: Right. I mean, the thing is that there's two
10 different versions here. In paragraph 59 of Schaffer, we have the highly-
11 compliant deformable material that's non-compressible. And then they do
12 have an embodiment that's this self-sticking one. They're not all the self-
13 sticking ones. It doesn't seem to be limiting.
14 MR. HAMILTON: That's right. They don't all have to be self-
15 sticking, but they all have to be highly deformable and compliant. That's
16 fundamentally how Schaffer operates. And that's what this paragraph
17 shows. Petitioner said there's more materials, so therefore, it doesn't have to
18 be highly deformable.
19 Please.
20 JUDGE FREDMAN: Go ahead.
21 MR. HAMILTON: There is, in Schaffer, when Schaffer says, this
22 is how our device seals, it's described as an embodiment that has 165 that
23 has this highly-deformable, compliant material that is deformed to fill in
24 gaps. There is no other disclosure on how Schaffer seals. Sure, it's called an
25 embodiment, but there is no other disclosure.
26 So, what Petitioner is saying is a person of skill in the art would

1 look at Schaffer and say, okay, let's remove that. The only material
2 disclosed is interacting with the external rigid members.
3 Okay, if we do that, now we have to change the rigid members to a
4 string, and then we lose all the advantages of Schaffer. We lose all this
5 balance that Schaffer says is provided by this.
6 And I understand Your Honor disagrees with me on the principle
7 of operation, but this principle of operation of compressing an internal
8 compliant seal member with a rigid actuating member.
9 JUDGE JESCHKE: Can you explain one more time, Counsel,
10 how -- so, I'm back on your Slide 36 looking at the Schaffer Figure 32 and
11 Hartley's string combination.
12 MR. HAMILTON: Yes.
13 JUDGE JESCHKE: Can you explain to me one more time why in
14 that proposed modification the presence of element 165 would be a technical
15 issue?
16 MR. HAMILTON: Okay. So first I'll reiterate, one, Petitioner has
17 provided no evidence that it would seal the same, better, or worse. They
18 -- this is not Petitioner's proposed combination. It's Petitioner's burden here.
19 But here's why this figure and this testimony from Petitioner's
20 expert confirms that if you include the seal member, it won't seal as the
21 -- this internal highly-compliant seal member, it won't seal as well as
22 Schaffer's rigid U-shaped actuating members. One, it's easier to compress
23 that internal compliant seal member with a rigid member. Someone skilled
24 in the art would understand that.
25 JUDGE JESCHKE: Okay. It's -- maybe it's easier, but does that
26 say that Hartley's string would not be sufficient, I guess, is why I'm trying to

1 understand why it would not be sufficient to seal. You understand the
2 distinction that I'm trying --
3 MR. HAMILTON: I do. So, one, highly-compliant member, it's
4 more likely to fill in gaps if you have a rigid member compressing it.
5 Second issue is how much of that material are you compressing? If there are
6 gaps, the more material you compress, the more likely you are to fill in those
7 gaps and empty -- excuse me, a -- something that has, like an irregularly
8 shaped instrument or the multiple instrument case. If there is a more -- if
9 there, more of that material is deformed and compressed, it's more likely to
10 fill in those gaps as opposed to a string, which only compresses in that single
11 line, a string or a wire, in Petitioner's proposed combination, around the
12 outer member. And what that would do is push the material to the outside,
13 not push it in to fill in gaps.
14 JUDGE JESCHKE: Okay.
15 MR. HAMILTON: So, one, there's no evidence that it would work
16 equally as well or better. And two, there is enough evidence to conclude
17 that it would not. I see I've gone, I think, a little over time.
18 JUDGE FREDMAN: No, you have nineteen minutes left. You
19 can go into your other time if you want.
20 MR. HAMILTON: Yeah. Please, if I may.
21 JUDGE FREDMAN: I'll let you know when you have like ten
22 minutes left, if you want to leave yourself at least ten minutes.
23 MR. HAMILTON: So, here's Petitioner's motivation or reason to
24 change the references. Someone looking at Schaffer would look at this
25 device that has an, let's call it an embodiment, whatever it is, that -- and the
26 only embodiment on how Schaffer meets all these requirements and

