IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:	)
U.S. Patent No. 6,719,767	)
Issued: April 13, 2004	)
Application No.: 09/670,082	)
Filing Date: September 26, 2000	)

For: Device and a Method for Treatment of Atrioventricular Regurgitation

FILED VIA E2E

PETITION FOR *INTER PARTES* REVIEW OF US PATENT NO. 6,719,767

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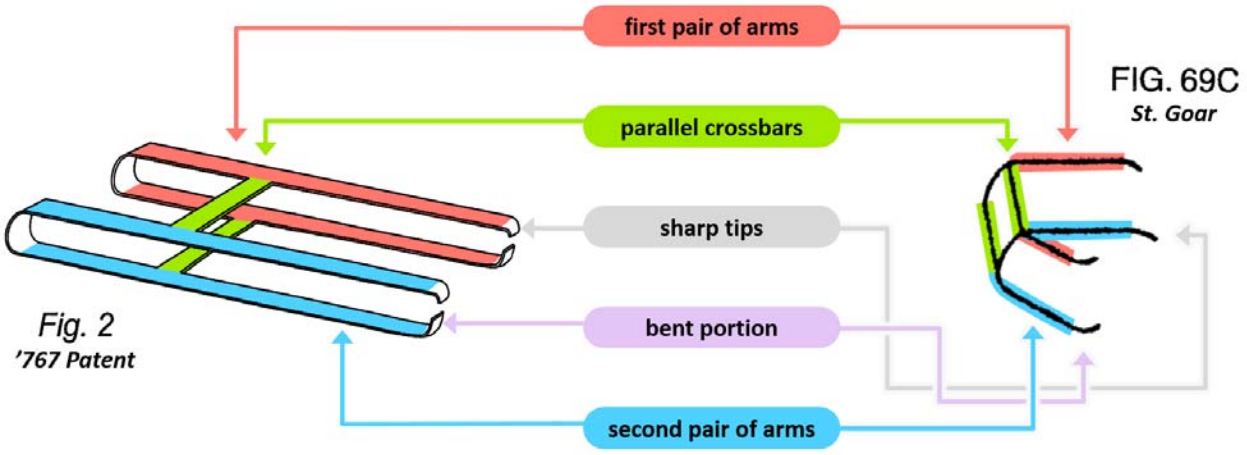
I. INTRODUCTION

Abbott Laboratories requests *inter partes* review of claims 1–3, 5, and 14 of US Patent 6,719,767, titled "Device and a Method for Treatment of Atrioventricular Regurgitation" ("'767 patent") (Ex. 1001).

The '767 patent claims nothing new. The claims recite a clip that can be delivered with a catheter passing through a patient's blood vessels and used to repair the mitral valve in the heart, rather than via open-heart surgery. But before the earliest asserted effective filing date, Abbott's subsidiary, Evalve, had already developed and patented several such clips. Specifically, Abbott's prior art US Patent 6,629,534 to Frederick St.Goar and others ("St.Goar") describes clips for catheter-based mitral valve repair. And as can be seen from a comparison of St.Goar, Figure 69C (annotated, left, below), and Figure 2 of the '767 patent (annotated, right, below), St.Goar teaches a clip that is indistinguishable materially from the clip disclosed in the '767 patent—both have two pairs of arms, with sharp tips, connected by crossbars. Indeed, the clips are ***nearly identical***, other than the (unclaimed and irrelevant) fact that the crossbars of the prior art clip are at the ends of the arms, whereas the crossbars of the '767 patent's clip are closer to the middle.



Annotated; Declaration of Lishan Aklog, M.D. ("Aklog"), 99.

St.Goar anticipates claims 1–3, which claim structural details relating to the clip of the '767 patent's preferred, and only disclosed, clip embodiment. The two other challenged claims (claims 5 and 14) are equally invalid, for they add only a retractable "outermost sheet" to a catheter used to deliver the clip to the heart. St.Goar discloses one such form of an outermost sheet—a guide catheter—which by Patent Owner, Edwards's, own admission satisfies the claims. Thus, St.Goar anticipates claims 5 and 14 (as discussed in Ground 1).

And it had long been common practice to use a retractable outermost sheet, such as a guide catheter or protective sheet, to cover a device during catheter based delivery. They were used, for example, to protect a patient's vessels and cardiac tissue from the device, *e.g.*, as it travels through the vasculature (and to protect the device itself, including from inadvertent dislodgement) during delivery, and then retracted when the device was positioned to be implanted. An

ordinary artisan would have found it obvious to use such a commonplace retractable outermost sheet to deliver and implant St.Goar's clips (as discussed in Grounds 2 and 3 respectively).

Accordingly, Abbott asks the Board to institute review and find claims 1–3, 5, and 14 of the '767 patent unpatentable.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real-Parties-in-Interest (37 C.F.R. § 42.8(b)(1))

The real-parties-in-interest are Abbott Laboratories, Abbott Cardiovascular Systems, Inc., Evalve, Inc., and Abbott Laboratories, Inc. (collectively, "Abbott").

B. Related Matters (37 C.F.R. § 42 8(b)(2))

The '767 patent is asserted in the following case that may be affected by a decision in this proceeding: *Edwards Lifesciences Corp. v. Abbott Cardiovascular Sys.*, No. 8:19-cv-00345-JLS-JDE (C.D. Cal. filed Feb. 22, 2019).

C. Lead and Backup Counsel and Service Information

Under 37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4), and 42.10(a), Abbott designates the following lead counsel:

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Under 37 C.F.R. § 42.10(b), a power of attorney from Abbott is attached. Abbott consents to electronic service.

D. Fee for *Inter Partes* Review

The Director may charge the fee specified by 37 C.F.R. § 42.15(a) to deposit Account No. 506269.

III. GROUNDS FOR STANDING AND IDENTIFICATION OF CLAIMS BEING CHALLENGED (37 C.F.R. § 42.104(A) AND (B))

A. Grounds for Standing

Abbott certifies that the '767 patent is available for *inter partes* review and that Abbott is not barred or estopped from requesting *inter partes* review of the challenged claims of the '767 patent on the grounds identified herein.

B. Statutory Ground for the Challenge

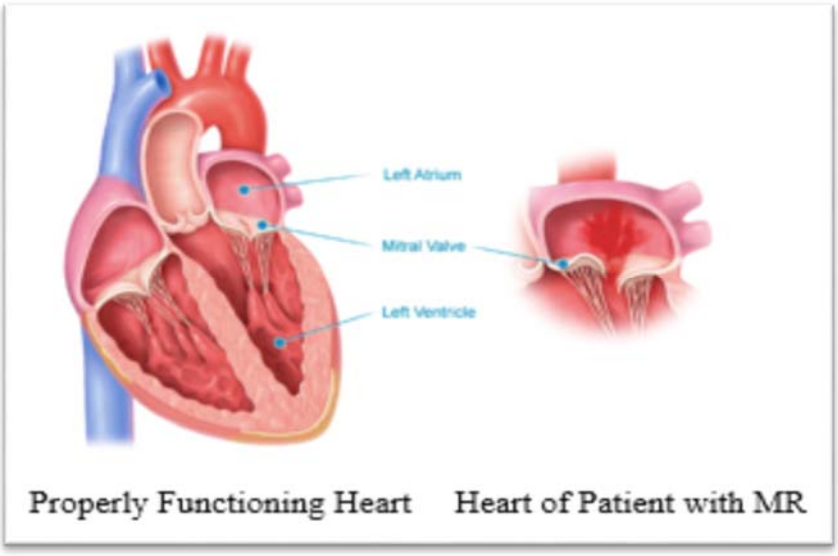
The claims are unpatentable on the following grounds:

Ground	Claims	Basis
1	1–3, 5, 14	§ 102: St.Goar
2	5, 14	§ 103: St.Goar in view of the knowledge of a person of skill in the art
3	5, 14	§ 103: St.Goar in view of the knowledge of a person of skill in the art, and in view of Garrison (Ex. 1009)

IV. BACKGROUND

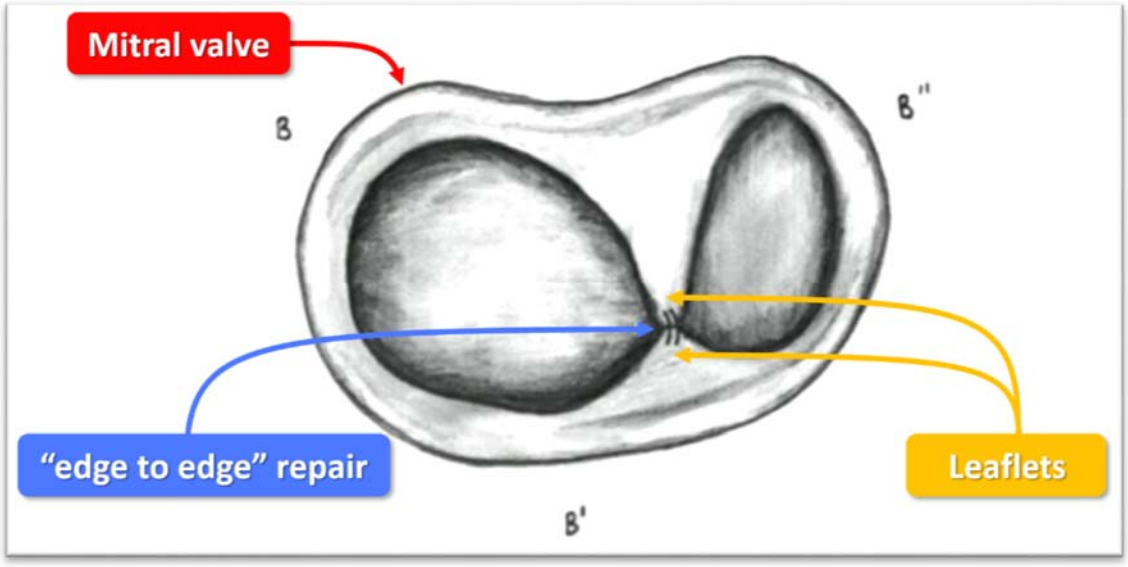
A. Mitral Regurgitation and the Old, Open-Heart Surgery Treatments

In a properly functioning heart, blood flows from the left atrium into the left ventricle, but not in the other direction. Aklog, 38-41. The mitral valve connects those two chambers, and opens (during ventricular relaxation) and closes (during ventricular contraction) to allow blood flow only in the proper direction. *Id.* If the mitral valve's leaflets do not close properly, blood leaks in the backward direction—a condition called "atrioventricular regurgitation," "mitral regurgitation," or simply "MR." St.Goar (Ex. 1008), 1:21-39, 2:49-54, 13:25-63; *see* Aklog, 42.



Aklog, 42.

Traditionally, surgeons treated MR through open-heart surgery to surgically repair or replace the faulty mitral valve. Aklog, 43. In the early 1990s, Dr. Ottavio Alfieri developed a new way to repair a mitral valve, referred to as the "edge-to-edge" technique. He directly sutured the leaflets' edges to pull them together at a local site along the coaptation line to create a "double orifice," which closed more completely during ventricular contraction. Aklog, 43.



Aklog, 43; *see also* St.Goar, 1:43-51.

Alfieri's technique helped, but still required the trauma, risk, and long recovery of open-heart surgery. *Id.* For those reasons, Evalve (which became an Abbott subsidiary in 2009) developed and patented novel mitral valve repair devices (such as described in St. Goar (Ex. 1008) discussed in the Grounds below, and ultimately leading to the "MitraClip™") using a catheter to remotely perform the Alfieri technique, eliminating the need for open-heart surgery.

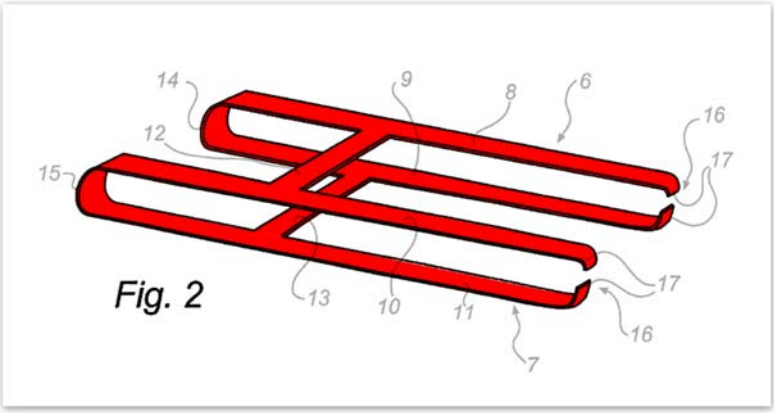
Before MitraClip, the standard treatment for treating MR was highly invasive open-heart surgery. MitraClip avoided that high risk surgery with a brand new catheter-based, non-surgical treatment. MitraClip is, and has been for several years, the only one of its kind; it was approved for use in Europe in 2003, and in the US in 2009. The MitraClip, which is based upon a series of Abbott's own patents, is still the only such product that is FDA approved and has since been used in treating over

100,000 patients world-wide. Meanwhile, the '767 patent also claims to be directed to a catheter-based treatment of MR, but there has never been a product that looks anything like the clip design disclosed in the '767 patent.

B. The '767 Patent (Ex. 1001)

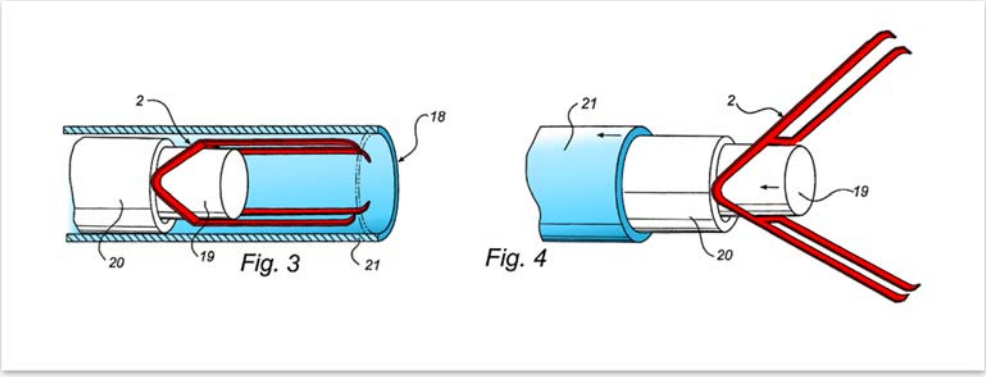
The '767 patent claims priority to a Swedish Application filed on August 11, 2000, over a year after the St.Goar provisional patent application, and four months after the St.Goar non-provisional application. Like the prior-art St.Goar patent discussed with respect to Ground 1 below, the '767 patent explains that treating "mitral insufficiency" traditionally required open-heart surgery, and that catheter based mitral-valve clips allow less-invasive repair. '767 patent, 2:6-12; Aklog, 44-45.

The '767 patent claims a "suturing means having such dimensions as to be introducible, via blood vessels leading to the heart, to two leaflets of the atrioventricular valve" capable of "binding together the two leaflets in a position along the free edges of the leaflets." '767 patent, cl. 1, Abstract. The only disclosed "suturing means" is the clip illustrated in Figure 2 below:



'767 patent, Fig. 2 (annotated); Aklog, 46-47.

The patent also claims "a catheter for introduction of the clip via the blood vessels to the heart, said catheter having an outermost sheet covering the clip and being retractable." '767 patent, cl. 5, 3:3-6; Aklog 49. The figures illustrate two ways to deliver the clip "into a beating heart 1 by using a catheter," depending on the anatomical path used to approach the mitral valve. *Id.*, 5:11-12; Aklog 50-55. The first example is illustrated in Figures 3 and 4:



'767 patent, Figs. 3, 4 (annotated), 5:12-14; Aklog, 51.

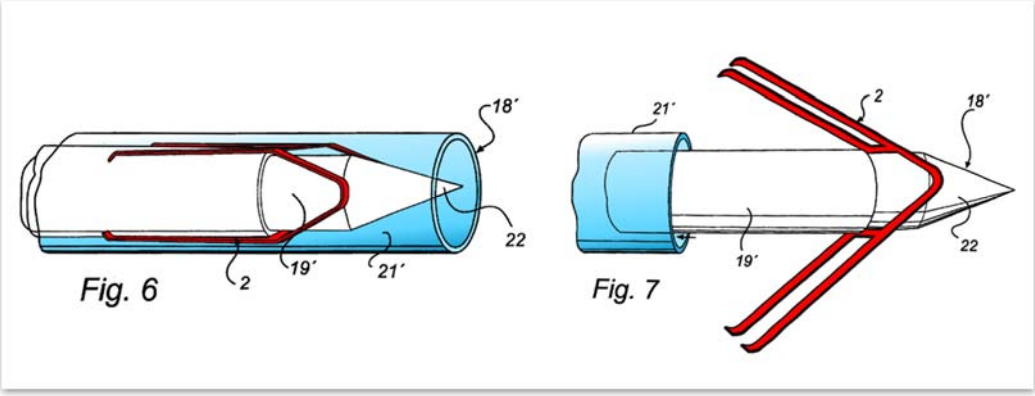
In the first way, the catheter is passed "retrograde along the [brachial] artery into the left ventricle of the heart." '767 patent at 6:11-13, Fig. 5; Aklog, 50. In this

embodiment, the catheter has an internal "supportive rod 19 that is slidable in a hollow applicator 20." *Id.*, 5:13-15. Further, "[i]n its outermost part the catheter 18 has a protective sheet 21 that also is slidable upon the applicator 20." *Id.*, 5:15-17. Figure 3 depicts the device in its initial state, in which the "protective sheet 21 can be pushed over the clip 2 to make the catheter 18 easier to introduce into the heart 1" by ensuring that "clip 2 does not get stuck [i.e., by catching on vascular and/or heart tissue] as it is passed into the heart 1." *Id.*, 5:25-31; Aklog, 50-52.

Figure 4 shows "the protective sheet 21" after it is "drawn back along the applicator 20, thus uncovering the clip 2 and allowing the clip 2 to take the form of its first [open] state." *Id.*, 5:33-35. From this arrangement "clip 2 can then be transformed into its second [closed] state by retracting the supportive rod 19" that "keep[s] the clip 2 in its first, open state," *id.*, 5:24-25, 5:35-38, purportedly allowing the clip to bind the leaflets together and improve atrioventricular closure. Aklog, 48, 53.

