

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case IPR2025-01562
Patent No. 12,109,384

**SUPPLEMENTAL DECLARATION OF TROY L. THORNTON
IN SUPPORT OF PETITIONER'S REPLY
FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 12,109,384**

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I, Troy L. Thornton, do hereby declare:

I. INTRODUCTION

1. I have been retained on behalf of Imperative Care, Inc. (“Imperative Care”) to provide my opinions regarding the patentability of Claims 1-4, 6-18, and 20-30 of U.S. Patent No. 12,109,384 (“the ’384 patent”). For the reasons discussed herein and in my prior Declaration, I have concluded that Claims 1-4, 6-18, and 20-30 of the ’384 patent are unpatentable because the prior art references anticipate the claims or render them obvious.

2. I understand that this Supplemental Declaration supports Imperative’s Reply for the above-captioned *inter partes* review (“IPR”) of the ’384 patent.

3. I reserve the right to supplement, change, clarify, or modify my opinions should additional information and/or documentation become available to me.

4. I am being compensated at my customary hourly rate for my work in this matter and I am being reimbursed at cost for my expenses. My compensation in no way depends upon the substance of my opinions or the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding.

**II. A PERSON OF ORDINARY SKILL IN THE ART WOULD HAVE
BEEN MOTIVATED TO SUBSTITUTE SCHAFFER'S U-SHAPED
ACTUATING MEMBERS FOR TWO LOOPED STRINGS/WIRES**

5. The claims of the '384 patent each require that the hemostasis valve includes "a first filament extending in a first loop around the tubular member, wherein the first filament is flexible; a second filament extending in a second loop around the tubular member, wherein the second filament is flexible." As I explained in my prior Declaration, a person of ordinary skill in the art would have been motivated replace Schaffer's two U-shaped metal/plastic actuators with two of Hartley's strings or Eller's wires that are each looped around Schaffer's tubular member for several reasons: (1) this combination would entail a simple substitution of known elements – Schaffer's two actuating members for two strings/wires – that would produce the predictable result of sealing Schaffer's seal module; (2) Eller discloses using two wires to seal a hemostasis valve and expressly recognizes that persons of ordinary skill in the art were able to "select a suitable number of wire members to include in a selective" hemostasis valve; (3) a person of ordinary skill in the art would have recognized that using two strings/wires would provide a more robust and reliable seal than a single string/wire; and (4) Hartley discloses that its string is preferably wrapped twice around its tubular member and a person of ordinary skill in the art would have

recognized that using two strings/wires would provide advantages over a single string/wire wrapped twice. Ex. 1003 (Thornton Decl.) at ¶¶78-84, 102-106.

6. I understand that Patent Owner and Dr. Zalesky argue that a person of ordinary skill in the art would not have been motivated to replace Schaffer's U-shaped actuating members with two of Hartley's strings or Eller's wires looped around Schaffer's seal module. I disagree with Patent Owner and Dr. Zalesky for the reasons I explained in my prior Declaration and the additional reasons I explain below.

A. Eller Would Have Motivated A Person Of Ordinary Skill In The Art To Replace Schaffer's Actuating Members With Two Looped Wires/Strings

7. Eller discloses a hemostasis valve that uses first and second wire members (i.e., filaments) to constrict and seal a flexible tubular member within the valve. Ex. 1007 (Eller) at 5:1-5, 16:7-19, Fig. 2. Eller expressly discloses the valve "can include any suitable number of wire members," including "one, at least one, two, a plurality, three, four, five, or any other number considered suitable for a particular embodiment." *Id.* at 16:7-19. Eller also states that "[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment." *Id.* I agree with Eller's statement regarding the level of skill a person of ordinary

skill in the art would possess. Such a person would possess the skill to select and optimize the number of wires used to constrict the lumen of a hemostasis valve. As I explained in my prior Declaration, Eller's suggestion to use two or more wire members would have motivated a person of ordinary skill to replace Schaffer's U-shaped actuating members with two of Eller's wires (i.e., filaments). Eller's recognition that multiple wires can effectively seal a tubular member within a valve would have given a person of ordinary skill in the art a reasonable expectation of success in making the substitution.