1 provides all these advantages, sealing around multiple instruments, sealing
2 around different shaped instruments, et cetera, and that mode of operation is
3 to compress this internally compliant member.
4 Someone skilled in the art -- what Petitioner says is, someone
5 skilled in the art would look at that and say, well, actually, even if it's one
6 embodiment, I don't have to use that embodiment. I'm going to do
7 something else. I'm going to get rid of all these advantages and all these
8 situations that Schaffer has, and I'm going to change those rigid members to
9 something flexible.
10 If the seal member is not included, it doesn't seal in several of the
11 situations that Schaffer is intended to seal, and that's the advantage of the
12 device. So, now you've got a lesser device. Maybe it seals in the easiest
13 situation to seal, but it doesn't seal in -- the advantage of Schaffer of sealing
14 in all these situations, a device that does this.
15 So, if someone skilled in the art is going to look at that -- look at
16 Schaffer, say, let's get rid of the only way Schaffer says we seal. Let's come
17 up with a new way that doesn't seal in some portion of the ways, the possible
18 uses of the device. Let's ignore all the balance that Schaffer has come to
19 with respect to how much compression is applied versus the internal seal
20 member and I'll come back to where that's disclosed in Schaffer in just a
21 minute. Let's get rid of that balance, this balance of all these things that
22 Schaffer has to make a device that maybe seals as well, at best, let's say, and
23 would have to change the only way of manufacturing the actuating members
24 disclosed in Schaffer and change the only way of assembling the device,
25 changed to Schaffer.
26 Putting all that together, why would one skilled in the art look at

1 Schaffer and a string and decide, okay, let me create all these problems and
2 come up with a whole new way to make this device, as opposed to just doing
3 exactly what Schaffer says, include the highly-compliant seal member with a
4 rigid U-shaped actuating member to compress that member?
5 So even if it's --
6 JUDGE MAJORS: Mr. Hamilton?
7 MR. HAMILTON: -- the same, there are still many disadvantages
8 of doing that. Even if sealing is the same, there are many disadvantages of
9 making that change that would discourage a person of skill in the art from
10 doing it.
11 JUDGE MAJORS: Mr. Hamilton, can I interrupt you for a
12 second?
13 MR. HAMILTON: Sure.
14 JUDGE MAJORS: One thing I'm struggling with is, where do we
15 see in Schaffer language that we can hang our hat on to say that the use of
16 the third seal member material is critical, in some fashion, to elevate that to
17 the device as a principle of operation?
18 We've looked at some language that suggests it's being used in an
19 option or being used for illustrative purposes or even used in every
20 embodiment. But I'm just trying to see where is there an indication where
21 we say, okay. This is, in fact, the device's principle of operation.
22 That may manifest in several ways. For example, we see this in
23 patents oftentimes where they say, here's some piece of prior art. Let's
24 imagine a world where they said, you know, this piece of prior art uses
25 flexible strings. We're going in a different direction. We're flipping the
26 script and using rigid actuating members and a super compliant central seal

1 member.
2 Now, that's an extreme example, I will grant you, but I'm just
3 trying to figure out, you know, it seems like we're picking little breadcrumbs
4 out of Schaffer and saying, okay. Altogether, this is the device's principle of
5 operation.
6 MR. HAMILTON: Let me --
7 JUDGE FREDMAN: If I could say one thing. I mean, you keep
8 arguing better. And, I mean, the case law is pretty clear that just because
9 better alternatives exist in the prior art doesn't mean that it an inferior
10 combination, and I'm quoting, is inept for obviousness purposes. That's in
11 re: Mouttet.
12 MR. HAMILTON: So, an inferior sealing? Is that what you
13 mean? An inferior difference?
14 JUDGE FREDMAN: Yeah. I mean that's what you're saying.
15 MR. HAMILTON: So, Schaffer has so many different advantages
16 from its method. The simple substitution is to -- if, for example, there is not
17 an embodiment or 165 is not critical in Schaffer, let's say, there are so many
18 advantages of including it. The simple substitution, the obvious thing to do,
19 is do exactly what Schaffer tells you to do, not go change the actuating
20 member so that you have to change all these other portions of Schaffer.
21 JUDGE FREDMAN: And address Judge Majors question, please.
22 MR. HAMILTON: And let me – oh, okay. Yes. So, why it's
23 critical? It doesn't have to be critical. The issue is it is the only way
24 Schaffer discloses its seals.
25 So, let's talk about Figures 30 through 34. This is the embodiment.
26 And Schaffer says that embodiment seals -- Petitioner's expert says that