The second way to reach the mitral valve uses what was commonly referred to as an "antegrade" approach. Aklog 54. In this "second alternative embodiment of the catheter 18" shown in Figures 6 and 7 (annotated below), the catheter reaches the mitral valve through the left atrium rather than the left ventricle. *Id*. Here, the catheter is passed through "the femoral vein into the vena cava and further into the right atrium." *Id.*, 6:32-35, Fig. 8. A "needle 22 is then used to puncture the

interatrial septum to give the catheter 18' a passage into the left atrium." *Id.*, 6:37-39.



'767 patent, Figs. 6, 7 (annotated); Aklog, 54.

This second arrangement is described as having a "catheter 18' compris[ing] a supportive rod 19'" that "hold[s] the arms 8-9 and 10-11 in the pairs of the clip 2 apart, thus keeping the clip 2 in its first [open] state." *Id.*, 5:39-46; Aklog, 54-55.

C. The Person of Ordinary Skill in the Art ("POSITA")

A POSITA would have been an interventional cardiologist or cardiac surgeon, or someone who has received an advanced engineering degree, such as a master's degree or Ph.D., in a relevant engineering discipline, such as mechanical engineering or biomedical engineering, with at least some experience contributing to the design, testing, and/or evaluation of heart treatment devices, or someone who has obtained a lesser degree but has more experience contributing to the design, testing, and/or evaluation of heart treatment devices. Aklog, 33-35. If the POSITA was an

interventional cardiologist or cardiac surgeon she may have worked on a team working with engineers, or vice-versa.

This Petition does not turn on this definition, and the claims would be unpatentable from the perspective of any reasonable POSITA. *Id.*, 37.

V. CLAIM CONSTRUCTION

The Board construes the claims "using the same claim construction standard that would be used" in district court. 37 C.F.R. § 42.100.

A. "suturing means"

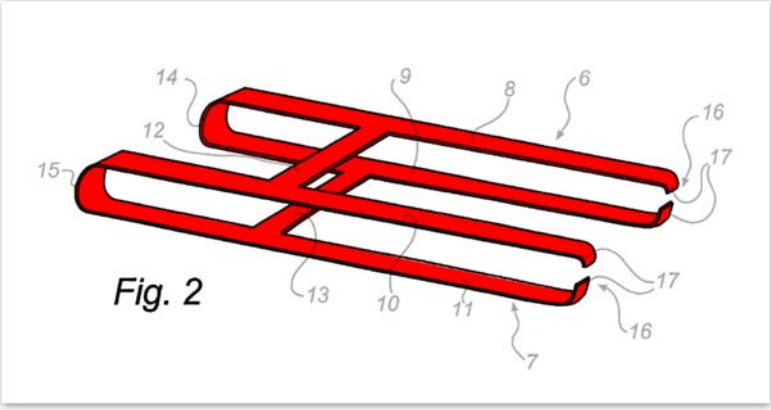
Claims 2 (via claim 1) and 14 recite that the claimed device comprises a "suturing means."

As an initial matter, Patent Owner Edwards contends in district court that the "suturing means" is *not* subject to 35 U.S.C. § 112 ¶ 6, and should be construed to cover any clip satisfying the other limitations in the claims. Ex. 1006 ("Edwards Claim Construction Disclosure") Ex. A, 3. Abbott disagrees, and has argued in district court that "suturing means" in claims 2 and 14 should be subject to § 112 ¶ 6. And although Abbott continues to believe "suturing means" should properly be construed as subject to § 112 ¶ 6 ("means plus function" or "MPF"), for purposes of this proceeding ***only***, Abbott adopts Edwards's district court construction of "suturing means."

Alternatively, if the Board concludes that "suturing means" should be construed under § 112 ¶ 6, the challenged claims are still unpatentable.

Construing a means-plus-function claim requires first identifying the claimed function, then identifying the corresponding structure in the specification. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351-52 (Fed. Cir. 2015). Thus, under § 112 ¶ 6, "suturing means" would be limited to the patent's disclosed embodiments and equivalents thereof. *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1987). Here, the function of the suturing means is "binding together the two leaflets in a position along the free edges of the leaflets, whereby the closing of the atrioventricular valve is improved." Aklog, 59-62.

The '767 patent discloses only one structure performing this function of the "suturing means," the "clip" in Figure 2 and described at columns 4:66-5:4 of the '767 patent:



'767 patent, Fig. 2 (annotated); Aklog, 60.

The patent explains that when the clip's arms are open, "[t]he clip 2 is capable of grasping the mitral leaflets 4, 5 at their free edges and binds the edges together by capturing the leaflets 4, 5 in the first [open] state of the clip 2 and keeping them together in the second state of the clip 2." '767 patent, 5:4-10, Figs. 3-4, 6-7; Aklog, 60-61.

B. "biased towards its second state"

Claim 1 recites "said suturing means being transitional between two states, being open in a first state and ***substantially closed in a second state***, and said suturing means being ***biased towards its second state***." As Edwards explained during prosecution, "[t]his bias means that when a restraint on the device is released, the device will automatically assume the shape of its second, i.e., closed, state." Ex. 1002 at 242. But under any reasonable construction, the claims are invalid, in view of the St.Goar clips. Aklog, 63.

VI. GROUND 1: ST.GOAR ANTICIPATES CLAIMS 1–3, 5, AND 14

A. Evalve's Prior Work to Develop a Non-Surgical Treatment for MR

Abbott's subsidiary, Evalve, and its founder Dr. Frederick St. Goar already invented the claimed suture means, and filed a patent application describing it, before the '767 patent's earliest asserted effective filing date. This application eventually issued as St.Goar (Ex. 1008). St.Goar is § 102(e) prior art because it was

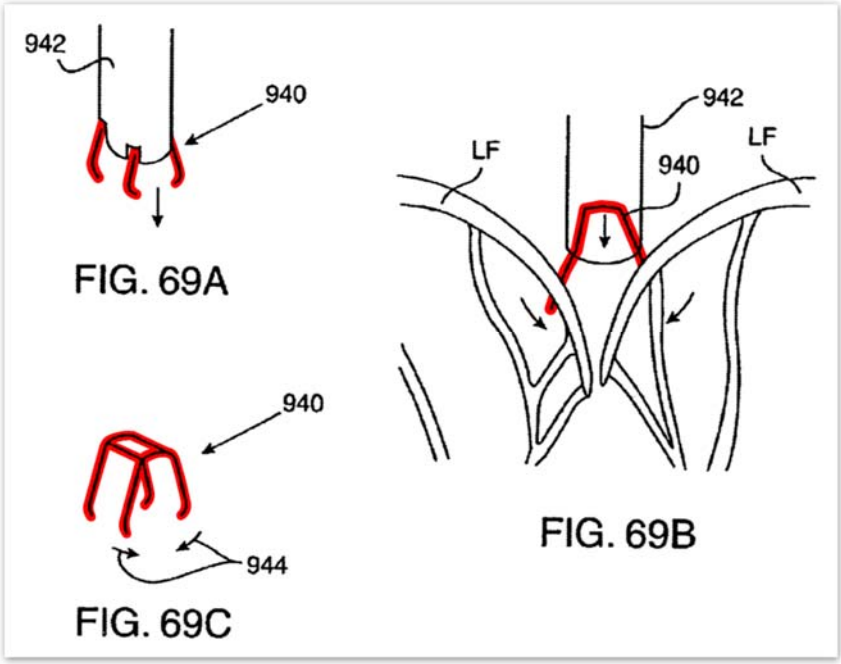
filed before the '767 patent's earliest asserted priority date.[1] St.Goar was not cited during prosecution of the '767 patent, and as set forth below, anticipates claims 1–3, 5, and 14 of the '767 patent.

St.Goar solved the same problems in the same way as the '767 patent, but did so earlier. Aklog, 65-66. St.Goar explains that prior existing techniques to treat MR relied on "suturing adjacent segments of the opposed valve leaflets together" using "open heart surgery." St.Goar, 1:44–50. St.Goar recognized that alternative MR treatment methods "should preferably not require open chest access and be capable of being performed endovascularly, i.e., using devices which are advanced to the heart from outside the body, through an entry location in the patient's vasculature remote from the heart." *Id.*, 1:51–61; Aklog, 65-66.

[1] Should Edwards attempt to antedate St.Goar's non-provisional filing date, St.Goar is also entitled to the April 9, 1999 filing date of the provisional, as Edwards itself has argued to the Board in IPR2019-01285, where it needed St.Goar's provisional date to support its position that St.Goar is prior art—unlike here, St.Goar's actual filing date was insufficient. Ex. 1053 at 36-39. Abbott reserves the right to seek a reply to Edwards's Patent Owner's Preliminary Response to claim benefit to St.Goar's provisional filing date.

To solve that problem, St.Goar's "clips" are "used to draw leaflets together in a suitable coaptation configuration." *Id.*, 37:45–46. The disclosed clips are sized to be delivered through blood vessels, after which it binds the mitral valve leaflets together to improve closing of the mitral valve. *See e.g.*, *id.*, 31:64–37:44; Figs. 49–68; Aklog, 66-67.

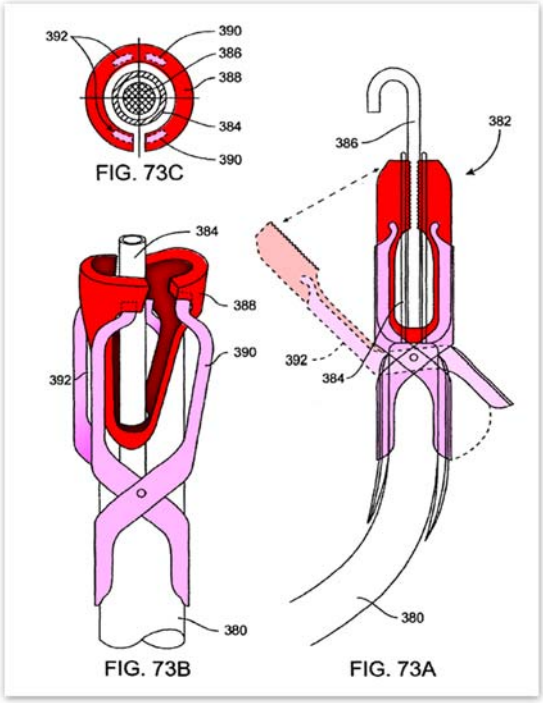
St.Goar shows an exemplary clip design in Figures 69A-C:



St.Goar, Figs. 69A–C (annotated); Aklog, 67.

This Figure 69 "clip 940 may be mounted on a delivery catheter [942]" to be positioned at the desired location in the heart to capture the mitral valve leaflets and pull them together. St.Goar, 37:50–56; Aklog, 68.

St.Goar shows another clip for binding mitral valve leaflets together in Figure 73, annotated below, used with a "clip-applying catheter" for intravascular deployment:

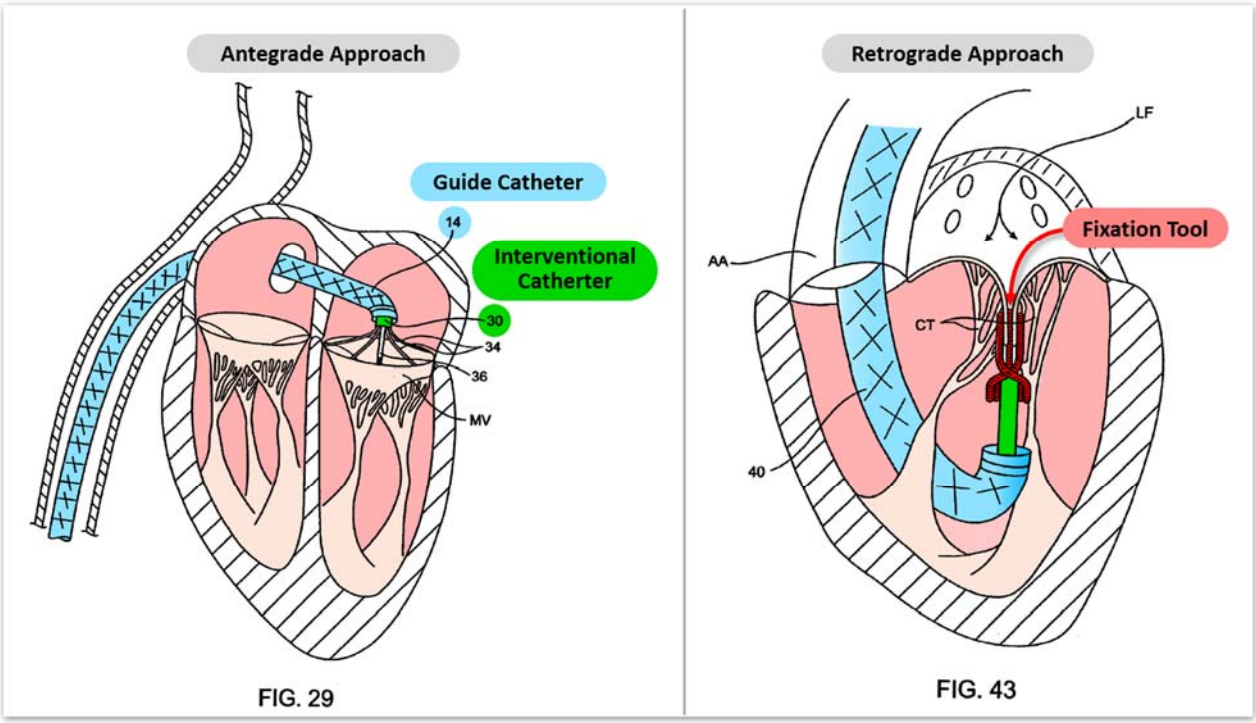


St.Goar, Figs. 73A–C (annotated), 38:35-37; Aklog, 69, 70.

To avoid invasive open-heart surgery, St.Goar introduces the mitral valve repair device—such as the Figures 69 and 73 clips—through the skin: *i.e.*, percutaneously. St.Goar, 14:39–46. It is then "advanced to the heart intravascularly [*i.e.*, through the blood vessels] where they [the clips] may be positioned adjacent the target cardiac valve in a variety of manners" that were well known in the art. St.Goar, 14:53–57; *id.*, 14:46–48 ("The ability to percutaneously access the remote vasculature is well-known and described in the patent and medical literature."). The

clips repair the mitral valve by binding its leaflets together, forming a double orifice opening. *Id.*, 37:45–57, 38:35–58, Figs. 69, 73, 74; Aklog, 71.

St.Goar discloses the same two ways of delivering its clips to the mitral valve leaflets as the '767 patent: "antegrade or retrograde endovascular access through the vasculature." St.Goar, 7:21–25. The two approaches are shown side-by-side below. In either approach, the "interventional tools [*e.g.*, clips] and supporting catheter(s) will be advanced to the heart intravascularly [via the vasculature]." *Id.*, 14:52–55, 7:27–32, 8:26–27, 9:3–7; Aklog, 72-74.



St.Goar, Figs. 29, 43 (annotated); Aklog, 73-74.

In the "antegrade" approach, the mitral valve is accessed "through the right atrium RA, across the interatrial septum IAS, and into the left atrium LA above the

mitral valve MV," (St.Goar, 14:64–16-4), as shown in Figure 29 of St.Goar (above, left). *See also id.*, Fig 7. In the "retrograde" approach, the "mitral valve MV may be accessed by an approach from the aortic arch AA, across the aortic valve AV, and into the left ventricle below the mitral valve MV," (*id.*, 15:39–43) as shown in Figure 43 of St.Goar (above, right). *See also id.*, Fig. 10. In both cases, St.Goar explains that it will "be desirable to position the interventional tool [i.e., clip] toward the target tissue structure using a preformed and/or ***steerable guide catheter***." *Id.*, 7:51–53; Aklog, 73-74.

B. Claim 1 Is Anticipated by St.Goar

1. 1[pre]—St.Goar discloses clips for treating atrioventricular regurgitation

To the extent the preamble is limiting, it requires "A device for treatment of atrioventricular regurgitation in a heart, comprising." St.Goar discloses this feature. St.Goar discloses "methods, ***devices***, and systems" for the "repair of cardiac values, ***particularly the atrioventricular valves which inhibit back flow of blood from a heart ventricle during contraction (systole)*****,*** most particularly the ***mitral valve*** between the left atrium and the left ventricle." St.Goar, 2:49-54; *id.*, 1:14-67; Ex. 1042 (St.Goar provisional), 2:1–6; 3:15–18.[2] A POSITA would have understood this refers to the treatment of atrioventricular regurgitation; as discussed in Section

[2] All emphases added unless otherwise noted.

IV.A, atrioventricular regurgitation refers to the pathological backwards flow of blood from the heart ventricle to the atrium, resulting from the defective operation of the mitral valve. Aklog, 75-78.

Further, St.Goar's "Figure 73 clip" and "Figure 69 clip" in Figures 73A–C and 69A–C respectively (collectively, "Figures 73 and 69 clips") are devices that "draw [mitral valve] leaflets together in a suitable coaptation configuration" to treat atrioventricular regurgitation. St.Goar, Figs. 69A–C, 73A–C, 71, 74, 37:45–46, 38:53–59 ("After the valve leaflets are captured and held in a proper orientation, valve improvement can be confirmed by visual observation [e.g., through fluoroscopy]. If improvement is sufficient, the clip can be detached from the catheter and left in place, as shown in FIG. 74."). Aklog, 76-77; St.Goar, 19:6–29.

2. 1[a]—St.Goar's clips are the claimed "suturing means"

This limitation requires "a suturing means having such dimensions as to be introducible, via blood vessels leading to the heart, to two leaflets of an atrioventricular valve between an atrium and a corresponding ventricle of the heart and being capable of binding together the two leaflets in a position along the free edges of the leaflets, whereby the closing of the atrioventricular valve is improved."