8. Dr. Zalesky does not appear to disagree that Eller would have motivated a person of ordinary skill in the art to use two wires in a hemostasis valve. *See* Ex. 2001 (Zalesky Decl.) at ¶¶92-104. Dr. Zalesky appears to only disagree with whether Eller would have motivated a person of ordinary skill in the art "to have substituted two of Eller's wire members for Schaffer's U-shaped actuating members **such that the wire members are '[configured/extending] in a first loop' and '[configured/extending] in a second loop'** as required by [the] Claims." *Id.* at ¶92 (emphasis added). According to Dr. Zalesky, a person of ordinary skill in the art would not have found it obvious to arrange Eller's two wires in loops around Schaffer's seal module because "Eller does not disclose any embodiment including more than one, single wire member forming a loop." *Id.*;

see also id. at ¶¶94-103. I disagree with Dr. Zalesky's opinions for several reasons.

9. First, looping a flexible filament completely around the tubular member of a hemostasis valve was a known and predictable configuration for constricting a hemostasis valve. Eller itself expressly discloses an embodiment in which the wire "extends at least one full revolution around the outer surface of the sleeve." Ex. 1007 (Eller) at 22:22-24. Hartley similarly discloses a flexible string that is looped entirely around the tubular member of a hemostasis valve. Ex. 1006 (Hartley) at [0031]. Thus, looping a filament around the tubular member of a hemostasis valve was known and the references illustrate that the looped wires behaved predictably.

10. Second, Dr. Zalesky focuses on Eller's preferred embodiment illustrating one wire member looped around the tubular member. *See* Ex. 1007 (Eller) at 21:37-22:24; *see also* Ex. 2001 (Zalesky Decl.) at ¶¶94-103. However, Dr. Zalesky fails to explain why a person of ordinary skill in the art would not have found it obvious to employ the same configuration with two wires. Dr. Zalesky certainly does not explain why the person would have been dissuaded from using two wires. And I do not see any reasons.

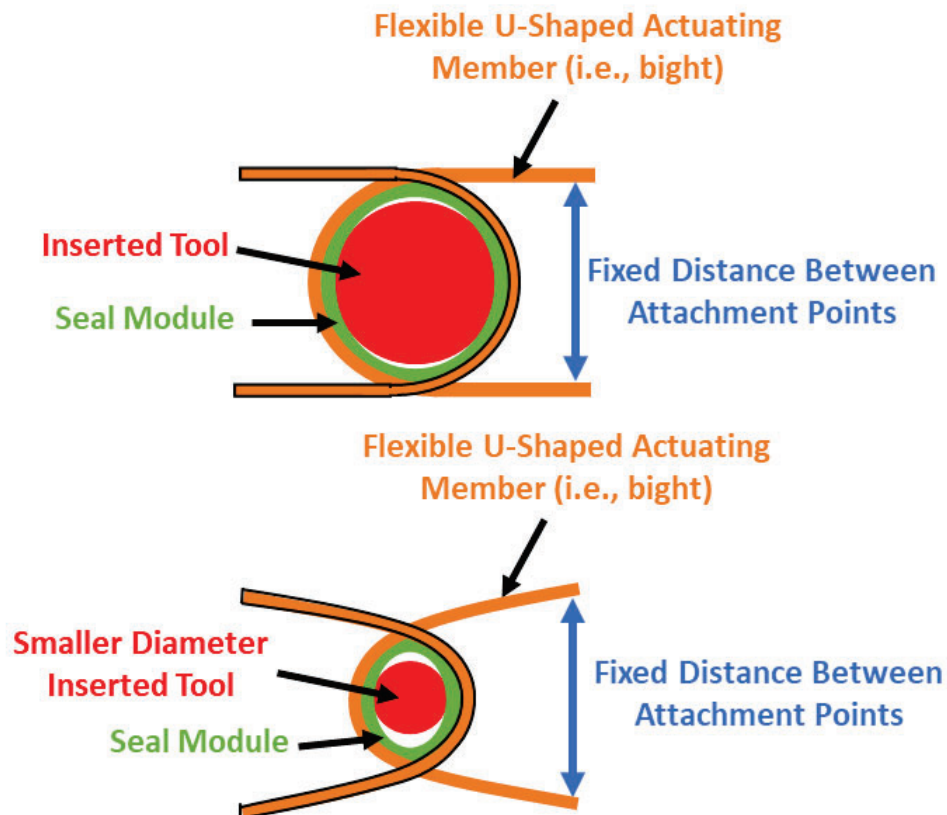
11. Third, a person of ordinary skill would have had only a couple options for arranging wires to constrict Schaffer's hemostasis valve. Schaffer

illustrates embodiments the use of two U-shaped actuating members to constrict the tube. Ex. 1005 (Schaffer) at [0077]. A person of ordinary skill in the art would have found it obvious to use different materials for the U-shaped actuating members, including Eller's wires or Hartley's strings. I have discussed this in other IPRs.