1 embodiment seals works in all situations. The only situation it wouldn't
2 work is if you chose poor materials. A person of skill in the art would never
3 do that. They'd choose the right materials to make it work.
4 But on Slide 27 we have that statement about this embodiment, the
5 third central seal member includes material 166. So, earlier I showed you
6 the slide that says, the third seal member, no matter what material you make
7 is always going to be highly compliant.
8 And then there's this example of this third seal member that
9 includes this material 166, and what Petitioner has said is, a person of skill
10 in the art would never use that in Figures 30 through 34 because it wouldn't
11 work.
12 Well, in fact, that's the only material disclosed in Schaffer with
13 respect to Figures 30 through 34, specifically disclosed with respect to those
14 two figures.
15 And I just want to point out, so, in one embodiment, third central
16 seal member includes material 166, and then it goes on in the highlighted
17 portion to say what makes up that material. And then it sums up in -- just
18 after the highlighted portion, this provides a material 166 that is extremely
19 soft, compliant, intrinsically sticky.
20 Now, if you go to the embodiment Figures 30 through 34, and
21 that's shown on Slide 27 again. That's paragraph 81 of Schaffer. The only
22 material disclosed, expressly disclosed for that embodiment is the exact
23 same materials in the previous embodiment.
24 So, of course, it is an embodiment, but it's the only embodiment.
25 So, what Petitioner is saying is someone skilled in the art would look at
26 Schaffer and say, let's get rid of the only embodiment in Schaffer. Let's

1 redesign the actuating members. And now we lose all these advantages in
2 Schaffer, this complex balance of all these factors that make a valve useful
3 for a physician, get rid of all the situations in which it seals.
4 And what I submit is a person of ordinary skill in the art wouldn't
5 do that based on thinking these things are interchangeable because they're
6 not interchangeable. I see --
7 JUDGE FREDMAN: You have 11 minutes.
8 MR. HAMILTON: Eleven minutes. So, I'll sit down unless there's
9 some questions right now and save the next ten.
10 JUDGE FREDMAN: Okay.
11 MR. STOWELL: All right. Well, thank you, Your Honors, we're
12 getting the slides set up here.
13 But I do just want to clarify Petitioner's position in this IPR
14 because I don't think it's fairly representative. I think we heard multiple
15 times that we're trying to remove the seal member from Schaffer's device,
16 and that's just not accurate. Schaffer, in paragraph 75, describes Figures 30
17 through 34 as including a seal module 100. We are not proposing that the
18 seal module needs to be removed.
19 It goes on to explain that it may have one or more seal members,
20 and it may be formed of one or more materials. So, our position is the seal
21 module is there. It could be made of a variety of different materials. It is
22 not limited to third seal member 165. It is not limited to a sticky or
23 gelatinous material. It includes the whole range of materials that are
24 described in Schaffer.
25 Here we are. And if we go to slide -- maybe we just go to Slide
26 21. Even the third seal member is described as having a bunch of different