For this proceeding only, Abbott adopts Edwards's position that "suturing means" is not subject to MPF. *See* Claim Construction section above. Under that

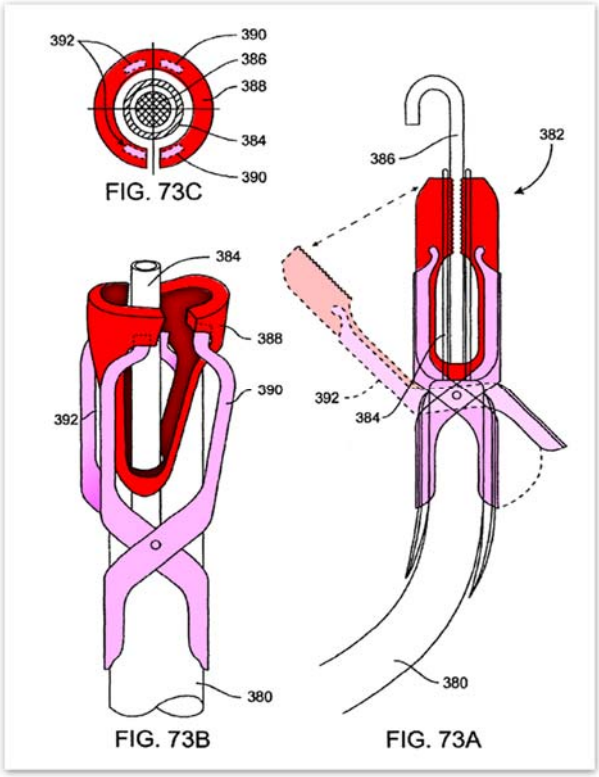
construction, St.Goar's Figures 73 and 69 clips each disclose this limitation. And even under MPF, St.Goar's Figure 69 clip discloses this limitation. Aklog, 79-80.

a. St.Goar's Figure 73 and 69 clips are "suturing means" if not construed as MPF

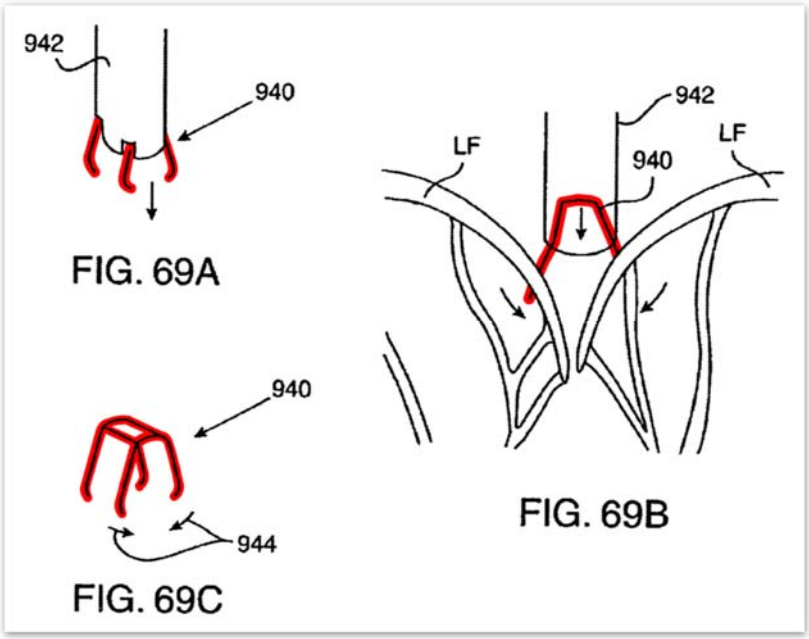
If "suturing means" is construed ***not*** to be subject to MPF, this limitation requires that it (1) is sized to be guided through the patient's blood vessels to the leaflets of the mitral valve, which is an atrioventricular valve, (2) binds the leaflets along their free edges, and (3) improves the closing of the mitral valve. Aklog, 81. St.Goar discloses clips (the claimed "suturing means") having these features. *Id.*

(1) St.Goar's Figures 73 and 69 clips are sized to be guided through the patient's blood vessels to the mitral leaflets

St.Goar discloses that "clips may be used to draw [mitral valve] leaflets together in a suitable coaptation configuration." St.Goar, 37:45-46. The Figure 73 clip is shown below (in red) in Figures 73A–C, and the Figure 69 clip is shown below (in red) in Figures 69A–C (annotated). Aklog, 82-84.



St.Goar, Figs. 73A–C (annotated); *id.*, Fig. 74 (showing Figure 73 clip in its closed state); Aklog, 82.



St.Goar, Figs. 69A–C (annotated); Aklog, 83.

St.Goar explains that these clips are sized to be guided through a patient's blood vessels. Aklog, 85. For example, St.Goar discloses that "the procedure(s) of the present invention are performed with interventional tools and supporting catheters and other equipment introduced to the heart chambers ***from the patient's arterial or venous vasculature*** remote from the heart." St.Goar, 2:49–59; *id.*, 3:36–42 ("The methods of the present invention will usually comprise accessing a patient's vasculature at a location remote from the heart, advancing an interventional tool through the vasculature to a ventricle and/or atrium, and engaging the tool against a tissue structure which forms or supports the atrioventricular valve.").

St.Goar also specifically explains that its Figure 73 clip can be transported via a catheter "introduced over a guidewire 386, where the guidewire may be placed through the atrioventricular valve prior to catheter positioning." St.Goar, 38:35-45. Similarly, St.Goar explains that the Figure 69 clip "may be mounted on a delivery catheter," as shown in Figure 69A. *Id.*, 37:50-53; *id.*, 1:53-61 (explaining that "it would be desirable" to perform valve repair "using devices which are advanced to the heart from a point in the patient's vasculature remote from the heart"), *id.*, 14:39-57. St.Goar also states that its clips can be introduced to the mitral valve through the patient's arteries to the left ventricle, or through the patient's veins to the right atrium and then the left atrium. St.Goar, 31:55-59, 7:23–38 (describing a retrograde

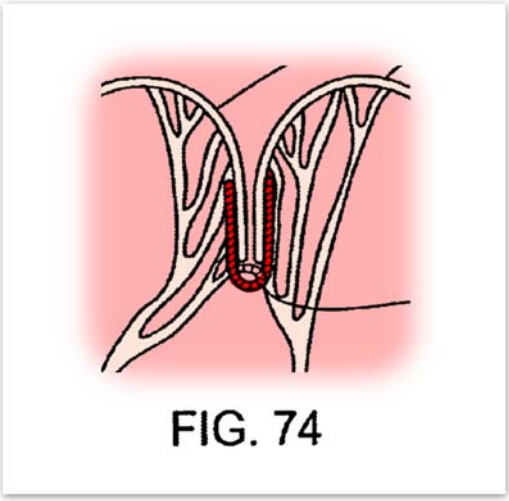
endovascular approach to mitral valve), *id*., 8:6–20 (describing an antegrade endovascular approach to mitral valve), *id*., 14:38–16:11 (section entitled "Access to the Mitral Valve"), Figs. 7–10.

Because St.Goar's clips are delivered through a patient's "vasculature" to an atrioventricular valve, those clips would be sized to have "such dimensions as to be introducible, via blood vessels leading to the heart, to two leaflets of an atrioventricular valve between an atrium and a corresponding ventricle of the heart," as claimed. Aklog, 86-87.

(2) St.Goar's Figures 73 and 69 clips bind the valve leaflets along their free edges

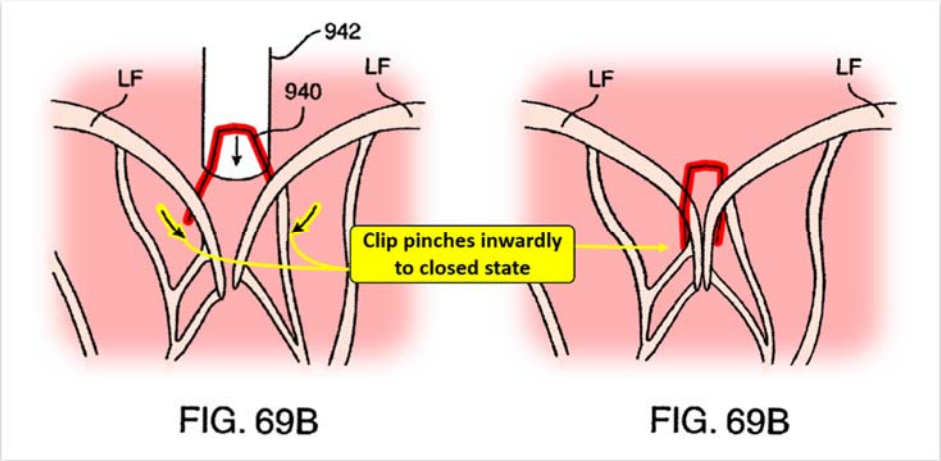
St.Goar discloses that "clips may be used to draw leaflets together in a suitable coaptation configuration" and to hold "two or more leaflets in a desired configuration." St.Goar, 37:45–50. The Figure 73 clip "has a V-shaped structure and is normally closed so that a force is required to open the distal ends of the clip." *Id.*, 38:45–47, Fig. 73B. "Jaws 390 and 392 hold the clip and can open the clip by selectively opening either jaw, with jaw 392 shown in open [position] in broken line in FIG. 73A." *Id.*, 38:47–53. So "jaw 392 may be opened first to capture a free end of a first valve leaflet." *Id*. Next, "the other jaw 390 can be opened and used to capture the second valve leaflet." *Id*.; Aklog 84, 88-92.

St.Goar depicts the Figure 73 clip in its final deployed configuration in Figure 74 below, wherein the clip is in its closed position and binds the first and second valve leaflets along their free edges:



St.Goar, Fig. 74 (cropped, annotated); Aklog, 89.

The Figure 69 clip also binds the leaflets of the mitral valve together along their free edges, and improves the valve's closing. St.Goar explains that "[i]n the deployed and activated state, depicted in FIG. 69C, the [Figure 69 clip] may tend to pinch inwardly, pulling the leaflets together, as indicated by arrows 944." St.Goar, 37:50–56; Fig. 69C; Aklog, 90. The result of the leaflets pinched inwardly by the clip is illustrated below (annotated):



St.Goar, Fig. 69B (cropped and annotated on left, modified on right); Aklog, 90.

St.Goar's Figures 73 and 69 clips thus each bind the leaflets of the atrioventricular valve and hold them together in the closed state. Aklog, 89-90. And Edwards has argued in an IPR petition that, as to the Figure 73 clip, St.Goar discloses the step of capturing two valve leaflets, drawing them together, and attaching them. *See* Ex. 1053 at 45–51; Aklog, 95.

(3) St.Goar's Figures 73 and 69 clips improve the closing of the mitral valve

St.Goar's Figures 73 and 69 clips improve the "closing of the atrioventricular valve," as claimed. For example, St.Goar discloses that clips can be "used to draw leaflets together in a suitable coaptation configuration." St.Goar, 37:45–46. And the "end result" is "***improved ability of the atrioventricular valve to close*** against the elevated pressures within the ventricle during systole." *Id.*, 4:9–16, 38:53–58 (once "the valve leaflets are captured [by the clip] and held in a proper orientation, ***valve improvement can be confirmed*** by visual observation"), *id.*, 10:12–31 (clips

"can be applied on to the valve[]" leaflets for "improvement in valve function"), 31:11–29 (improvement in valve function by coaptation of the leaflets); Aklog, 93.

In addition, as discussed below in connection with limitation 1[b] and 1[c] in Ground 1, the Figures 73 and 69 clips are "transitional between two states, being open in a first state and substantially closed in a second state," and "biased towards its second state." *Infra* at 29-36; Aklog, 103-114.

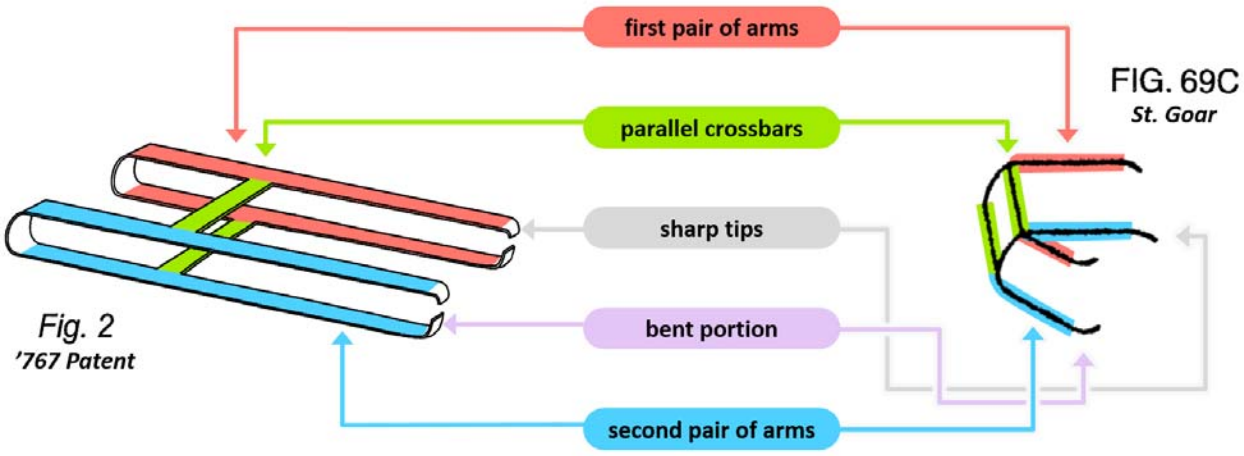
b. St.Goar's Figure 69 clip is a "suturing means," even under MPF

If the Board determines that "suturing means" should be construed as MPF, the recited "suturing means" corresponds to the "clip" shown in Figure 2 and described at columns 4:66–5:4 of the '767 patent and equivalents thereof. *See* Claim Construction section above. St.Goar's Figure 69 clip meets that construction, as it performs the claimed function with the same or equivalent structure as the '767 patent's clip. Aklog, 79-80, 97-102.

The '767 patent explains that "the suturing means 2 … being a clip consist[ing] of two pairs 6, 7 of arms 8–9 and 10–11," which "are connected in one end 14, 15" and "are bent towards each other in a bent portion 16" at the other end. '767 patent, 4:50-56. "The bent portions 16 are terminated with a sharp tip 17 so as to be able to engage and grab the mitral leaflets 4, 5." *Id.*, 4:56–57. Further, the "clip 2 has two parallel crossbars 12, 13 that each connect one arm 8, 9 in one pair 6 to one arm 10, 11 in the other pair 7," are "equally long," and are "connected to

the arms 8–9 and 10–11" "near the connection ends" and "at equal distance from the connections 14, 15." *Id.*, 4:58–65. The '767 patent also explains that "clip 2 is made of a memory metal, such as Nitinol," where "[t]he memory material of the clip 2 biases the clip 2 towards its second, closed state." *Id.*, 4:66–5:4; *see also* '767 patent, Figs. 2–7; Aklog, 98.

The Figure 69 clip has the same or equivalent structure to the '767 patent's clip. Other than the fact that the crossbars (green below) are in a slightly different location, the two clips are essentially ***identical***, or at the very least, they are equivalents. The two clips are compared below:



'767 patent, Fig. 2 (left, annotated); St.Goar, Fig. 69C (right, annotated); Aklog, 99-100.

Like the clip in the '767 patent, St.Goar's Figure 69 clip has two pairs of arms (red and blue), which are bent towards each other in a bent portion at the other end.

St.Goar, Figs. 69A–C; Aklog, 98-99. Further, the bent portions in St.Goar's Figure 69 clip comprise sharp tips used to engage and then grab the mitral leaflets. St.Goar, 37:45–56 ("[T]he [Figure 69] clip may tend to pinch inwardly, pulling the leaflets together, as indicated by the arrows 944."). And the Figure 69 clip's two parallel crossbars connect the pairs of arms, wherein the crossbars are equally long, near the connection ends, and at an equal distance from the connections. St.Goar, Figs. 69B–C; Aklog, 101. St.Goar also teaches that, like the clip of the '767 patent, the Figure 69 clip can be made of a "memory metal," so it "tend[s] to pinch inwardly, pulling the leaflets together." St.Goar, 37:53–57; Aklog, 101.

St.Goar's Figure 69 clip also performs the function recited in feature 1[a], as already discussed with respect to limitation 1[a] in Ground 1: it is introducible via blood vessels to the leaflet of the atrioventricular valve of the heart and can bind the leaflets together and improving the closing of the atrioventricular valve. *See also* '767 patent, cl. 1; St.Goar, 37:45–57; Aklog, 102.

Thus, St.Goar's Figure 69 clip discloses a "suturing means," whether or not that term is MPF. Aklog, 97-102, 59-62, 80-96.

3. 1[b]—St.Goar discloses transitional between open and closed states

This feature requires "said suturing means being transitional between two states, being open in a first state and substantially closed in a second state." As discussed regarding 1[a], St.Goar's Figures 73 and Figure 69 clips are "suturing

means." St.Goar also discloses that the Figures 73 and 69 clips are transitional between open and closed states. Aklog, 104-110.

a. The Figure 73 clip transitions between open and closed states

St.Goar explains that the Figure 73 clip has a first "open" state where the clip is held open by the jaws of the clip-delivering catheter. As to the open state, St.Goar teaches that the "[j]aws 390 and 392 hold the clip and can ***open the clip*** by selectively opening either jaw." St.Goar, 38:47–49. A POSITA would thus understand that the Figure 73 clip can be opened. So jaw "392 may be opened first to capture a free end of a first valve leaflet." *Id.*, 38:49–51. Then, "[w]ith the catheter 380 thus attached to just thes first valve leaflet, the catheter can be repositioned so that the other jaw 390 can be ***opened***." *Id.*, 38:50–54. Annotated Figure 73B below shows the Figure 73 clip with one jaw open, which opens the clip:

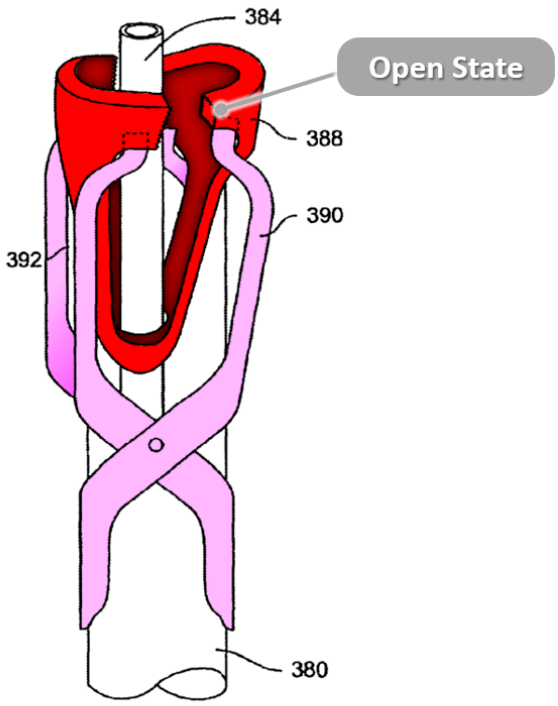


FIG. 73B

St.Goar, Fig. 73B (annotated); Aklog, 104. Thus, the Figure 73 clip can be opened. Aklog, 104.