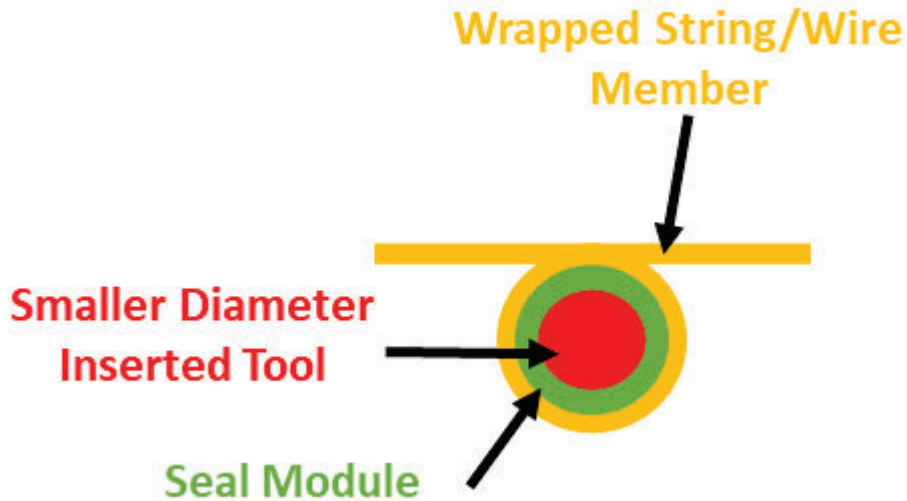
12. Hartley illustrates embodiments that use a string that forms a loop around the tube to constrict the tube. Ex. 1006 (Hartley) at [0031]. Similarly, Eller discloses using one or more wires that form a loop around a tube to constrict the tube. Ex. 1007 (Eller) at 22:11-24. Based on these disclosures, a person of ordinary skill in the art would have found it obvious to use one wire/string or two wires/strings, each forming a loop around the tube, to constrict the tube. *See* Ex. 1003 (Thornton Decl.) at ¶95. A person of ordinary skill in the art would have been motivated to try any of these finite and predictable configurations in Schaffer's valve based on the descriptions in the prior art and the additional reasons discussed herein.

13. Fourth, a person of ordinary skill in the art would have been motivated to loop the wires/strings around Schaffer's tubular member because they would have expected that a loop would create a better seal in some circumstances. Specifically, a person of ordinary skill would have understood that if the wires/strings are arranged in two U-shapes, the fixed attachment points to

the actuator buttons may prevent the U-shaped wires/strings from completely conforming to the exterior of a tool with a smaller diameter than the distance between the attachment points, as I've illustrated below:



See Ex. 1003 (Thornton Decl.) at ¶111. Wrapping the wires or strings completely around Schaffer's seal module, as both Eller and Hartley disclose, would enable the wires/strings to better conform to the varying diameter tools in those situations, as illustrated below:



Id.

14. Further, as I explained in my opening declaration (*see* Ex. 1003 (Thornton Decl.) at ¶¶78-84, 102-106) and discuss more below, a person of ordinary skill in the art would have had several specific reasons for preferring two loops of wire, including Hartley's disclosure that two loops around the tube are preferred. Accordingly, while a person of ordinary skill would have found it obvious to use any of the configurations (two U-shapes, one loop, or two loops), they would have been particularly motivated to use two loops in order to provide the best seal around a variety of tool shapes and sizes.

15. Accordingly, for these reasons and the reasons I explained in my prior Declaration, it is my opinion that Eller would have motivated a person of ordinary skill in the art to loop two of Eller's wires or Hartley's strings around

Schaffer's tubular member and would have provided a person of ordinary skill with a reasonable expectation of success in doing so.