1 potential materials. If you look on the left hand side here, it says, in another
2 embodiment, one or more, of the first, second, and third seal members
3 include self-lubricating, the coated materials, specialty silicones, natural
4 latex. All of these would have varying levels of compressibility and
5 deformability. There isn't this one, kind of, magic, gelatinous, or whatever
6 you want to call it, material that's required by Schaffer to make Schaffer
7 work. Any of these various seal members would work with Schaffer's valve.
8 JUDGE FREDMAN: So, how do you address, I mean, their
9 quotation of Thornton's testimony that harder material would be able to
10 deform a softer material more readily because that's, I think, what they're
11 kind of hanging their hat on, quite a bit.
12 MR. STOWELL: I would agree. And I guess I struggle to see
13 how that proves Patent Owner's point. I think we agree that a harder
14 material would deform a softer material more readily, but that doesn't mean
15 that the highly compliant third seal member is required in Figures 30 to 34
16 as Patent Owner argues. It also doesn't mean that the U-shaped actuating
17 members necessarily need to be rigid. If they were made of a metal or
18 plastic, they may be harder than the silicone or the elastomeric compounds
19 that make up the compressible tube. So, that particular quotation doesn't
20 really prove any particular element.
21 JUDGE FREDMAN: What are the materials in like Eller and
22 Hartley, I mean are those string materials? What are they made of?
23 MR. STOWELL: The string materials? Yeah. So, in Hartley, it's
24 described as being a string, a suture, a band. In Eller, it's described as being
25 a wire member. And there are a number of other descriptions in Eller's. So,
26 it's --

1 JUDGE FREDMAN: The wire --
2 MR. STOWELL: -- a relatively --
3 JUDGE FREDMAN: Is the wire a good metal choice?
4 MR. STOWELL: Metal is one choice, yeah.
5 Here we go. Thank you, Brian.
6 On Slide 12 of Petitioner's slides, you can see that the wire, it can
7 be formed of compliant materials, flexible materials, nylon, polyethylene,
8 polystyrene, steel, nickel, titanium, so a whole range of materials.
9 JUDGE FREDMAN: Okay. Yeah. Thank you.
10 MR. STOWELL: Thank you. What I thought was curious was I
11 did not hear Patent Owner dispute, and I think Judge Jeschke, you framed it
12 correctly, that a string would create more uniform compression around an
13 instrument that's inserted.
14 I didn't hear Mr. Hamilton dispute that. He certainly didn't point to
15 any evidence in the record that suggests that the string would not create
16 more uniform compression around an inserted device. And that's precisely
17 Mr. Thornton's testimony, is that you would have this conformability of the
18 string that you wouldn't have with the U-shaped actuating members. And
19 that is one of the motivations to combine that Patent Owner has identified.
20 What I also thought was interesting about the Patent Owner's
21 presentation is when we got to your question about the simple substitution,
22 why isn't this a simple substitution? And I looked at their slides. There are
23 seven slides beginning at page 30, and there's no evidence cited here where
24 any party has said that the substitution wouldn't be simple. Their own expert
25 doesn't provide any explanation for why that wouldn't be a simple
26 substitution, simply taking a string and adding it between the buttons of

1 Schaffer. There's no evidence cited in these slides that would support that.
2 I also just briefly like to touch on the definition of a POSITA.
3 Judge Major [sic], I appreciate your question about maybe some of
4 the other IPRs.
5 But again, I didn't really hear a dispute here that these claims recite
6 a very simple mechanical device. Right? This is not a claim to a hemostasis
7 valve in Claim 1. It's a claim to a valve. That valve has components that
8 would be well known to any mechanical engineering student, springs,
9 buttons, sutures.
10 And so, I've yet to see any evidence provided by Patent Owner that
11 the person of ordinary skill in the art would need some sort of heightened
12 education beyond merely a mechanical engineering degree and some
13 experiences.
14 JUDGE FREDMAN: My question on that is just if there were a
15 -- if you did have a person of ordinary skill, who was of heightened skill,
16 wouldn't this be easier for them?
17 MR. STOWELL: Well, and Judge Fredman, that's exactly one of
18 the arguments we raised in opposing the motion to exclude Mr. Thornton's
19 testimony based on the definition of a POSITA. That's exactly right. A
20 person with even more skill would recognize the obviousness of the
21 substitution even more. So, I agree with you.
22 The other thing I would just point out is that if we look at Slide 9
23 on the POSITA issue of Patent Owner' demonstratives, there -- they have
24 quoted a part of Mr. Thornton's testimony where he basically says, yeah,
25 when we decide -- when we design hemostasis valves, we need to
26 understand what the problems are that are being treated. Well, that's true of