As to the closed state, the Figure 73 clip transitions to a second, substantially closed state after capturing and pulling together the valve leaflets. St.Goar, 38:45–49 (the Figure 73 clip "has a V-shaped structure and is normally ***closed***."); *id.*, 38:53–58 ("After the valve leaflets are captured [by the clip] and held in a proper orientation, valve improvement can be confirmed by visual observation [e.g., by fluoroscopy]. ***If improvement is sufficient, the clip can be detached from the catheter and left in place, as shown in FIG. 74***."). This closed state of the Figure

73 clip is depicted in Figure 74 below (annotated and cropped to better show the clip):

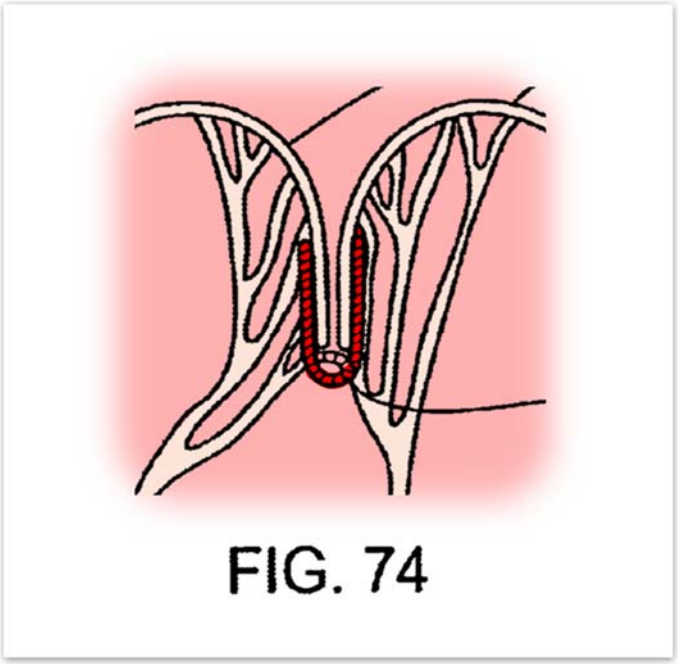
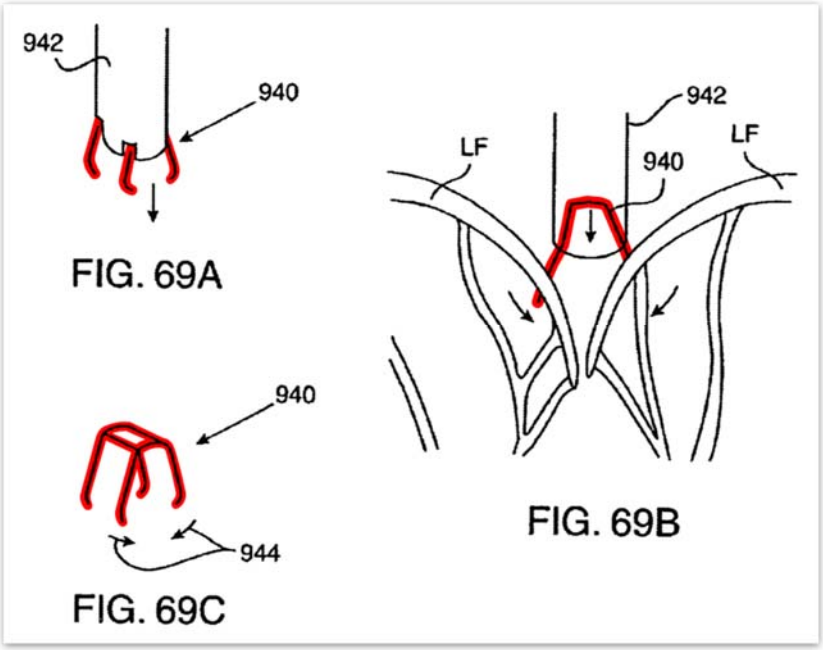


FIG. 74

St.Goar, Fig. 74 (cropped, annotated), 38:53-58; Aklog 105. This shows the final deployed configuration where the clip is holding the free edges of the mitral valve leaflets together. Aklog, 70, 83, 89, 105.

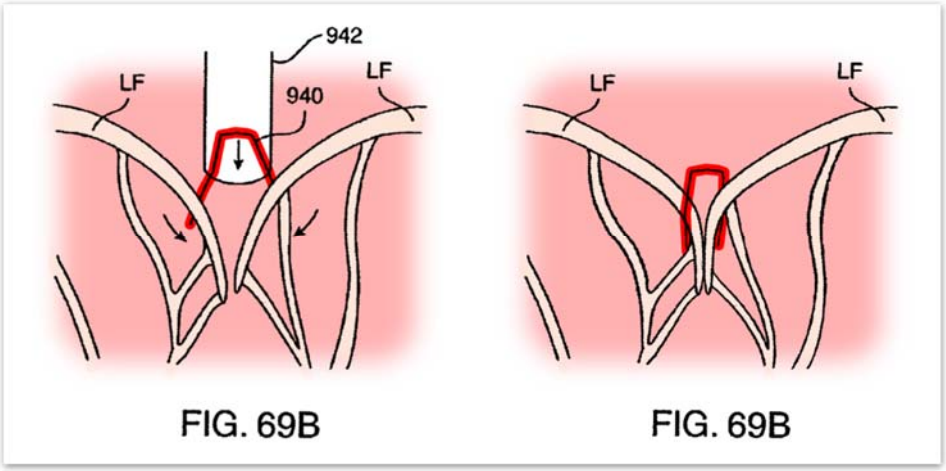
b. The Figure 69 clip transitions between open and closed states

St.Goar's Figure 69 clip has a first "open" state and transitions to a second "closed" state. Aklog, 108. As depicted below, the Figure 69 clip has a first state in which the arms are spread apart until the clip is "positioned in a desired location to hold the leaflets LF, as shown in FIG. 69B." St.Goar, 37:52-53. Figure 69B shows the clip in an open state:



St.Goar, Figs 69A-C (annotated); Aklog, 108.

Once properly positioned, the clip transitions to a second, substantially closed state, called the "***deployed*** and activated state," in which the arms of the clip "pinch inwardly, pulling the leaflets together," and bringing the tips of the device closer together in Figure 69B below:



St.Goar, Figs. 69B (cropped and annotated on left, modified to show closed state on right), St.Goar, 37:52-61; Aklog, 109.

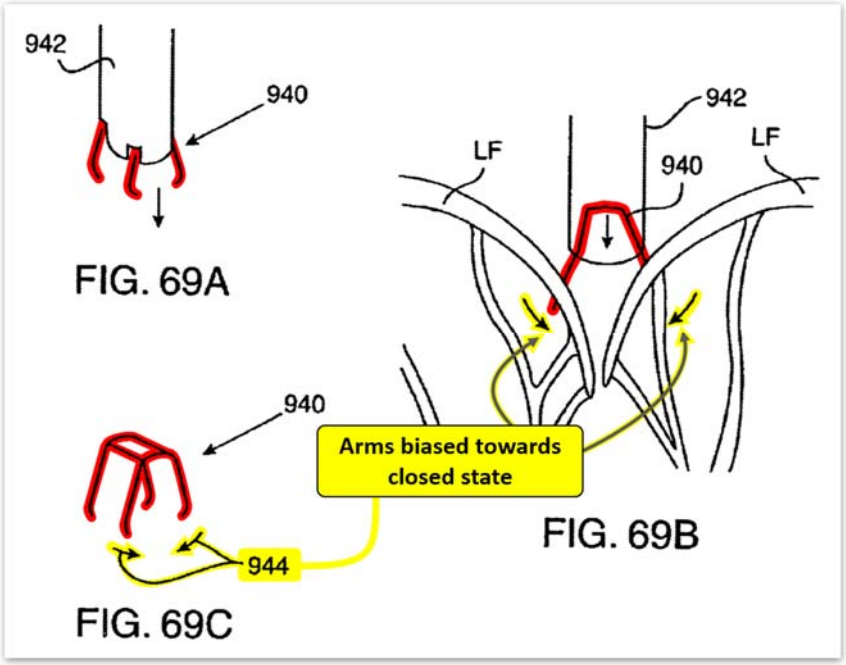
Given the disclosure that the Figure 69 clip's "deployed and activated state" pulls "the leaflets together," a POSITA would understand this state to be a closed state. Aklog, 110; St.Goar, 37:53–56, Fig. 69.

4. 1[c]—St.Goar's clips are biased towards a closed state.

This feature requires "said suturing means being biased towards its second state." St.Goar discloses this feature under both the conventional construction (both the Figure 73 and Figure 69 clips) and under the § 112 ¶ 6 construction (Figure 69 clip only) of "suturing means." Aklog, 111-114.

First, St.Goar discloses that the Figure 73 clip "has a V-shaped structure and ***is normally closed so that a force is required to open the distal ends of the clip***." St.Goar, 38:45-47; Aklog, 112. A POSITA would understand that "normally closed" means a force is needed to keep the clip open, which means that, absent a restraint, the device of the Figure 73 clip (the claimed suturing means) automatically assumes its closed state. *Id.*, 38:45-47. So, the Figure 73 clip is "biased towards its second state." Aklog, 112. Edwards has also admitted this in another proceeding. *See* Ex. 1053 at 52 ("[T]he clip (388) draws the leaflets closer together because of the 'normally closed' ***bias*** (i.e., clipping force) of the clip."). Aklog, 113.

Second, St.Goar explains that the Figure 69 clip, "[i]n the deployed and activated state … may tend to pinch inwardly, pulling the leaflets together, as indicated by arrows 944." St.Goar, 37:50–56, Fig. 69. And this tendency to "pinch inwardly"—*i.e.*, to adopt a closed state—can be "achieved by activation of super elastic or shape memory material." *Id.*, 37:56–57. Here, "activation" allows the clip to assume its normally closed state. Just above that paragraph, referring to Figure 67, St.Goar explains that activating "shape memory material" allows the clip to "assume its pre-configured shape." *Id.*, 37:26–30. A POSITA would have thus understood "activation of super elastic" material to refer to endowing the material with a natural bias towards a particular configuration. Aklog, 114. And that the Figure 69 clip is biased towards its substantially closed state is also demonstrated by the "arrows 944" in Figures 69B–C below that "indicate[]" that "clip 940 may tend to pinch inwardly, pulling the leaflets together" (St.Goar, 37:53-56), where the arrows 944 depict the arms of the clip closing to bring the valve leaflets together.



St.Goar, Figs. 69A-C (annotated); Aklog, 114.

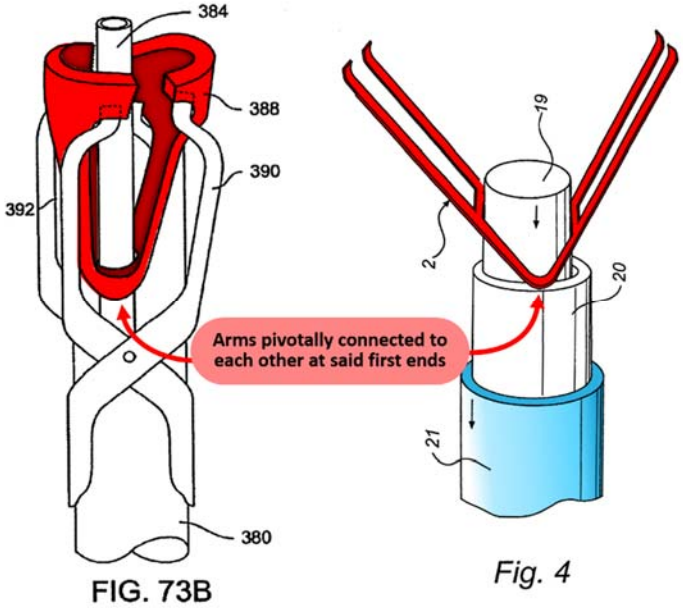
Because the Figure 69 clip is activated by "shape memory material" and "tend[s] to pinch inwardly," a POSITA would understand that this clip, absent a restraint, automatically assumes its closed state, and is "biased towards its second [substantially closed] state." Aklog, 114.

C. Claim 2 Is Anticipated by St.Goar

Claim 2 depends from claim 1 and recites that "the suturing means comprises a clip." St.Goar's Figures 73 and 69 clips each comprise a clip, as discussed above. Accordingly, St.Goar discloses this feature under both the conventional construction (both clips) and under the MPF construction (Figure 69 clip only). Aklog, 115.

D. Claim 3 Is Anticipated by St.Goar

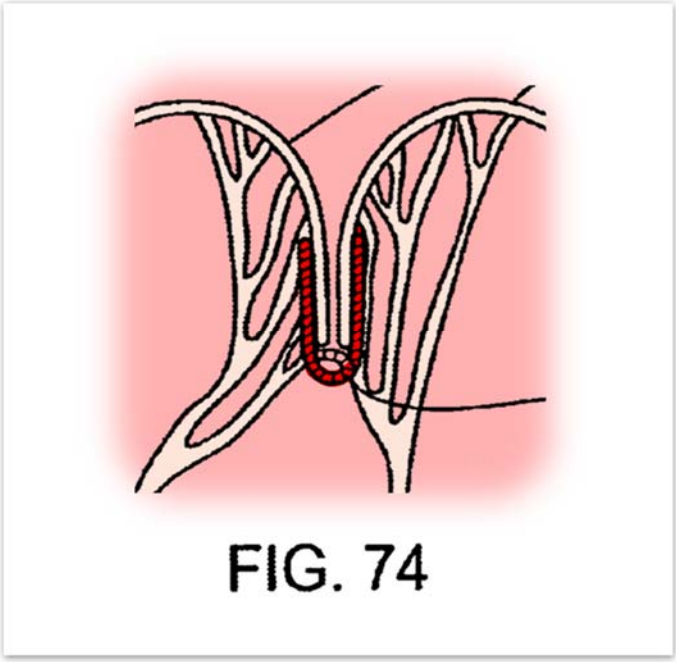
Claim 3 depends from claim 2 and recites that "the clip has two arms pivotally connected to each other at a first end thereof, the arms forming a V in the first state of the clip and being substantially parallel in the second state of the clip." The claimed "first state" and "second state" refer to "being open" and "substantially closed," as recited in claim 1[b]. St.Goar's Figure 73 clip discloses this feature. Aklog, 116-118. The Figure 73 clip has two arms in "a ***V-shaped structure*** and is normally closed so that a force is required to open the distal ends of the clip." St.Goar, 38:45-47; Aklog, 117. As shown below, the two arms of the Figure 73 clip are pivotally connected to each other at the bottom of the "V" shaped clip (oriented as it is on the page), similar to the clip in the '767 patent.



St.Goar, Fig. 73B (annotated); '767 patent, Fig. 4 (annotated); Aklog, 117. As the angle in the connection of the first ends of the two arms (at the bottom of the V) of

the Figure 73 clip is increased due to jaws 390 and 392, the arms open, because of the pivotal connection between the first ends of the two arms. Compare '767 patent, 5:4-6 ("In a first state, the arms 8-9 and 10-11 in the pairs are opened, forming a V, as the angle in their connections 14, 15 is increased"), Aklog, 117.

Furthermore, Figure 74, annotated and cropped below, shows the Figure 73 clip in its second, closed state, where the clip arms are substantially parallel to one another with the valve leaflets in between:



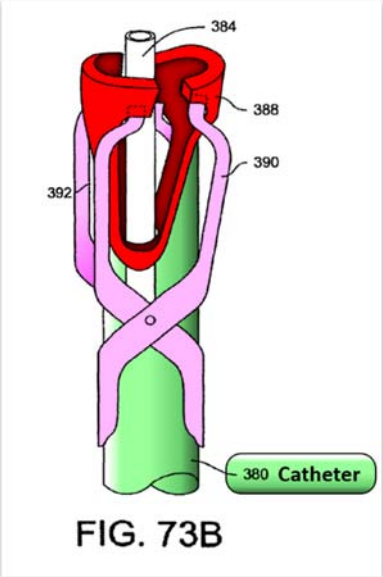
St.Goar, Fig. 74 (annotated); Aklog, 118.

E. Claim 5 Is Anticipated by St.Goar

Claim 5 depends from claim 3 and recites "further comprising a catheter for introduction of the clip via the blood vessels to the heart, said catheter having an outermost sheet covering the clip and being retractable therefrom." St.Goar

discloses the use of a guide catheter—an outermost sheet—for "introducing," *i.e.*, delivering, Figure 73 clip to the heart, and catheters having an "outer sheet" retractable from its implantable devices. Aklog, 119-123.

St.Goar discloses using a delivery catheter to introduce a clip, including Figure 73 clip discussed above regarding features 1[a]-1[c], 2 and 3 in Ground 1, via the blood vessels to the mitral valve. *See, e.g.*, St.Goar, 2:49–59, 38:36–58 (describing a "clip-applying catheter 380"), Fig. 73 (depicting catheter 380); *id.*, 31:55–59, 7:23–38 (describing retrograde endovascular approach to mitral valve), 14:38–16:11 (section entitled "Access to the Mitral Valve"), Figs. 7–10; Aklog, 120-121. The catheter 380 used to deliver St.Goar's Figure 73 clip is shown below (green).