B. Hartley Would Have Motivated A Person Of Ordinary Skill In The Art To Replace Schaffer's U-Shaped Actuating Members With Two Looped Wires/Strings

16. Hartley discloses a hemostasis valve that uses a string looped around a cylindrical diaphragm to constrict and seal the valve. Ex. 1006 (Hartley) at [0031]. Hartley discloses that its string is "is wound preferably twice around the cylindrical diaphragm." *Id.* As I explained in my prior Declaration, Hartley does not state why its string is preferably wound twice around its tubular member, but a person of ordinary skill in the art would have recognized that two loops of string would create a more robust and reliable seal by applying constricting force along a greater length of the tubular member. Ex. 1003 (Thornton Decl.) ¶79.

17. As I also explained in my prior Declaration, a person of ordinary skill would have recognized that another way to create two loops (or windings) around the tubular member would have been to use two strings, each forming a single loop, as opposed to a single string wrapped twice around the tubular member. *Id.* I also explained that there would be several advantages to using two strings wrapped once around the tubular member instead of a single string wrapped twice, including: (1) two strings would reduce the frictional resistance on the outside of

the tubular member; (2) two strings would enable a wider sealing area; and (3) two strings would provide redundancy to ensure a better seal. *Id.* at ¶¶80-82.

18. Patent Owner and Dr. Zalesky argue that Hartley's disclosure of wrapping its string preferably twice around the tubular member would not have motivated a person of ordinary skill in the art to replace Schaffer's U-shaped actuating members with two of Hartley's strings. Ex. 2001 (Zalesky Decl.) at ¶¶70-80. I disagree with Patent Owner and Dr. Zalesky for the reasons I explained in my prior Declaration and the additional reasons below.

1. Two Strings/Wires Would Reduce Friction On The Tubular Member

19. As I explained in my prior Declaration, wrapping a single string twice around the tubular member of a hemostasis valve will create more friction with the outer surface of the tubular member than wrapping two strings a single time around the tubular member. Ex. 1003 (Thornton Decl.) at ¶80. That increased friction would make it more difficult for the string to slide along the outer surface of the tubular member as the valve is opened and closed, requiring more pulling force from Schaffer's springs to close the valve and more resiliency from the tubular member to return to the expanded, open configuration. *Id.* Patent Owner and Dr. Zalesky argue that a single string wrapped twice around the tubular member would not create more friction than two strings each wrapped once because "the same total amount of string contacts the tubular member." Ex.

2001 (Zalesky Decl.) at ¶75. Patent Owner’s and Dr. Zalesky’s assumption that the frictional force is simply governed by the “total amount of string [that] contacts the tubular member” is incorrect. *See id.*

20. Patent Owner and Dr. Zalesky fail to understand that the force needed to overcome frictional resistance of a flexible string/wire against a cylindrical object increases exponentially with the wrap angle (θ) of the string/wire around the cylinder according to the equation below:

$$T_1 = T_2 e^{\mu\theta}$$

where:

T_1 = tension force on one end of the string

T_2 = tension force on the other end of the string

μ = coefficient of friction

θ = total wrap angle of the string in radians

e = base of the natural logarithm (2.718)

Ex. 1064 (Hibbeler) at 422; Ex. 1065 (Marks) at 3–31–3–32. This equation is commonly referred to as the Capstan Equation, and it appears in mechanical engineering textbooks used to teach undergraduate mechanical engineering students. *See id.*

21. For simplicity of illustration, assume that $T_2 = 1$ and $\mu = 0.5$. Under those assumptions, the force required to overcome the frictional resistance of a single string wrapped twice around the tubular member would be:

$$T_{\text{Twice Wrapped}} = e^{2\pi} = 535.5$$

Under those same assumptions, the force required to overcome the total frictional resistance of two strings each wrapped once around the tubular member would be:

$$T_{\text{String 1}} = e^{\pi}$$

$$T_{\text{String 2}} = e^{\pi}$$

$$T_{\text{Total}} = T_{\text{String 1}} + T_{\text{String 2}} = 2e^{\pi} = 46.3$$