1 any engineering problem. There's yet to be anybody to say, and in order to
2 understand that problem, you would have to understand something about a
3 medical device. Right? And I don't know what it is because Patent Owner
4 hasn't provided that information.
5 But of course, a person with a mechanical engineering degree
6 could be -- have the problem explained to them and they could understand it
7 based on their engineering perspective. You need X amount of force, you
8 need the, you know, you want to be able to push the buttons this hard.
9 That's all basic mechanical engineering stuff. There's simply nothing in the
10 claims that's been identified that would require some heightened level of
11 experience with medical devices or intravascular procedures. And so on that
12 point, I will rest. Thank you for your time.
13 JUDGE FREDMAN: Thank you.
14 MR. HAMILTON: May I begin?
15 Your Honors, first, I want to address the point that someone of
16 higher skill -- it would be easier for someone of higher skill. The tests for
17 obviousness is not how easy is the substitution? The test is, there has to be a
18 motivation to make the substitution and whether one is capable of doing it, a
19 higher --
20 JUDGE FREDMAN: KSR, I mean, motivation is not required.
21 Reason is required.
22 MR. HAMILTON: There has to be a reason. Yes, yes, a reason.
23 JUDGE FREDMAN: Let's not use -- I dislike the word
24 motivation.
25 MR. HAMILTON: Okay. Thank you, Your Honor.
26 But it doesn't matter how easy it would be. There has to be a

1 reason to make the change. What a -- the -- that level of skill that Petitioner
2 argues that would make it easier to make the change is irrelevant to why one
3 would make the change. And, in fact, actually understanding why you're
4 designing the device and what it's for and what it's going to be used for
5 demonstrates that there is no motivation to make the change. That's why
6 that matters on that level, someone understanding why Schaffer does what it
7 does, all these advantages of Schaffer, wouldn't look at Schaffer and say,
8 okay. Let's remove all those advantages and do it differently.
9 And the simple substitution and the RJR case and the Altra case
10 cited in Petitioner's surreply go right to this point. The simple substitution,
11 if there are other ways to do something that are actually the simple
12 substitution, actually the substitution one skilled in the art would make, that
13 it is simple to make some other substitution doesn't mean that -- or that's not
14 enough for obviousness for a simple substitution. And in fact, someone
15 skilled in the art looking at Schaffer would say, this is how Schaffer work.
16 JUDGE FREDMAN: So, if I have a car brake, and as a mechanic,
17 I want to make it electrical, that's not obvious because of the simple
18 substitution?
19 That's KSR.
20 MR. HAMILTON: So, what KSR says is, a simple substitution
21 into a device that's ready for improvement is --
22 JUDGE FREDMAN: Every device is ready for improvement.
23 That a case called --
24 MR. HAMILTON: That's right. So, now --
25 JUDGE FREDMAN: -- that says that.
26 MR. HAMILTON: Sorry. I didn't mean to interrupt.

1 JUDGE FREDMAN: Go ahead.
2 MR. HAMILTON: So now, how is Schaffer ready for an
3 improvement? The only way Petitioner argues that Schaffer is ready for
4 improvement is sealing. That's the only way Petitioner argues Schaffer is
5 ready for improvement.
6 Petitioner argues that someone skilled in the art would look at
7 Schaffer and decide to eliminate what's in Schaffer that forms the seal, one
8 embodiment or not, have all the -- introduce all these disadvantages and
9 different use cases that Schaffer solves for this simple substitution.
10 In the case of the electrical, I don't know if you say carburetor or
11 whatever, the substitution would be, it would have to work in the same way,
12 have the same advantages, do the same things. It's a substitution of one
13 thing for another that is equivalent.
14 JUDGE FREDMAN: And so if I took the titanium wire from the
15 other reference and used it, why would that rigid, and fairly flexible, but it's
16 a fairly hard material, titanium. Why wouldn't that seal it as well as the U-
17 shaped members in Schaffer?
18 MR. HAMILTON: Because the filament -- because it's flexible.
19 So, a filament made of titanium is not hard like Schaffer's rigid U-shaped
20 members.
21 JUDGE FREDMAN: If it's pulled tight, it's pretty hard. It is
22 titanium, so the material has, you know, the durometer measurement would
23 be pretty high.
24 MR. HAMILTON: So, you could conceivably pull that tight
25 enough that it would seal anything. That's right. And then you would lose
26 that balance that Schaffer says is critical in designing a --