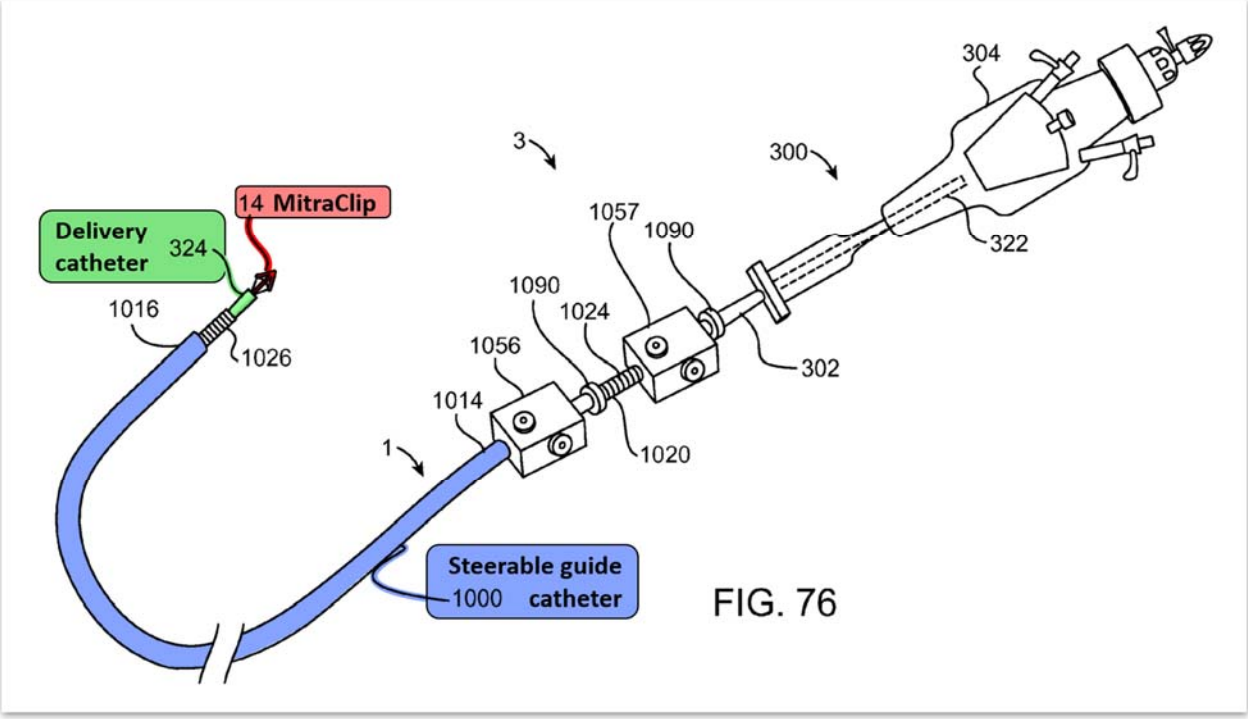
St.Goar, Fig. 73B (annotated); Aklog, 121.

1. St.Goar discloses covering clips with a guide catheter (an outermost sheet) that is retractable from the clips

St.Goar explains that "[o]ften, it will be desirable to position the interventional tool toward the target tissue structure using a preformed and/or ***steerable guide catheter***." St.Goar, 7:51–53, 8:46–56. This guide catheter can "include active steering or other positioning means," allowing it to be used "in whole or in part" to orient St.Goar's "interventional tools," such as the Figure 73 clip. *Id.*, 3:53–56, 8:27–38, 9:3–7 ("Specific interventional tools include … clip-applying devices."). Such steerable guide catheters help with "orientation of the interventional tool." *Id.*, 3:52–57; Aklog, 124, 150. This guide catheter is a catheter used for introducing the clip via blood vessels to the heart. And it is an "outermost sheet covering the clip," per Edwards's own contentions as discussed below. Aklog, 124.

Edwards asserts in the district court litigation that a "steerable guide catheter" used for delivering Abbott's MitraClip is an "outermost sheet" as claimed. Ex. 1005 ("Edwards's Infringement Contentions") Ex. A at 22 (citing MitraClip's Instructions for Use (IFU), 3); Aklog, 125-126. Specifically, Edwards alleges that the "outermost sheet of [MitraClip's] Steerable Guide Catheter is retractable from the clip," because it can be removed from the body and the MitraClip implant remains attached to the mitral valve leaflets. *Id.*, 24–25. As background, the MitraClip and its steerable guide catheter are described and claimed in US Patent 7,563,267, including in the

Figure below that shows MitraClip (14), attached to a delivery catheter (324), which is delivered through a Steerable Guide Catheter (1000).



US Patent 7,563,267 (Ex. 1039), Fig. 76 (annotated); Aklog, 126.

As the MitraClip IFU describes and the figure above depicts, MitraClip's steerable guide catheter is used in the same way that St.Goar uses a guide catheter: the guide catheter is inserted near the mitral valve, and the delivery catheter carrying the clip is introduced through the guide catheter. MitraClip IFU (Ex. 1052), 30.2.2; Aklog, 127. Once implanted, the guide catheter and the delivery catheter are retracted from the heart valve, and pulled out of the body together, leaving the clip behind. MitraClip IFU at 52-53; St.Goar, 8:29–56; Aklog, 127.

For this proceeding only, Abbott adopts Edwards's interpretation of "outermost sheet" that is "retractable therefrom" as including a guide catheter, which, like all catheters, is retractable from the body. Aklog, 128.

Under this interpretation, St.Goar's guide catheter is an "outermost sheet covering the clip and being retractable therefrom." '767 patent, cl. 5. Indeed, a guide catheter is a type of a sheath. US Patent 6,425,898 (Ex. 1032), 4:8–10 ("Often ***a sheath, such as, a guiding catheter***, is used with these delivery devices as a conduit into the vasculature."); US Patent 6,214,036 (Ex. 1028), 7:19–21 ("Apparatus 40 includes an outermost sheath ***50 which is essentially an elongated tubular member, similar to ordinary guiding catheters*** which are well known to those of ordinary skill in the art."); Aklog 129-143.

St.Goar's guide catheter is "configured to pass from the initial access location" through the patient's vasculature and heart and "into the left atrium, where it will be pre-shaped or deflected to approach the mitral valve from the top." St.Goar, 8:29–35. Then an "interventional tool," such as St.Goar's clip applying device and Figure 73 clip, may "be deployed ***through the guide catheter***." *Id.*, 8:43–45, 8:46–56, 9:3–7; so, the guide catheter covers the clip during delivery through the vasculature. Aklog, 131.

St.Goar discloses in Figure 74, annotated below, that the Figure 73 clip is delivered through a guide catheter 40 to the mitral valve leaflets.

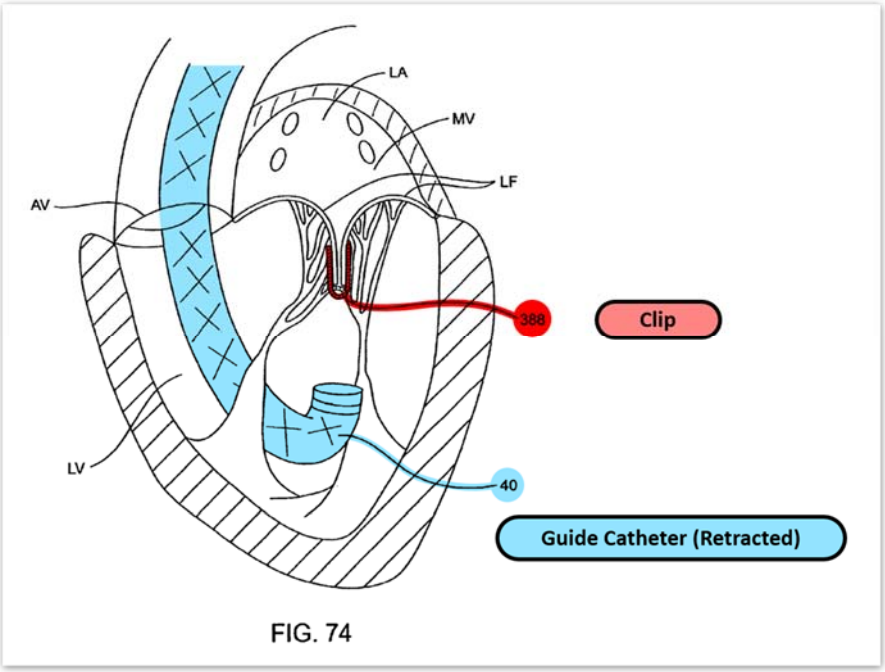


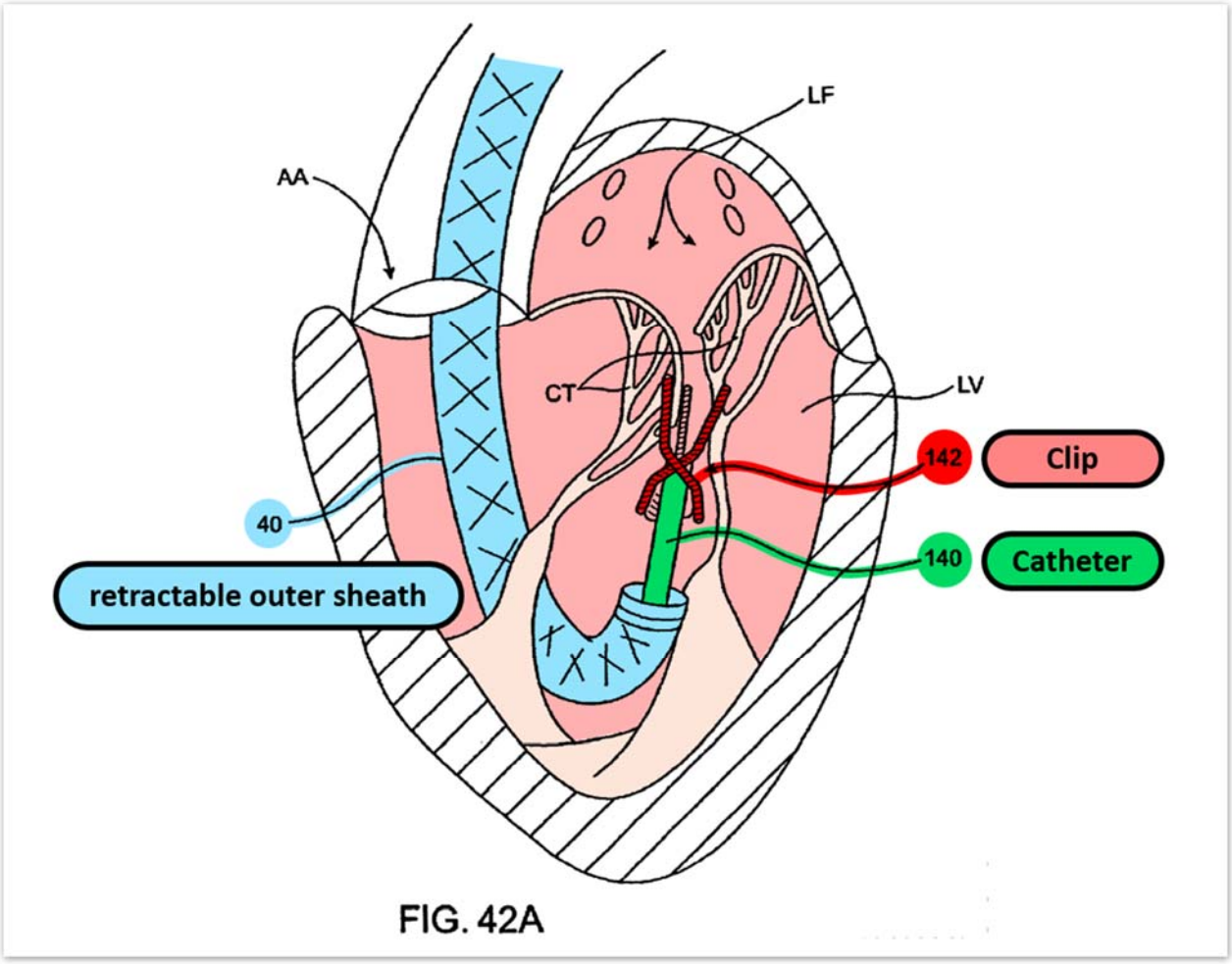
FIG. 74

St.Goar, Fig. 74 (annotated); Aklog, 132.

The element "40," shown in Figure 74, is a guide catheter with an outermost sheet. St.Goar, 16:45–49 ("Each of the guide catheters 40 shown in FIGS. 9 and 10 may find use under different circumstances."), Figs. 9–11. And as depicted in annotated Figure 74 of St.Goar above, the Figure 73 clip is delivered through the guide catheter 40, meaning it covers the clip during delivery. Aklog, 133. Then the guide catheter is retracted from the Figure 73 clip, and the clip is "detached from the [interventional/delivery] catheter and left in place." St.Goar, 38:55–57.

St.Goar also directs a POSITA to its description of Figures 42A, 42B, and 43 as describing the use of a grasping device, for details about the workings of the Figure 73 clip. *Id.*, 38:35-45; Aklog, 134. The referenced figures and corresponding description in St.Goar disclose a grasping structure mounted on an interventional

catheter 140, which is passed through the guide catheter 40 and the guide catheter is then retracted from the grasping structures, as shown in annotated Figure 42A below:

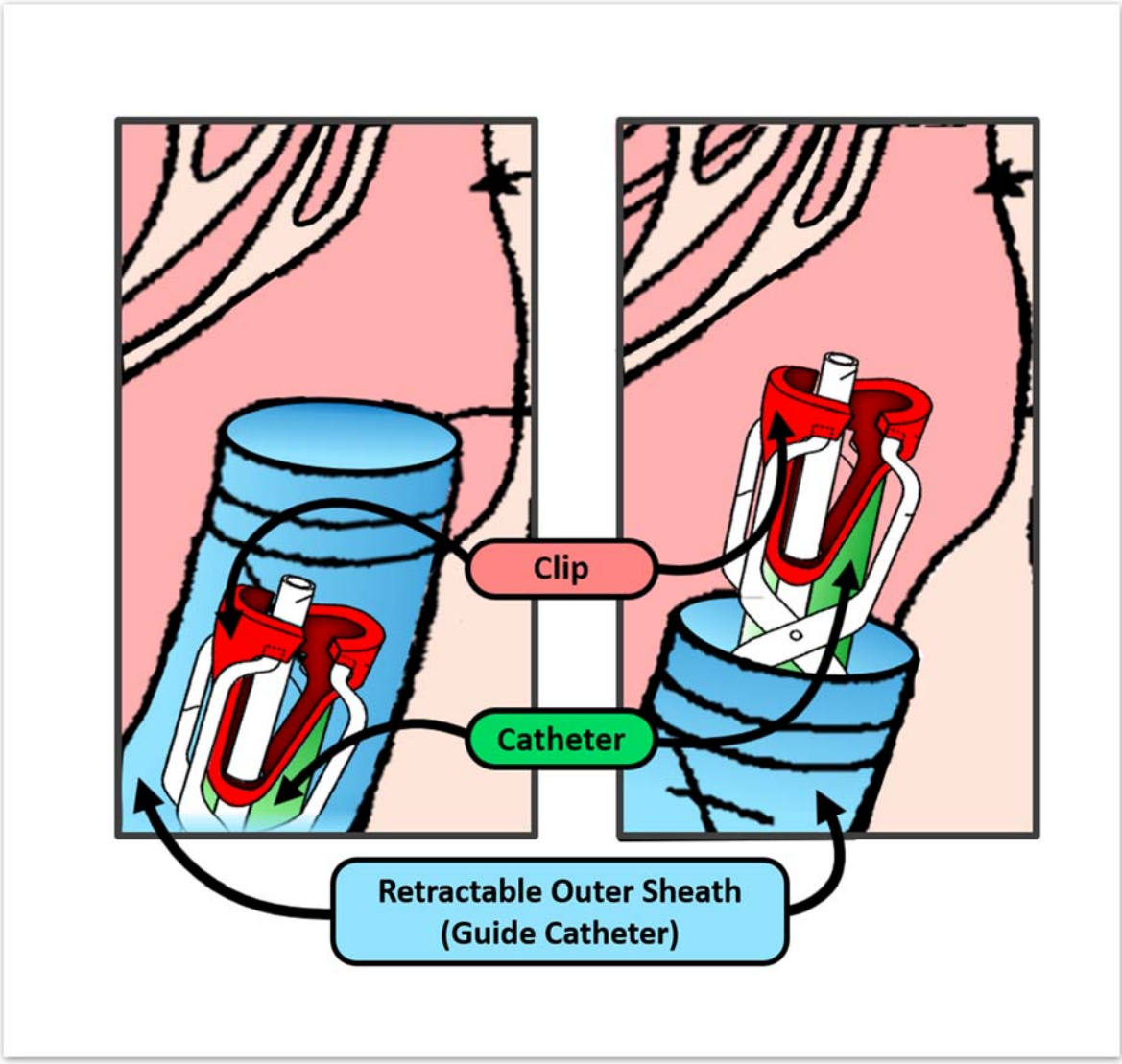


St.Goar, Fig. 42A (annotated); *id.*, 28:35–37 ("The catheter 140 can be delivered through a guide catheter generally."); Aklog, 134.

A POSITA would have understood that because St.Goar's clip applying device and the Figure 73 clip are used in the same manner as the graspers in Figure 42A, the Figure 73 clip would have the same delivery mechanism. So St.Goar discloses a guide catheter 40—which has a tubular wall (*i.e.*, an outermost

sheet)—covering the Figure 73 clip, which is attached to an interventional catheter (380), and this guide catheter is retractable from the Figure 73 clip when the clip is deployed. Aklog, 135-136.

In sum, St.Goar discloses a catheter with an outermost sheet (guide catheter 40) covering the Figure 73 clip and being retractable therefrom, as shown in modified Figure 42A below.