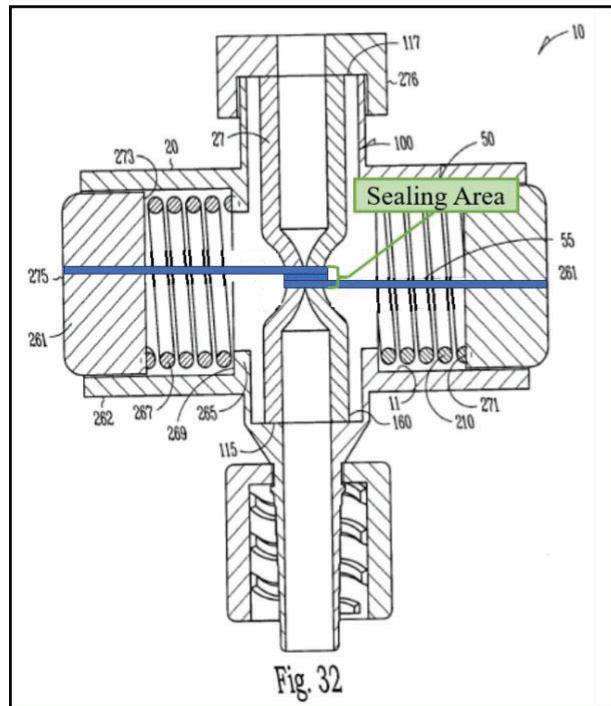
Thus, contrary to Patent Owner and Dr. Zalesky's argument, two individual strings/wires, each wrapped once around the tubular member would require significantly less force to overcome the friction on the tubular member compared to a single string wrapped twice.

22. Accordingly, two strings, each wrapped around once, would reduce the force needed to operate the valve compared to a single string wrapped twice, while still providing a larger sealing area than a single string wrapped once. These benefits would have motivated a person of ordinary skill in the art to use two strings instead of a single string wrapped twice.

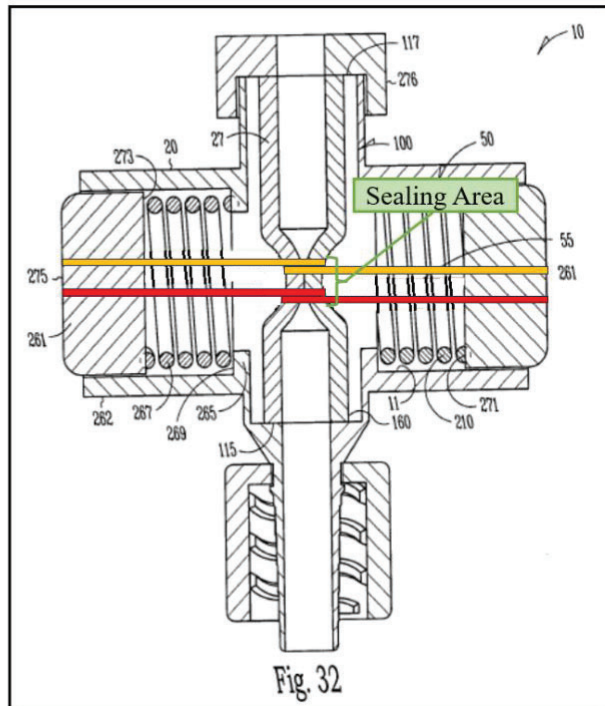
2. Two Strings/Wires Would Provide A Wider Sealing Area

23. As I also explained in my prior Declaration, wrapping two separate strings once around the tubular member would enable a person of ordinary skill in the art to provide a more robust and reliable seal by creating a wider area of constrictive force on tools inserted through Schaffer's hemostasis valve compared to a single string wrapped twice. Ex. 1003 (Thornton Decl.) ¶81. When a single string is wrapped twice around the tubular member, the two loops will end up directly next to one another because they are attached to the actuator buttons at directly opposing positions. *Id.*; *see also* Ex. 2009 (Thornton Dep.) at 49:25-50:14. In contrast, with two strings wrapped once around the tubular member, a person of ordinary skill in the art could design a small gap between the strings to ensure that the sealing area is wider. For example, as I've illustrated below, the person of skill could space the attachment points where the strings are connected to the buttons apart from each other, ensuring a small gap between strings:

Single String Wrapped Twice



Two Strings



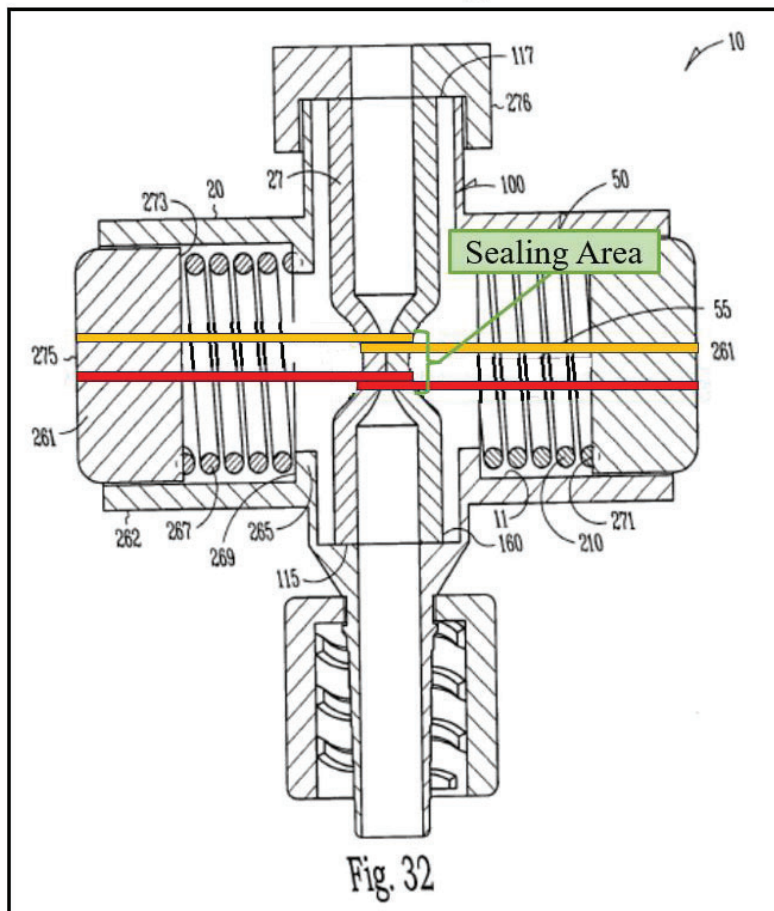
Ex. 1003 (Thornton Decl.) at ¶81. The wider sealing area created by this arrangement is beneficial because it applies constrictive sealing pressure along a larger area of any tools inserted through the valve.

24. Patent Owner and Dr. Zalesky argue that two strings would not provide a wider sealing area than a single string wrapped twice because they assume that the sealing area would be limited to the width of strings. Dr. Zalesky argues, “the sealing area is the same as the single string 14 of Hartley—Hartley’s single string seals where the two windings contact the tubular diaphragm and Petitioner’s purported two strings seal where the loops contact Schaffer’s seal module.” Ex. 2001 (Zalesky Decl.) at ¶77. Dr. Zalesky’s assumption is incorrect

and does not account for the flexible, deformable nature of Schaffer's seal module.

25. Schaffer discloses that its seal module is comprised of a "flexible, elongate tubular structure" that can be formed from "highly elastic, deformable, compliant and yet virtually non-compressible" materials. Ex. 1005 (Schaffer) at [0081]. A person of ordinary skill in the art would have therefore understood that because of the flexible nature of Schaffer's seal module, the small area of the seal module between the two strings would also compress inwardly when the strings are constricted around the seal module, helping to seal against a tool extending through the lumen as illustrated below:

Two Strings



Thus, the sealing area created by two spaced-apart loops in Schaffer's valve would not be limited to the width of the strings as Dr. Zalesky argues.

26. Patent Owner and Dr. Zalesky also argue that a “gap between the strings would create a stagnant blood pool from back bleed, that in turn can lead to thrombus (clot) formation.” Ex. 2001 (Zalesky Decl.) at ¶78. I disagree with Patent Owner and Dr. Zalesky for several reasons. First, as I explained in the preceding paragraph, a person of ordinary skill in the art would have understood that the small area of Schaffer's flexible, depressible seal module between the two

strings would be deformed and compressed inward on itself and/or the tool inserted through the valve when the strings are constricted. A person of ordinary skill would have understood that Schaffer's seal module would not be so incompressible as to remain in the uncompressed state over the short length of tubing between the strings. A person of ordinary skill would therefore not expect any significant amount of stagnant blood to pool in the space between the strings. In addition, Dr. Zalesky ignores that when a hemostasis valve is closed during an intravascular procedure "static" blood will necessarily exist within the catheter tubing on either side of the hemostasis valve (i.e., the blood that is prevented from passing through the hemostasis valve). Thus, even if there were a small amount of blood in the small space between the strings, a person of ordinary skill would not have expected that blood to pose any greater risk of thrombus formation than the blood within the catheter.