1 JUDGE FREDMAN: What balance are you losing?
2 MR. HAMILTON: -- hemostasis --
3 JUDGE FREDMAN: What do you lose if you do that?
4 MR. HAMILTON: The balance of --
5 JUDGE FREDMAN: If you pull it tight enough to tighten it.
6 MR. HAMILTON: The balance of compression force versus the
7 ability -- so, what Petitioner's expert said -- I asked him about that passage.
8 What do all these things mean? That means a doctor needs feedback, for
9 example, on the device that's inside the hemostasis valve. If you tighten the
10 -- tighten it until there's no feedback, that is an inferior valve, that will not
11 provide that feedback.
12 JUDGE FREDMAN: Does the claim require feedback? Is that
13 anywhere? Anywhere in the --
14 MR. HAMILTON: Does --
15 JUDGE FREDMAN: Is that anywhere in the record? In like, the
16 references? Do they ever say that?
17 MR. HAMILTON: The experts say that, yes. Both experts say
18 that. Not that the claim requires it, but that's a consideration in designing a
19 valve. So, why is one changing shape --
20 JUDGE FREDMAN: But the feedback as you move the device
21 through the valve, essentially? Is that what you're saying?
22 MR. HAMILTON: Well, I -- actually there's two. Two maybe, as
23 you move it through, as you push it through. But also once you get it in
24 there, you have to manipulate tools to do whatever they're going to do.
25 That's the -- that's what -- that's really where feedback is critical.
26 JUDGE FREDMAN: Well, when you're manipulating tools it's

1 usually a catheter and they're going through the catheter through the tube;
2 right? So, then once you're sealed around the catheter, the tools aren't being
3 sealed around the catheter. There's a metal tube inside; right?
4 MR. HAMILTON: That would be one possible --
5 JUDGE FREDMAN: -- ordinary way that physicians do this?
6 MR. HAMILTON: That's not what Schaffer says, and that's not
7 what the expert said. The expert said, you insert a tool, you need feedback
8 on the tool. You don't want to --
9 JUDGE FREDMAN: That's if the tool is not in catheter. But,
10 you're talking about multiple tools going through when they go through a
11 catheter. All right. Whatever. Keep going.
12 MR. HAMILTON: So, I think what I'm hearing is the only
13 situation in one -- in which one needs to form a seal is a tubular catheter that
14 other devices are put through and all these other things that Schaffer says it
15 is designed to do aren't actually used. There is nowhere in the record that
16 that is --
17 JUDGE FREDMAN: Sure, yeah.
18 MR. HAMILTON: -- the case.
19 So, again, and if you're thinking of substitution, a string for U-
20 shaped members, one skilled in the art would simply substitute strings, one
21 string for each of Schaffer's U-shaped members that retains Schaffer's -- the
22 ability to control each string independently, as opposed to having this
23 imbalance between two ends of a string. That would be the simple
24 substitution.
25 And Petitioner argued, for the first time on reply, one wouldn't do
26 that because of this example of the two strings that are spaced from each