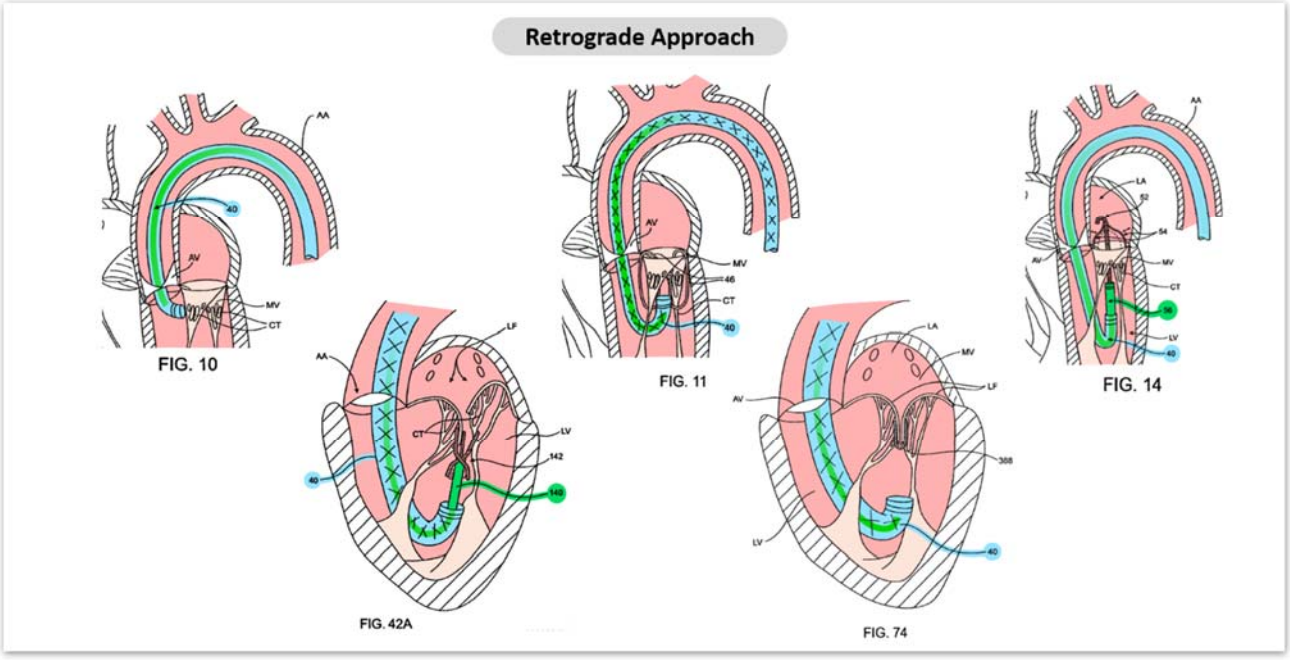
St.Goar, Fig. 42A (modified); Aklog, 136.

St.Goar's guide catheter 40 is retractable in two ways. *First*, Edwards' interpretation of "retractable" is simply that the guide catheter is withdrawn from the body, away from the implanted clip. The portion of the MitraClip IFU that Edwards cites is instructing a physician how to remove the MitraClip delivery system, including the guide catheter, out of the body after the clip is implanted. Aklog, 138-139; Ex. 1052 at 52-53. Under Edwards's interpretation, which Abbott adopts here, St.Goar's guide catheter is "retractable" because it is removed from the body to leave behind the implanted Figure 73 clip. *See* St.Goar, Fig. 74; Aklog, 137-140.

Second, a POSITA would have understood that St.Goar's guide catheter—like all guide catheters—was movable relative to the inner interventional catheter and attached elements, to enable an inner interventional catheter that holds the clip to deliver the clip. That guide catheters were retractable from an inner delivery catheter was well-known in the art. For example, Watkinson (Ex. 1046), 207, 208, teaches delivery of a balloon-expandable stent (the "Palmaz stent") with a balloon catheter and an outer guiding catheter. Watkinson at 208. Watkinson discloses that, in delivery, "the stent balloon assembly is preferentially introduced across the lesion to be treated through a guiding catheter; ***on retraction of the guiding catheter,*** balloon inflation releases the stent." *Id.*; *see also* US Patent 6,458,151 (Ex. 1035), 4:25–28 (A "guide catheter 80 may be ***advanced or retracted*** over the stent positioning device 10 to selectively allow expansion or collapse of the expandable member 20."); US

Patent 5,334,217 (Ex. 1011), 1:9–11, 13:1–3 ("[O]ne may retract the guiding catheter at any time after the delivery catheter C' is positioned on the distal side of the septal defect."); US Patent 5,906,605 (Ex. 1024), 5:24–31 ("As soon as [a basket mapping catheter] has reached the desired mapping location, the torquable ***guiding catheter 11 can be retracted*** and the basket deployed from the distal extremity thereof."); Aklog, 141.

In fact, St.Goar shows multiple figures (annotated below) showing retrograde delivery with the guide catheter (in blue) in different positions relative to the mitral valve (red) and the delivery catheter (blue). A POSITA would thus understand that St.Goar's guide catheter (40) has been retracted from the interventional tool being delivered.



St.Goar, Figs. 10, 11, 14, 42A, 74 (annotated); Aklog, 142.

Thus, St.Goar anticipates claim 5.

F. Claim 14 Is Anticipated by St.Goar

Claim 14 is an independent claim with identical limitations to features recited in 1[pre], 1[a], 1[b], claim 2, and claim 5 (but does not include the limitations of claim 3 or 1[c]). Aklog, 145. Thus, for the reasons described above with respect to features 1[pre], 1[a], 1[b], claim 2, and claim 5, St.Goar anticipates claim 14. Aklog, 145.

VII. GROUND 2: CLAIMS 5 AND 14 ARE OBVIOUS OVER ST.GOAR AND THE KNOWLEDGE OF A POSITA

This Ground demonstrates that, in addition to anticipation, adding an outermost sheet on the delivery catheter covering St.Goar's Figure 73 clip (claims 5 and 14) and Figure 69 clip (claim 14 only) wherein such an outermost sheet covers the clip and is retractable therefrom would have been obvious in view of St.Goar's guide catheter and the knowledge of a POSITA. Aklog, 146.

A. Claim 5 Is Rendered Obvious by St.Goar in View of the Figure 73 Clip and the Knowledge of a POSITA

As set forth in Ground 1, incorporated herein by reference, St.Goar's Figure 73 clip discloses every element of claim 5 of the '767 patent, arranged as in the claims (under no MPF construction only). *See* Ground 1 above. Aklog, 147-154.

Even if Edwards argues that St.Goar does not disclose that its guide catheter used with the Figure 73 clip is "retractable" from the clip, that feature would have been obvious in view of the knowledge of a POSITA. Aklog, 150-152.

As discussed above in connection with claim 5 in Ground 1, a POSITA would have understood that St.Goar's guide catheter—like all guide catheters—was movable relative to the inner catheter, to enable an inner interventional catheter that holds the clip to deliver the clip. If Edwards argues otherwise, it also would have been obvious to make a guide catheter move relative to the inner, delivery catheter, and thus retractable from the delivery catheter (380) that carries the Figure 73 clip. Aklog, 150.

A POSITA would have been motivated to use a guide catheter that was retractable. *First*, St.Goar teaches that "orientation of the interventional tool"—including Figure 73 clip—may be accomplished in whole or in part using a separate guide catheter that includes "active steering or other positioning means." St.Goar, 3:54–56. In fact, St.Goar stresses the importance of relative positioning of the guide catheter with the inner delivery catheter. *Id.*, 18:50–54 ("Both the orientation of the devices and the components of the devices, in relation to cardiac structures and to each other, are of concern."). This flexibility in "positioning means" and the need to properly position the guide catheter relative to the delivery catheter would have informed a POSITA to position the guide catheter by both advancing the delivery catheter and retracting the delivery catheter, making the guide catheter retractable from the clip. *Id.*, 8:59-62; *see also id.*, 22:5–9; 28:35–36; 29:10–13, 33:22–25, 34:36–39, 35:7–11, 40:39–50. Lauer (Ex. 1043), for example, teaches that, in the

context of another catheter-based laser angioplasty in the heart, "[g]uiding catheter and ***laser delivery*** catheter ***are freely movable against each other*** so that all areas within the left ventricular cavity can easily be reached." Lauer at 1664. So, a POSITA would have understood to make St.Goar's guide catheter movable relative to the interventional (delivery) catheter and the Figure 73 clip, and consequently make it "retractable" from the clip. Aklog, 150.

Second, a POSITA would have known to use a guide catheter as an outermost sheath to protect a patient's vasculature from damage by an abrasive clip passing through it, and vice versa. Aklog, 151. As explained below, a POSITA would have covered St.Goar's clip when navigating that tortuous vasculature which expands, contracts, twists and bends, and are generally sensitive structures highly susceptible to damage from an exposed implanted device. Aklog, 151-152; St.Goar, 22:24–26 ("[G]uide catheters are flexible along their length to facilitate introduction through the tortuous paths of the vascular system."). Besides the general notion that implantable devices should be covered when delivered through the vasculature and cardiac tissue, St.Goar's Figure 73 clip is designed with jaws to "capture" and "hold" the valve leaflets. St.Goar, 37:58–61, 38:47–53. A POSITA would have understood that these features pose a risk of (i) damaging the blood vessels during delivery, and (ii) damaging the heart from accidentally reengaging the cardiac tissue. Aklog, 151.

As the prior art teaches, a guide catheter prevents damage to a patient's vasculature during delivery of implantable devices. A guide catheter is a type of a sheath. US Patent 6,425,898 (Ex. 1032), 4:8–10 ("Often ***a sheath, such as, a guiding catheter***, is used with these delivery devices as a conduit into the vasculature."); Aklog, 152. For example, US Patent 7,153,322 (Ex. 1037) teaches that the vasculature takes a "tortuous" path, with "curves, turns, and sharp bends likely to be encountered." Ex. 1037 at 6:55–56. To navigate this tortuous path, "a guide catheter is inserted initially through the path of the vascular system to be followed by the balloon catheter-mounted stent." *Id*., 6:51–55. Other prior art references teach the use of a guide catheter as a protective sheath to protect the vasculature from the implantable device and vice versa:

- Klein (Ex. 1020), 2:29–34 ("The methods and systems … should provide for containment of the stent in the ***guide catheter during delivery to inhibit trauma to the vasculature and jamming of the stent and to prevent loss or misalignment of the stent from the delivery apparatus***.").
- Wallace (Ex. 1029), 3:63–66 ("After treatment, the balloon is deflated and the catheter 30 is extracted ***using the guide catheter as a protective sleeve***").

- Kiemeneij (Ex. 1036), 1:33–43 (A guide catheter "should also assure a good coaxiality for proper alignment with the ostium of the artery to avoid loss of push force on the guided catheter or ***the risk of trauma caused by a stent loaded balloon catheter entering the vessel*** in a misaligned condition.").

See also Ground 3, Section VIII.A *infra* (discussing more references); Aklog, 152.

A POSITA would have reasonably expected success in retracting a guide catheter with the delivery catheter of Figure 73 because retractable guide catheters were ubiquitous in the art, and St.Goar teaches that a guide catheter could and would be used for proper positioning of the clip, when introduced in retrograde fashion as in the Figure 73 clip. *See* St.Goar, Figs. 9, 14, 32A–B, 36A–B, 40, 42A–B, 43, 51, and 74 (showing a guide catheter 40 used to deliver interventional tools). Aklog, 153.

B. Claim 14 is Rendered Obvious by St.Goar in View of the Figure 73 Clip or Figure 69 Clip and the Knowledge of a POSITA

Claim 14 has identical limitations to features recited in 1[pre], 1[a], 1[b], claim 2, and claim 5, and is therefore rendered obvious by St.Goar's Figure 73 clip in view of the knowledge of a POSITA for the same reasons discussed above with respect to claim 5 in Ground 2. Furthermore, claim 14 is broader than claim 5 (*see* Section VI.F above), and is also rendered obvious in view of St.Goar's Figure

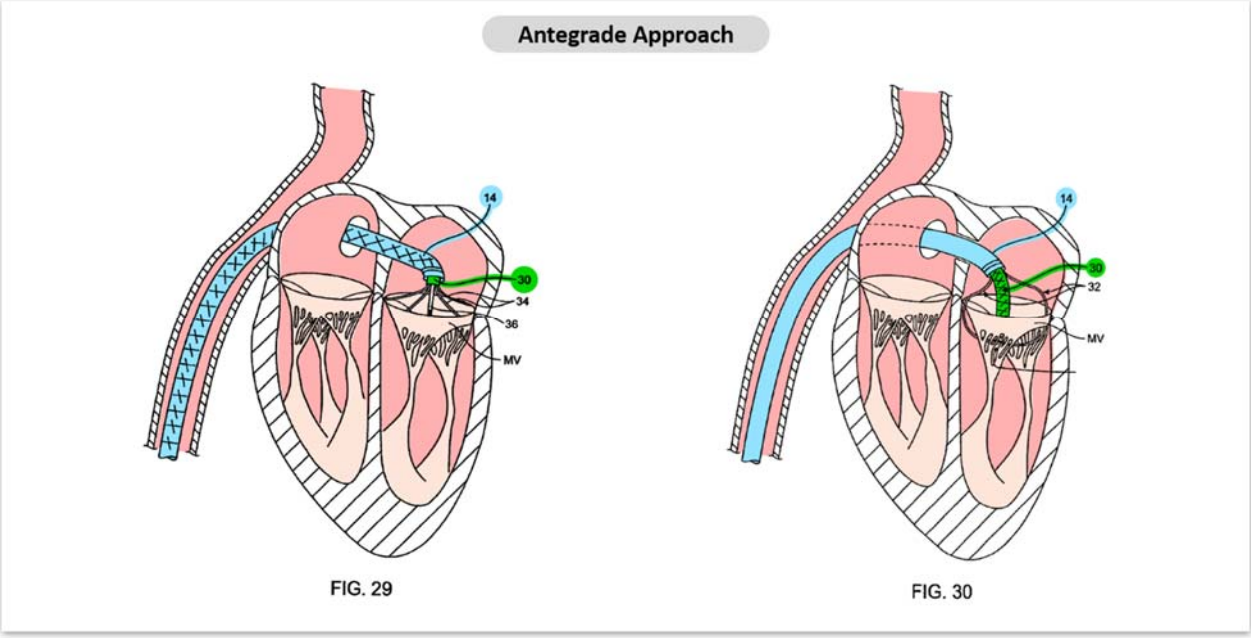
69 clip in view of the knowledge of a POSITA for the reasons discussed below. Aklog, 155-160.

A POSITA would have used a retractable guide catheter to cover St.Goar's Figure 69 clip. *First*, the Figure 69 clip is delivered with an antegrade approach, which requires access from the right atrium through the interatrial septum to the left atrium. Aklog, 157. And St.Goar teaches that "access through the interatrial septum IAS will ***usually be maintained by the placement of a guide catheter 14***." St.Goar, 15:12–15. A POSITA would have thus used St.Goar's guide catheter to access the left atrium through the interatrial septum to deliver the Figure 69 clip, and prevent damage to cardiac tissue and the vasculature. Section VII.A above; *id.*, Aklog, 157-158.

Second, St.Goar explains that the "ability to position the guide catheter will be of great benefit in performing the specific interventions and valve modifications described hereinafter," (St.Goar, 17:10–12) and that the guide catheter "may be provided with steering capabilities." *Id.*, 16:65–17:7; *id.*, 18:49–56 (describing the importance of relative positioning of various devices used for delivery). *Id.*, Figs. 29, 30; Aklog, 157.

In sum, a POSITA would have been motivated to use a guide catheter (with the delivery catheter 942) to deliver St.Goar's Figure 69 clip, to (1) access the left atrium and protect the patient's vasculature from damage caused by the sharp edges

of the clip, and (2) properly position the clip relative to the valve leaflets. *See* Section VI.E; Aklog, 158. And as discussed in Section VI.E above, a POSITA would have known that the guide catheter was retractable. Aklog, 148-153. Indeed, St.Goar discloses many figures with the guide catheter 14 covered and was retracted from the interventional tool after the tool was delivered via the antegrade approach:



St.Goar, Figs. 29, 30 (annotated); Aklog, 158.

A POSITA would also have had reasonable expectation of success in adding a guide catheter to the delivery system of the Figure 69 clip because (a) guide catheters were well known, and (b) St.Goar explicitly shows several examples of the use of guide catheters to deliver interventional tools in an antegrade manner. *See* St.Goar, Figs. 8, 26, 27, 29, 30, 60, 66, 78, 81, 82, and 84 (showing element "14" through which interventional tools are introduced). Aklog, 160.

VIII. GROUND 3: CLAIMS 5 AND 14 ARE OBVIOUS OVER ST.GOAR, THE KNOWLEDGE OF A POSITA, AND GARRISON

If Edwards argues that a guide catheter, such as expressly disclosed in St.Goar, is not an "outermost sheet covering the clip and being retractable therefrom," as claimed in claims 5 and 14, those claims would nevertheless have been rendered obvious by St.Goar's Figure 73 clip in view of US Patent 6,425,916 ("Garrison") (Ex. 1009), and the knowledge of a POSITA. Claim 14 also would have been rendered obvious by St.Goar's Figure 69 clip in view of Garrison, and the knowledge of a POSITA. Aklog, 161-171.

A. Retractable Sheaths Were Well-Known in the Art and Taught by Garrison

An "outermost sheet" was widely known and used with delivery catheters to deliver devices through the vasculature of a patient. St.Goar's clips, like the clip of the '767 patent, are delivered through a patient's vasculature. For example, in one approach disclosed in both the '767 patent and in St.Goar, the clips are delivered on a catheter that is inserted through the patient's femoral vein, typically accessed near the groin, and the catheter and clip are then navigated within that vein all the way to the heart. '767 patent, 6:28–51; St.Goar, 8:21–45; Aklog, 162.