27. Second, a person of ordinary skill would have understood that the procedures in which hemostasis valves such as Schaffer's are used typically take place over the course of minutes, not hours or days. Therefore, even if a small amount of blood were to collect in the space between the two strings, a person of ordinary skill would not expect that blood to "lead to thrombus (clot) formation" in the short period in which the valve is closed during the procedure. Additionally, the valve is being opened and closed during such procedures to

insert and withdraw tools. Thus, any blood in the space between the strings would not be “stagnant” for long. Also, the patients undergoing these procedures have typically received an anticoagulant that prevents clot formation. Due to all these factors, a person of ordinary skill in the art would not have been concerned about the formation of clots in the small space between the two loops.

28. Third, a person of ordinary skill would have understood that the size of the small gap between the strings would be on the order of millimeters given the relative size of hemostasis valves such as Schaffer’s. A person of ordinary skill would therefore not have expected any significant “stagnant blood pool” or thrombus to form in the small gap. Accordingly, for at least these reasons it is my opinion that a person of ordinary skill in the art would not have been dissuaded from using two spaced-apart strings in Schaffer’s valve by the risk of stagnant blood or thrombus formation between the strings.

3. Two Strings/Wires Would Provide Redundancy Protections

29. As I explained in my prior Declaration, another benefit to using two strings wrapped once around the tubular member would be to provide redundancy to the valve that cannot be accomplished with a single string. Ex. 1003 (Thornton Decl.) at ¶82. Specifically, the second string could help ensure that Schaffer’s valve seals even if the first string were to fail to completely tighten around the tubular member and/or a tool inserted through the tubular member. *Id.*

30. Patent Owner and Dr. Zalesky do not appear to dispute that a second string would provide redundancy benefits to Schaffer's valve. *See* Ex. 2001 (Zalesky Decl.) at ¶¶79-80. Instead, Patent Owner and Dr. Zalesky argue that: (1) the two strings "might interfere with one another," which outweighs the redundancy benefits and (2) I had testified in related IPRs that Hartley's strings could be formed from durable materials. *Id.* Neither of these arguments undermine the motivation to introduce redundancy with a second string.

31. I disagree with Patent Owner and Dr. Zalesky that a person of ordinary skill would have been dissuaded from using a second string because the two strings "might interfere with one another." *Id.* at ¶79. According to Dr. Zalesky, "when Schaffer's actuator buttons are depressed one of Hartley's strings might move underneath the loop of the other string, potentially reducing the effectiveness of the loops." *Id.* I disagree that this potential interference would have been a significant concern for a person of ordinary skill for several reasons.

32. First, Eller expressly discloses using multiple wires, including first and second wires, to seal the lumen of a hemostasis valve and that such an arrangement is effective. Ex. 1007 (Eller) at 5:1-6, 16:7-19. Eller does not state or suggest that the interference between these wires is a problem.

33. Second, the '384 patent also discloses loop and bight embodiments in Figures 7-9 that include multiple separate loops and bights:

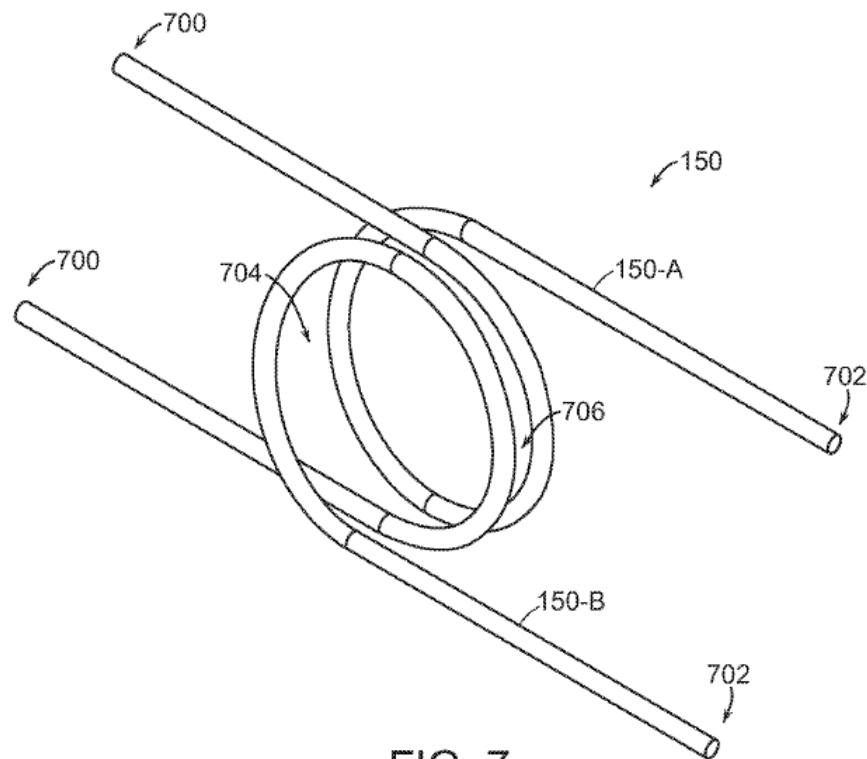


FIG. 7

Ex. 1001 ('384 patent) at 13:16-14:5, Fig. 7-9. The '384 patent never suggests that interference between the filaments is a problem, and the patent never suggests any solutions to this hypothetical issue.

34. Third, Eller explains that “[s]killed artisans will be able to select a suitable number of wire members to include in a selective fluid barrier valve device according to a particular embodiment based on various considerations, including the material(s) that forms the sleeve of an embodiment.” Ex. 1007 (Eller) at 16:7-15. Eller therefore confirms that a person of ordinary skill in the art would have possessed the skills to optimize the length and tension of the strings/wires to avoid significant interference. Such optimization would have

been a routine task performed by a person of ordinary skill designing a hemostasis valve. Notably, the '384 patent also presumes that a person of ordinary skill would have possessed these skills. The '384 patent merely states that “[i]n some embodiments, the filament 150 can comprise multiple filaments.” Ex. 1001 ('384 patent) at 12:61-64. The '384 patent does not disclose any means for preventing or addressing potential lateral movement of multiple filaments, for example the filaments illustrated in Figures 7-9, and instead presumes that a person of ordinary skill would have known how to prevent such issues.

35. Finally, even if a person of ordinary skill shared Dr. Zalesky's speculative concern regarding interference of the filaments, which is contrary to the prior art and the '384 patent, Dr. Zalesky fails to explain why that concern would have outweighed the other benefits (e.g., redundancy) of a second string. Dr. Zalesky also fails to consider the simple solutions to his hypothetical interference, such as adjusting the length and/or tension on the strings or the string material and/or spacing the attachment points between the strings and the buttons a small distance apart, that would have been within the abilities of a person of ordinary skill.

36. Patent Owner's and Dr. Zalesky's focus on my prior testimony that Hartley's strings could be formed from durable material is also misplaced. Patent Owner and Dr. Zalesky appear to assume, without explanation, that insufficient

durability would be the sole possible cause for one of the strings to not completely tighten around Schaffer's seal module and/or a tool inserted through the valve. *See* Ex. 2001 (Zalesky Decl.) at ¶80. A person of ordinary skill in the art would not have made such an assumption. They would have understood, for example, that an irregularly shaped and/or sized tool may inhibit a complete seal by a single string even if the string did not break or fail due to insufficient durability. As another example, the attachment point where the strings are connected to Schaffer's actuator buttons could fail or come loose due to manufacturing variability, even though the string itself does not break. The redundancy of a second string would be beneficial in these types of situations. In addition, as Dr. Zalesky acknowledges in his Declaration, he has repeatedly testified that Hartley's string "would undermine the durability of Schaffer's valve." *Id.* To the extent that durability would be concern for a person of ordinary skill as Dr. Zalesky has argued, the second would help to address that concern, which would provide even further motivation for a person of ordinary skill to use a second string.

III. CONCLUSION

37. For the above reasons and the reasons I explained in my previous Declaration (Ex. 1003), it is my opinion that challenged Claims 1-4, 6-18, and 20-30 of the '384 patent are unpatentable because they are obvious in view of the prior art.

38. I declare that the foregoing is true and correct, and further that the foregoing statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on August 31, 2026 in Glen Ellen, CA.

troy thornton

Troy Thornton