1 other for a U. Now, what I'll submit is in the petition and in the first expert
2 report that's exactly what both of them said. One skilled in the art would
3 replace the string -- each U-shaped member with a string or a wire.
4 And now on reply, because there's no motivation to not do that and
5 instead do this configuration that's not shown in any of the references, two
6 actuators in a single string or wire, Petitioner contradicts itself and
7 Petitioner's expert contradicts what they said before to say that there would
8 be some motivation to come up with the claimed or -- excuse me, the
9 proposed combination, Petitioner's proposed combination. There simply is
10 not a motivation, first, to combine the references to begin with, and second,
11 to combine them in the way Petitioner proposes one would combine the
12 references.
13 I want to refer to Petitioner's expert's first deposition, first
14 declaration. This is what he said about Schaffer. And this is in Exhibit
15 2007, page 38, line 7 through page 39, line 1. And this is with respect to that
16 figure on why there is some kind of issue in Schaffer.
17 So, does this figure show what you believe happens in the
18 hemostasis valve in Schaffer? His answer, not necessarily. I think Schaffer
19 would seal very well most of the time. It's possible if it didn't seal well, that
20 gaps could form, as shown in the image on page 56. And that's there -- that's
21 the image in the first petition that shows these gaps that would not be there if
22 the seal member was there.
23 The next question, why would Schaffer seal very well most of the
24 time?
25 Because it's designed to seal as a hemostasis valve.
26 And it would accomplish that goal; right?

1 The -- and answer, the patent states that it does seal when tools are
2 inserted with no tools and with -- or with no tools inside. That's shown in
3 the patent.
4 Oh, excuse me. No tools inside. And then next question, and do
5 you have any reason to doubt that statement in Schaffer?
6 I do believe it seals well, given the design that's shown in the
7 patent.
8 What Petitioner's expert said is, here we have this design in
9 Schaffer. Now, if I want to change it and make it so it doesn't work like
10 Schaffer says -- which Petitioner expert says it works well, the design in
11 Schaffer as well. If I want to change it to make it not work well, now one
12 skilled in the art would go and redesign all the aspects of Schaffer and lose
13 all the benefits of Schaffer, including sealing in all these different situations,
14 the -- all of this balance of factors of manipulating tools, etc.
15 One skilled in the art simply would not diminish Schaffer without
16 any reason to do so just because one thing could be substituted into the
17 other. Something more is required than that.
18 This issue about durability -- so, you -- Your Honors had discussed
19 it I think in the initial presentation by Petitioner. These devices are used
20 over a couple hours, maybe one time use. There's no evidence of any of that
21 in the record.
22 With respect to a valve in treating a patient that the valve does not
23 break is critical over those three hours, even if it's one time, even if it's a
24 certain procedure. That durability is much more critical for a hemostasis
25 valve. That's another thing that a physician, a person of ordinary skill in the
26 art, under Petitioner's definition, would not understand and would not

1 understand the importance of that durability.
2 JUDGE FREDMAN: If they didn't want to worry about durability,
3 they could use titanium; right?
4 MR. HAMILTON: Well, I guess, there's -- maybe there's two
5 aspects to durability, that the valve does what it's supposed to do. So, if you
6 put a string in the valve with two independent actuators, you put -- you push
7 on it and loosen it, those -- that string can move within the valve. So, it's not
8 -- it may not do the exact same thing every time. And Petitioner's expert
9 testified to that. String -- you don't know where it is. Depends on the
10 orientation of the valve. Things move around.
11 JUDGE FREDMAN: I think your time is up. But thank you.
12 MR. HAMILTON: Okay. Thank you.
13 JUDGE MAJORS: Mr. Hamilton, before you go, can I ask you
14 just a quick question on the motion to exclude.
15 MR. HAMILTON: Yeah. Sure.
16 JUDGE MAJORS: The Exhibit 1008, which are the Schaffer
17 prosecution drawings, I understand the point, I suppose. When we're talking
18 about a 102 anticipation and that those are not technically part of one
19 cohesive document. But when we get to 103, what's the reason why you
20 should exclude or why we would exclude Exhibit 1008 when we're
21 considering the obviousness challenges here?
22 MR. HAMILTON: Thank you, Your Honor.
23 So, whether it's anticipation or obviousness, a reference discloses
24 what it discloses, and extrinsic evidence can be used and I've explained, you
25 know, what extrinsic evidence is in this context, it's not when you interpret a
26 claim, but extrinsic evidence can be used to understand what's taught in a