POSITAs understood in August 2000 that implantable devices, particularly ones having sharp structures (here, sharp tips) for engaging cardiac tissue, need to be delivered in a covered state for passage through the vasculature to prevent

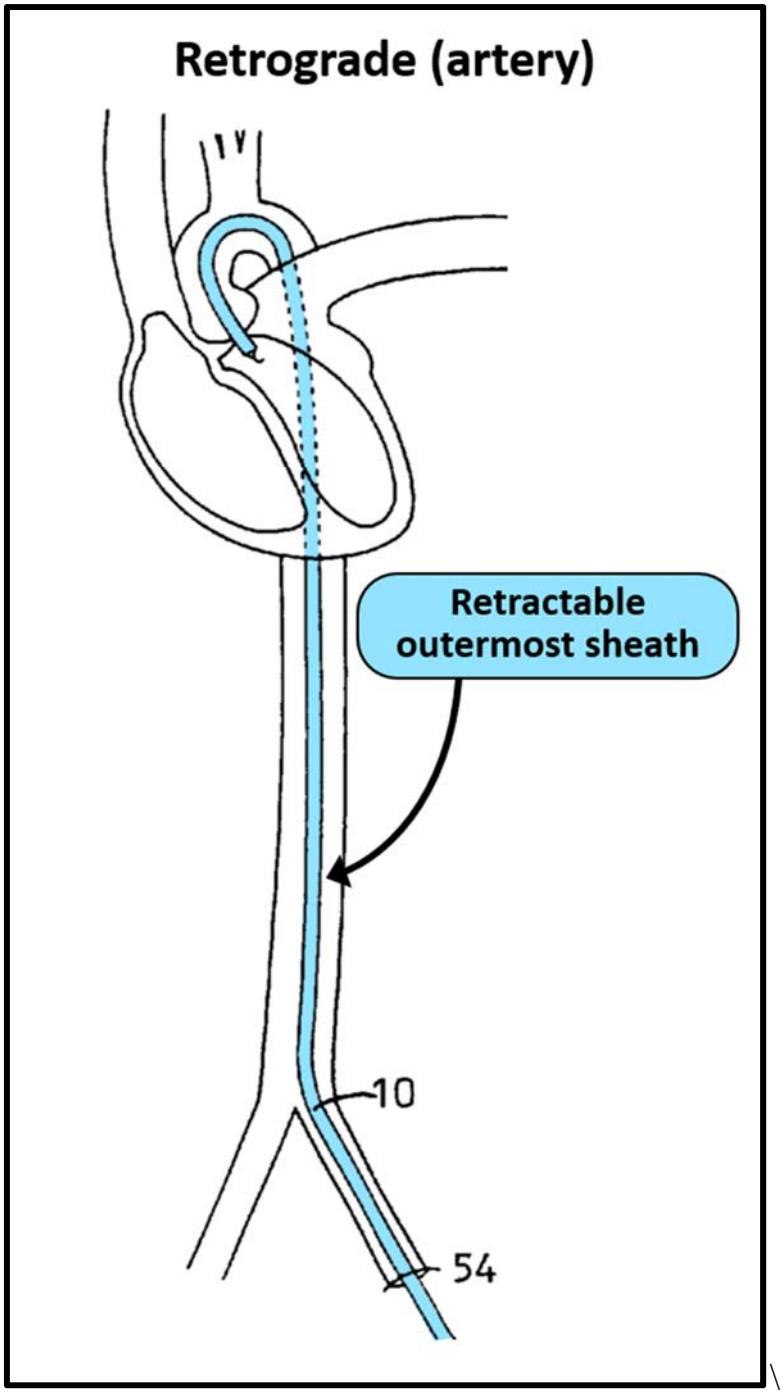
damaging and puncturing the blood vessels or cardiac tissue within the heart. Aklog, 162, 184.

Garrison is titled "Methods and Devices for Implanting Cardiac Valves," was filed on February 10, 1999 and issued on July 30, 2002, and is § 102(e) prior art. Garrison was not cited during prosecution of the '767 patent. Garrison is directed to a system for implanting a replacement cardiac valve, including a replacement atrioventricular valve, without requiring open-heart surgery. Garrison, 4:12–15. Importantly, Garrison describes that its valve replacement device can be introduced percutaneously on a catheter either "through a peripheral vessel such as the femoral artery" or "through the femoral vein, into the right atrium, through the intraatrial septum and into the left atrium to access the ***mitral valve***." *Id*., 4:23–29. These are identical to St.Goar's and the '767 patent's "antegrade" and "retrograde" approaches for delivering the mitral valve repair clips discussed in Ground 1 above. Aklog, 163.

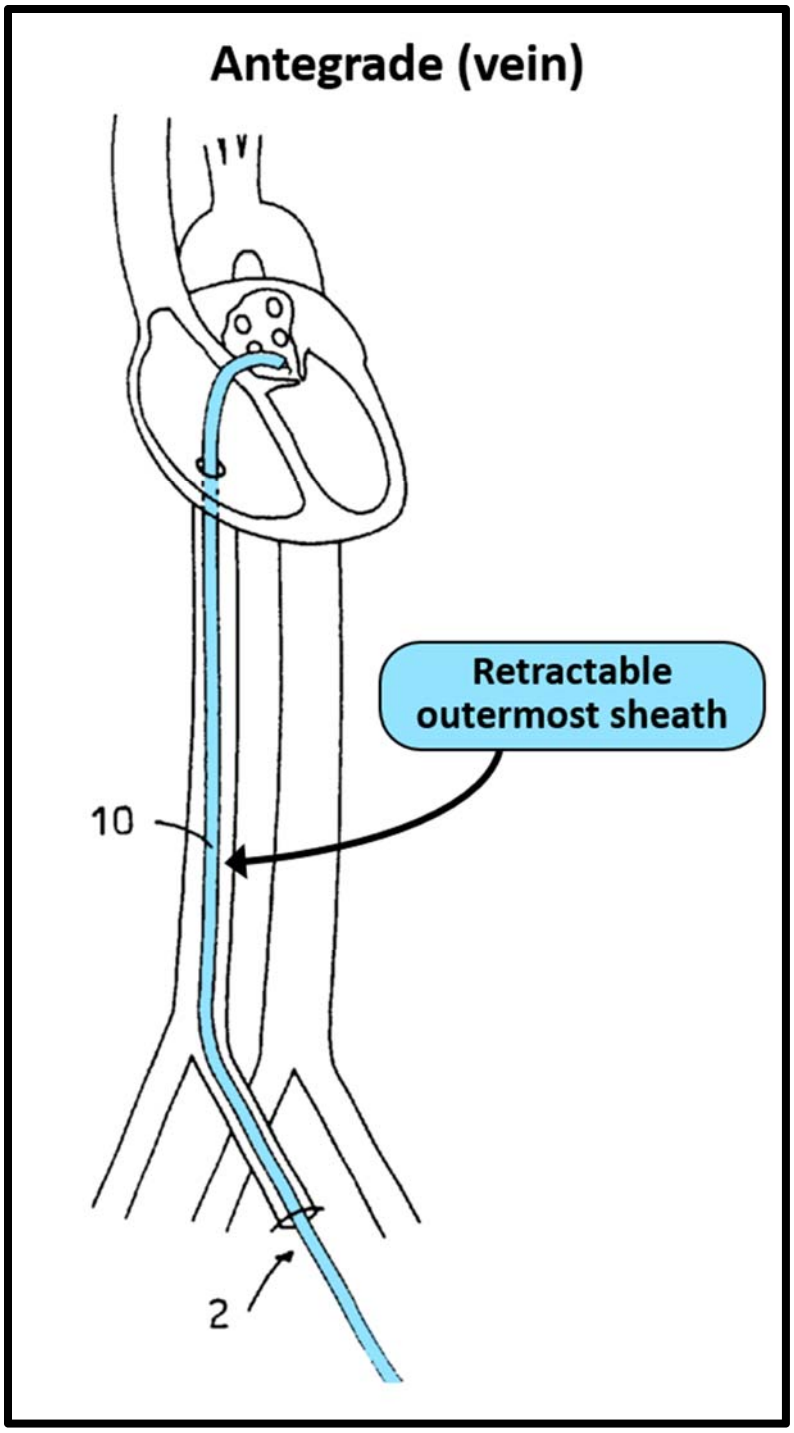
Garrison teaches that the system for implanting the replacement cardiac valve includes "a delivery catheter 4, a cardiac valve 6 and a valve displacer 8" and a "***protective sheath*** 10 [that] covers the delivery catheter 4, cardiac valve 6 and valve displacer 8 during introduction to prevent contact between the blood vessel" and the implanted device. Garrison, 4:15–20. Once the replacement valve is properly positioned, the sheath 10 is "***retracted to expose the cardiac valve 6*** and valve displacer 8." *Id.*, 4:20–23; Aklog, 164. The valve may then "be expanded with an

expansion mechanism, such as a balloon, or may be self-expanding." Garrison, 2:4–5.

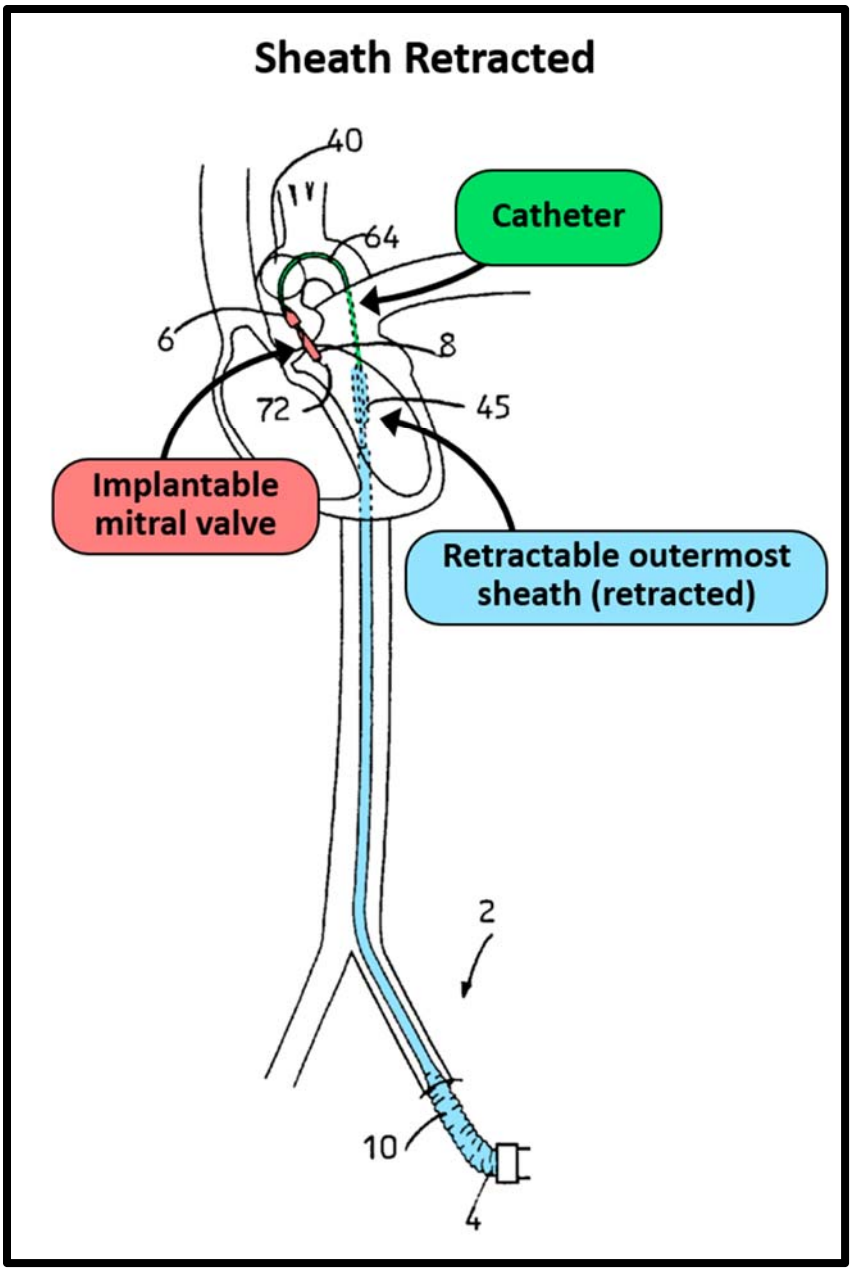
The retractable outermost sheath is shown covering the implantable replacement valve in annotated Figures 1A and 1B below, corresponding to a retrograde and antegrade delivery respectively, and after the sheath has been retracted in annotated Figure 2. Aklog, 165-168.



Garrison, Fig. 1A (cropped, annotated); Aklog, 165.



Id., Fig. 1B (cropped, annotated); Aklog, 165.



Id., Fig. 2 (cropped, annotated); Aklog, 167.

Garrison explains that it is "preferable" to use such a retractable protective sheath that (1) prevents contact with the blood vessel "when the catheter 4A is advanced through the blood vessel," and (2) prevents contact between the

implantable device and the blood vessel or the native valve once inside of the heart. Garrison, 4:19–22, 7:38–47, 8:41–43, 11:16–19. Aklog, 169.

Further, protective "outermost sheets" were ubiquitous for covering an implantable device delivered through a patient's vasculature:

- Kim (Ex. 1030), 4:58–61 ("The ***outer sheath is withdrawn proximally to expose the stent*** at the selected delivery site, and the stent is expanded to an enlarged condition with the expandable member.");
- Lau (Ex. 1012) ("protective sheath" covering a stent that can be retracted);
- Bevier (Ex. 1027), 2:52–68 ("This ***sheath*** is permanently mounted about the balloon catheter, yet ***able to slide in a proximal direction from the stent-covering position, to uncover the stent*** during inflation of the balloon and expansion of the stent");
- Goodin (Ex. 1025), Abstract (discussing a stent "carried by a delivery device within an axially retractable ***sheath*** at the distal end of the catheter and is deployed by ***retraction of the sheath***");
- M.Williams (Ex. 1022), 3:58–60 ("retractable sheath ***which protects the stent and the vessel wall as the stent*** is transported through the patient's vascular system");

- Barry (Ex. 1041), 18:19–21, ("***A removable sheath is disposed over the stent to protect the vessel*** and permit selective deployment of the stent.");
- Ryan (Ex. 1010), 10:34-39 ("The sheath ***protects the interior walls of the blood vessels from abrasion*** caused by the stent as the delivery catheter is advanced through the vessel.");
- Turnland (Ex. 1013), 2:64–3:3 ("During the transportation of the stent ***protective sheath 50 protects the patient's vasculature from the stent***.");
- Martinez (Ex. 1014), 5:16–17 ("The sheath 18 ***protects the vasculature from trauma*** that could be caused by tracking of the stent 24.");
- Del Toro (Ex. 1021), 4:10–15 ("During the placement of the stent, protective distal sheath 14 protects the patient's vasculature from the stent 18.");
- Edoga (Ex. 1017), 19:29–32 ("The sheath protects the blood vessel.");
- Priestley (Ex. 1045), 439 ("ACS Multi-Link® stent … is protected by a retractable sheath.").

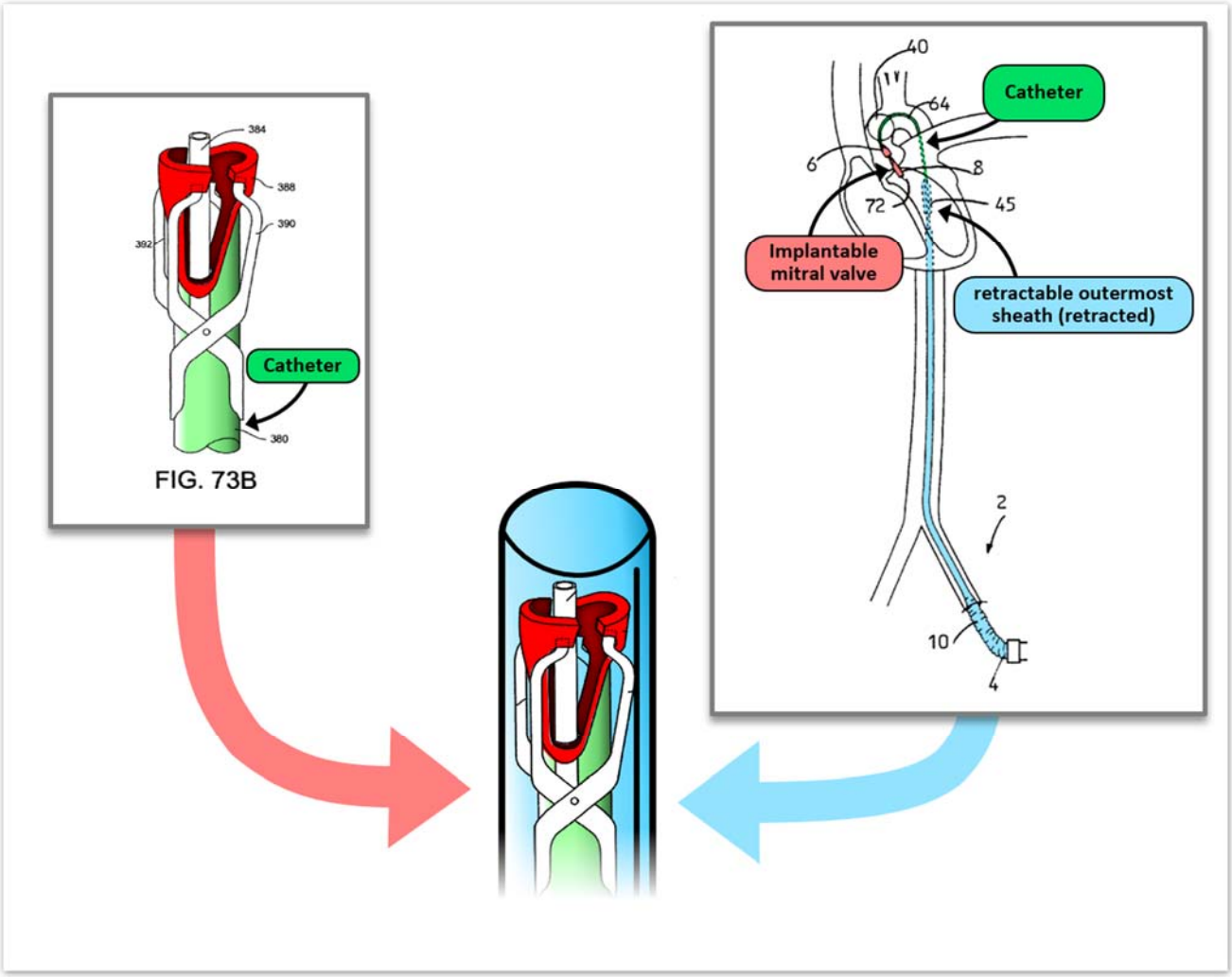
Aklog, 170-171.