1 reference. It cannot be used to supplement what's in a reference, whether it's
2 102 or 103.
3 Petitioner's ground in this IPR relies on Schaffer, not Schaffer plus
4 everything else that happened with Shaffer's prosecution, after the fact.
5 JUDGE MAJORS: What's your legal authority for the proposition
6 that you can't use a secondary reference to better understand a primary
7 reference for 103 purposes?
8 MR. HAMILTON: No. You absolutely can use a secondary
9 reference to better understand it. You cannot use it to supplement what is
10 not there. And what Petitioner's --
11 JUDGE MAJORS: Okay.
12 MR. HAMILTON: -- expert said is Schaffer figures -- this key
13 embodiment, 30 through 34, he can't see what's shown in that embodiment.
14 He had to go to 108 to understand what Schaffer actually discloses, not
15 understand additional aspects or somehow interpret some portion of
16 Schaffer. It's -- he's supplementing Schaffer as opposed to just using some
17 other evidence like the knowledge of one skilled in the art to understand
18 what Shaffer's disclosing. That's the issue.
19 And --
20 JUDGE MAJORS: Okay.
21 MR. HAMILTON: And that's in -- oh, I don't have the case in
22 front of me, but it's cited in that motion that that's exactly what happened in
23 the case. There was a -- the key issue was, what was the ground? This other
24 thing that was used to supplement that ground, that reference, could not be
25 used because it was not part of the ground, even though the devices were the
26 same. The patent that was the ground -- the device essentially was the

1 device that was shown in the patent or an article, something like that.
2 JUDGE FREDMAN: Here I think the patent office printed it with
3 the wrong figures, or at least the less readable figures; right? Isn't that
4 essentially what happened? It's not a different reference really. It's just we
5 -- when we published it chose figures -- we either chose or were -- I mean,
6 there are two sets of figures. We just picked the wrong one, the invisible
7 one and Schaffer, for whatever reason, didn't request that to be repaired. I
8 guess they could have.
9 MR. HAMILTON: They could have. Yep. They --
10 JUDGE FREDMAN: But --
11 MR. HAMILTON: They could have, but they didn't at the ground
12 --
13 JUDGE FREDMAN: It's still --
14 MR. HAMILTON: -- issue --
15 JUDGE FREDMAN: But it's still part of the actual filing of the
16 case; right? It's actually part of that record?
17 MR. HAMILTON: It is part of the record of the Schaffer
18 application, yes.
19 JUDGE FREDMAN: Okay.
20 JUDGE MAJORS: Doesn't your own expert, Dr. Zalesky, doesn't
21 -- I'm fairly certain the answer is yes, but I believe he uses, actually several
22 times, the figures from the supplemental and then the Exhibit 1008 in his
23 own discussion and understanding of the Schaffer. So, I'm just struggling
24 with this notion of, you know, that you can't use clearer drawings from the
25 prosecution file. And I don't think there's any dispute that it is the
26 prosecution file for Schaffer to better understand what are and for, you

1 know, not very clear drawings.
2 MR. HAMILTON: So, Patent Owner's expert does rely on it to
3 rebut what Petitioner says. But if that -- if -- excuse me, if Petitioner can't
4 rely -- Petitioner's expert can't rely on it in the first place, all that evidence
5 should be excluded. That's the issue. And now, if it's not excluded, we had
6 to put in an understanding based on what Petitioner's expert used, as well.
7 That is why. But that doesn't mean that one skilled in the art would rely on
8 these figures to supplement the disclosure of Schaffer, not just understand
9 what Schaffer means.
10 JUDGE MAJORS: Okay. Thank you, sir.
11 MR. HAMILTON: Thank you.
12 JUDGE FREDMAN: Any further questions?
13 So, I think we're off the record. And --
14 MR. HAMILTON: Okay.
15 JUDGE FREDMAN: -- thank you, guys.
16 JUDGE MAJORS: Thank every -- I'll close everything out here,
17 Judge Fredman. Thank you, everyone, for attending today. We appreciate
18 it. Counsel, if you could stick behind for just a few minutes to help our
19 court reporter, should she have any questions, that would be much
20 appreciated.
21 And with that, the matter is submitted to the panel for preparation
22 and the final written decision. And with that, we're adjourned. Thank you.
23 (Whereupon, the above-entitled matter went off the record at 11:14
24 a.m.)

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