B. Claim 5 Is Rendered Obvious by St.Goar's Figure 73 Clip in View of Garrison

All features of claim 5 are disclosed by St.Goar for the same reasons discussed above in Ground 1, incorporated here by reference. Furthermore, the "outermost sheet" feature of claim 5 would have been obvious in view of St.Goar's Figure 73 clip and Garrison. Aklog, 172-208.

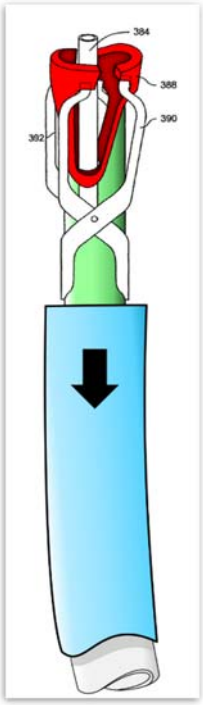
1. A POSITA would have found it obvious to add a retractable outermost sheath, as disclosed in Garrison, to St.Goar's delivery catheter of Figure 73 clip

A POSITA incorporating St.Goar's Figure 73 clip and corresponding delivery catheter shown in Figure 73 with a retractable outermost sheath covering the clip as disclosed in Garrison would have arrived in the configuration like that illustrated below (annotated):



St.Goar, Fig. 73B (modified); Aklog, 173.

And performing the obviously necessary step of retracting the sheath is illustrated below:



St.Goar, Fig. 73B (modified); Aklog, 174.

2. St.Goar and Garrison are analogous prior art

St.Goar and Garrison are analogous art. Prior art is analogous either if "the art is from the same field of endeavor, regardless of the problem addressed," or "if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010).

St.Goar and Garrison meet both *Wyers* prongs. Aklog, 176-180. They are from the same field of endeavor as the '767 patent: they both disclose implantable

devices delivered through the vasculature for curing heart valve defects, and the implantable devices were used by the same interventional cardiologists. St.Goar, 2:49-59; Garrison, 1:55-66; Aklog, 177. St.Goar teaches devices for treating mitral valve repair using implantable devices introduced through blood vessels, whereas Garrison teaches a delivery system to introduce replacement cardiac valves through blood vessels, including delivery to the mitral valve. Aklog, 177. Further, they both are reasonably pertinent to the same endeavor as the '767 patent: both seek to place devices into the heart with minimally invasive techniques without damaging the patient's blood vessels or cardiac tissue, or damaging or dislodging their heart valve repair/replacement implants. St.Goar, 1:53–56 (describing the desire to provide methods and devices "for performing the repair of mitral and other cardiac valves" without open heart surgery); Garrison, 1:49–52 ("An object of the present invention is to provide additional devices and methods which reduce the trauma associated with conventional open-chest methods and devices for implanting cardiac valves."); Aklog, 179.

3. Motivation to combine St.Goar with Garrison

A POSITA would have been motivated to combine the teachings of St.Goar and Garrison, and would have expected that the teachings could be combined with a reasonable expectation of success, because both describe devices for addressing deficiencies in a mitral valve by implanting a device in the heart. Aklog, 181-188.

A POSITA would have been specifically motivated to modify St.Goar's delivery catheters used for the Figure 73 clip to incorporate a retractable outermost sheath, as disclosed in Garrison to:

a. protect a patient's blood vessels and cardiac tissue from being damaged as the clips are delivered;
b. protect the clips from damage, or dislodgment during delivery;
c. improve the positioning and repositioning of St.Goar's clips.

Aklog, 181.

a. Protect blood vessels from damage by the clips

As discussed in the Ground 2 overview above, St.Goar's clips are delivered (pushed) through important veins or arteries in a patient, such as the femoral vein or femoral artery. The access point for that vasculature is at the patient's groin, and thus to get to the heart, the clip and delivery catheter must traverse multiple bends and turns before reaching the heart. St.Goar, 7:50–61; Aklog, 183. Moreover, St.Goar discloses that the clips are generally delivered while the heart is still beating, meaning the patient's heart will expand and contract as the clip is being delivered—and the blood vessels and cardiac tissues are constantly moving. St.Goar, 6:17–19 ("In all the aspects of the method described above, the heart will usually remain beating while the interventional tool is engaged against the tissue structure."); Aklog, 183.

A POSITA would have known that a retractable sheath could be used with St.Goar's Figure 73 clip to protect a patient's vasculature and a beating heart's cardiac tissue from the sharp tips of the clip, and that doing so was desirable in further view of Garrison, as well as the knowledge of a POSITA. Aklog, 184.

Garrison explains that it is "preferable" to use a retractable protective sheath around an implantable device to (1) prevent contact with the blood vessel "when the catheter 4A is advanced through the blood vessel," and (2) prevent contact between the implantable device and the blood vessel or the native valve once inside the heart. Garrison, 4:19–22, 7:38–47, 8:41–43, 11:16–19; Aklog, 185; Bevier, 3:11–15 (describing use of a stent delivery system with a retractable sheath "which surrounds and guides the stent delivery system into a position near the desired site"). A POSITA would have turned to Garrison's teachings, as Garrison discloses delivering an implantable device to a mitral valve through the vasculature in the same ways as St.Goar discloses delivering its Figure 73 clip, indicating that a similar outermost protective sheath (instead of or in addition to St.Goar's guide catheter) could be used with a reasonable expectation of success.

Several other prior art references establish that protecting a patient's vasculature from implantable medical devices delivered through tortuous blood vessels to a patient's heart was a well-known problem, and that delivery catheters with retractable sheaths were a common and well-known technique for addressing

that problem. For example, US Patent 5,776,140 ("Cottone") (Ex. 1019) teaches introducing implantable medical devices into blood vessels using a retractable sheath, rather than a guide catheter: "By this invention, a stent may be implanted without the need for a pre-emplaced guiding catheter while ***body tissues through which the stent is advanced are still protected from scraping by the irregularities*** that are typically found in a stent. This is accomplished with little increase in the diameter of the overall system." Cottone, 1:26–34. Cottone's solution was to use a delivery catheter that carries "an outer, semi-flexible sheath surrounding at least part of the catheter and the stent." *Id*., 1:44–51; 2:13-21 ("***walls of blood vessels or other body lumens may be protected by the sheath*** from injury by the advancing stent, while the stent also may be protected from bending or damage if it is forced past a calcified area."); Aklog, 186.

Further, it was known, and St.Goar explicitly contemplates, using a delivery catheter with a retractable sheath, as in Garrison, with a guide catheter. St.Goar discloses the use of a sheath to cover pointed prong graspers (disclosed in Figure 83), even when the device was also delivered using a guide catheter. St.Goar, Fig. 83, 40:51–41:21 (referring to Figure 83, which shows retractable grasping sheath 1020 covering prongs 1021 of graspers using a guide catheter 14). And it was well known in the art to use both a guide catheter and a delivery catheter having an outermost sheath to deliver a cardiac implant. Bevier, 3:11–15 (describing

the use of a stent delivery system with a retractable sheath "in ***conjunction with an outer guiding catheter***, which surrounds and guides the stent delivery system into a position near the desired site"); US Patent 6,379,365 (Ex. 1031), 6:66–7:7 ("The operation of the stent delivery system is depicted in FIGS. 5-9, may be inserted percutaneously along a guidewire and within an ***outer guiding catheter*** (not shown), until the guiding catheter distal end reaches the vicinity of the desired site. … The ***sheath*** is then partially retracted to uncover the stent."); US Patent 6,443,979 (Ex. 1034), 6:9–12 ("Referring now to FIG. 4, ***sheath device 10 is retracted into guiding catheter 30***, by adjusting the position of deployment catheter 20 relative to guiding catheter 30, thereby exposing stent-delivery catheter 60 and stent 70."); Aklog, 187.

Several other references discussing the use of retractable sheaths to protect blood vessels from damage are discussed in the overview of Ground 2 above, incorporated by reference here. In view of this knowledge of a POSITA, it would have been obvious to cover St.Goar's clips with Garrison's delivery catheter's outermost retractable sheath to protect the patient's vasculature and cardiac tissue from the clips, and the clips from the patient's body, as addressed next. Once a protective sheath is used, it must be retractable as well as protective, as the device must be exposed before implantation in the body.

b. Protect St.Goar's clips from damage or dislodgement

A POSITA would have also been motivated to cover St.Goar's Figure 73 clip with a retractable outermost sheet to prevent damage or dislodgement of the clips as they were being transported through the vasculature. Aklog, 189-191. For example, a POSITA would have understood that when delivering St.Goar's clip, bending or damage could occur if the device was uncovered and "forced past a calcified area." Cottone, 2:17–21; Aklog, 190. This problem was routinely addressed using a retractable sheath. Cottone, 2:17–21 (teaching the use of a sheath to protect a stent "from bending or damage if it is forced past a calcified area"); US Patent 5,489,288 at Abstract (a retracting sheath for "protecting the suture during introduction"); US Patent 5,108,416 (Ex. 1010), 10:34-39 ("The sheath protects the interior walls of the blood vessels from abrasion … and also prevents the stent ***from inadvertently slipping off the distal end of the delivery catheter*** when the delivery catheter is moved proximally."); US Patent 5,453,090 (Ex. 1014), 5:18-21 ("The sheath 18 minimizes the possibility of ***dislodgement of the stent 24*** from the balloon 20 during tracking of the stent 24 and the balloon 20 through the vasculature.").

A POSITA would have understood that St.Goar's mitral valve repair clips could be improved in the same way (adding an outermost sheath retractable from the clip), to achieve the same result (protecting the clip from damage or dislodgement

while traversing a patient's vasculature on its way to the heart). *See* St.Goar, 2:49–59; 37:50–56; 38:36–58; Aklog, 191.

c. Improved positioning and repositioning of St.Goar's clips

St.Goar expressly recognizes the need to perform "repositioning steps" when placing its clips "until a position is identified in which the regurgitation is sufficiently inhibited." St.Goar, 5:13–17, 4:49–53 (explaining that after the interventional tool captured the valve leaflets and "prior to affixation [of the device], the valve leaflets may be ***positioned*** and, if necessary, ***repositioned*** in order to determine that a particular cooptation and affixation are capable of inhibiting the valve regurgitation"). But, as discussed, a POSITA would have understood that positioning or repositioning St.Goar's Figure 73 clip could cause damage to the cardiac walls unless the jaws were covered. Because St.Goar does not expressly disclose how to cover the Figure 73 clip, a POSITA would have been motivated to look to other disclosures in St.Goar for positioning and repositioning the clips. Aklog, 192-196.

One method disclosed by St.Goar for positioning and orienting devices is the use of a retractable guiding sheath, as discussed above. St.Goar states, for example, regarding the graspers of Figure 83, that the prongs may be deployed by "either ***retraction of the grasping sheath 1020*** or advancement of the prongs 1021 beyond the grasping sheath 1020." St.Goar, 41:10–17. And a POSITA would have been

specifically motivated to use a sheath that could be retracted (as opposed to pushing the clip out of the sheath) to enable more precise clip placement. Aklog, 193-194. For example, St.Goar explains that "retraction of the sheath 1020 does not significantly affect the position of the graspers, thus enabling the user to contact the valve leaflets LF1, LF2 with the prongs 1021 housed within the sheath 1020 and then to initiate grasping the leaflets at the contacted location by retracting the grasping sheaths." St.Goar, 41:12–21; Aklog, 193-194.

In other words, a retractable outermost sheath would allow St.Goar's clips to be covered until they were positioned to engage the mitral valve leaflets, thus minimizing risk to the cardiac vessels from the clip. Aklog, 194. A POSITA would have understood that positioning and repositioning St.Goar's clips with a retractable sheath in this way was commonly used for other types of implantable medical devices. *See, e.g.*, Masura (Ex. 1044), 391 (describing that its septal occluder device "could be retracted back inside the delivery sheath" if "there was device misplacement"); Williams (Ex. 1047), 287 ("retractable sheath design (Magic Wallstent), allowing ***repositioning of the stent***, greater trackability, and greater accuracy in deployment"); US Patent 7,157,361 (Ex. 1038), Abstract ("[R]etraction of the sheath deploys the stent," whereas "retracting the core returns the distal portion of the stent into the sheath."), *id.*, 7:52–56 (So, a "surgeon after partially deploying a stent can, upon observing a problem such as incorrect positioning or the

like, ***retract the stent within the sheath 24 and then reposition the distal end 13 at a selected location*** and commence deployment of the stent."); US Patent 6,214,036 (Ex. 1028), 7:56–62 ("[I]f the physician decides that the placement of the stent as shown in FIG. 4 is incorrect, he would then push on the outer member of the apparatus while keeping the inner member stationary, thereby resulting in the stent ***being retrieved or retracted within outer sheath 50 so that the physician could reposition the stent.***"); Aklog, 195.

d. Reasonable expectation of success in adding Garrison's retractable outermost sheath to St.Goar's Figure 73 clip

A POSITA would have understood that adding a retractable outermost sheath to St.Goar's clips would have a reasonable expectation of success. Aklog, 197-208. *First*, as described above, use of retractable outermost sheets was commonplace and widely described. There were many commercial stents, which are devices used by the same interventional cardiologists who implant mitral valve repair devices, which used outermost sheets. Abbott's Multi-Link stent, which was introduced in 1996, was one example. Priestley (Ex. 1045), 439 ("ACS Multi-Link® stent mounted on an elastic membrane which covers the delivery balloon. The stent is protected by a retractable sheath."); Aklog, 198.

Second, St.Goar, like Garrison, teaches the use of outermost sheaths to cover certain interventional tools delivered through the vasculature—a sheath would

readily accomplish this purpose. St.Goar teaches that graspers for temporarily holding the mitral valve leaflets together are delivered to the mitral valve in the same way as St.Goar's clips and include a retractable outermost sheath. Aklog, 200-201; St.Goar, 15:60–16:11, 28:10–21, 31:33–63, 37:45–38:57. An exemplary grasping tool is shown in Figure 47C below, which includes a three prong "grasper 800" that is delivered to the mitral valve leaflets on a "prong-tipped tube 802" (*i.e.*, a catheter) with an outer "grasping sheath 801" (*i.e.*, an outermost sheet). Once the graspers are in the desired position to capture and hold the mitral valve leaflets together, St.Goar discloses that the prongs of the graspers are extended to grasp the tissue structure by "either extending the prongs 800 axially or retracting the grasping sheath." St.Goar, 30:14–16, Fig. 47C; Aklog, 200.

St.Goar also discloses similar three prong graspers comprising "grasping sheaths 1020 and three opposing prongs 1021 configured to partially or fully penetrate or pierce," referring to Figures 83–85. St.Goar, 40:64-41:12. The prongs are deployed by "retraction of the grasping sheath 1020," which "does not significantly affect the position of the graspers, thus enabling the user to contact the valve leaflets LF1, LF2 with the prongs 1021 housed within the sheath 1020 and then to initiate grasping the leaflets at the contacted location by retracting the grasping sheaths 1020." St.Goar, 41:10–17. Further, the "opposing prongs 1021" can be withdrawn within the grasping sheath (to cover the prongs). St.Goar, 41:18–

21 (Prongs "may be closed to grasp (pinch, partially penetrate or pierce) the leaflet tissue by advancing the grasping sheaths 1020 or retracting the prongs 1021 ***within the sheaths*** 1020."). Thus, the graspers are covered by the grasping sheath when closed and can be opened and uncovered by retracting the grasping sheath. Aklog, 201.

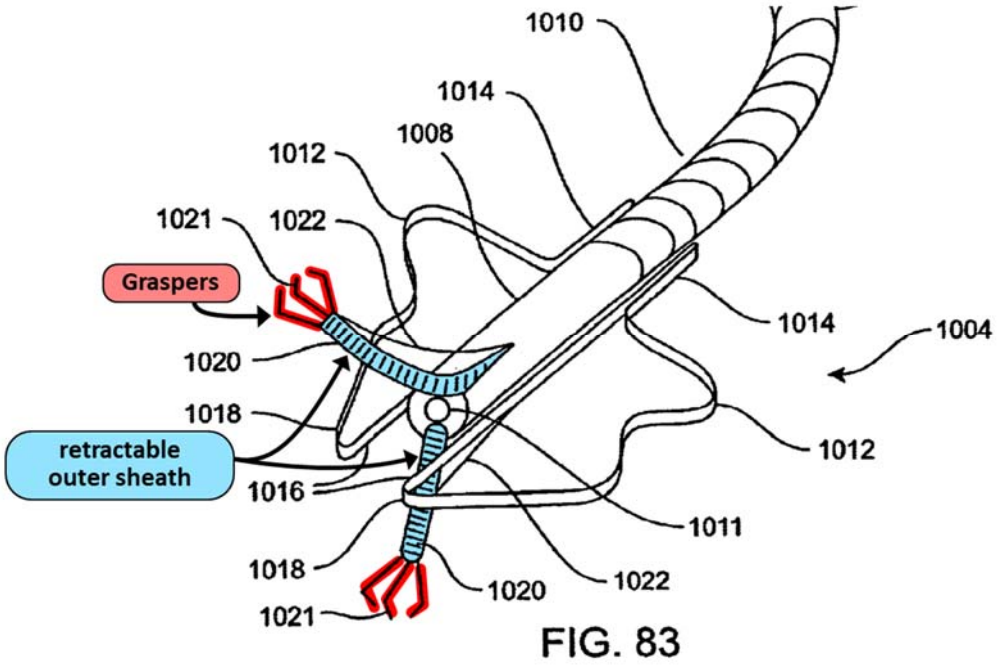


FIG. 83

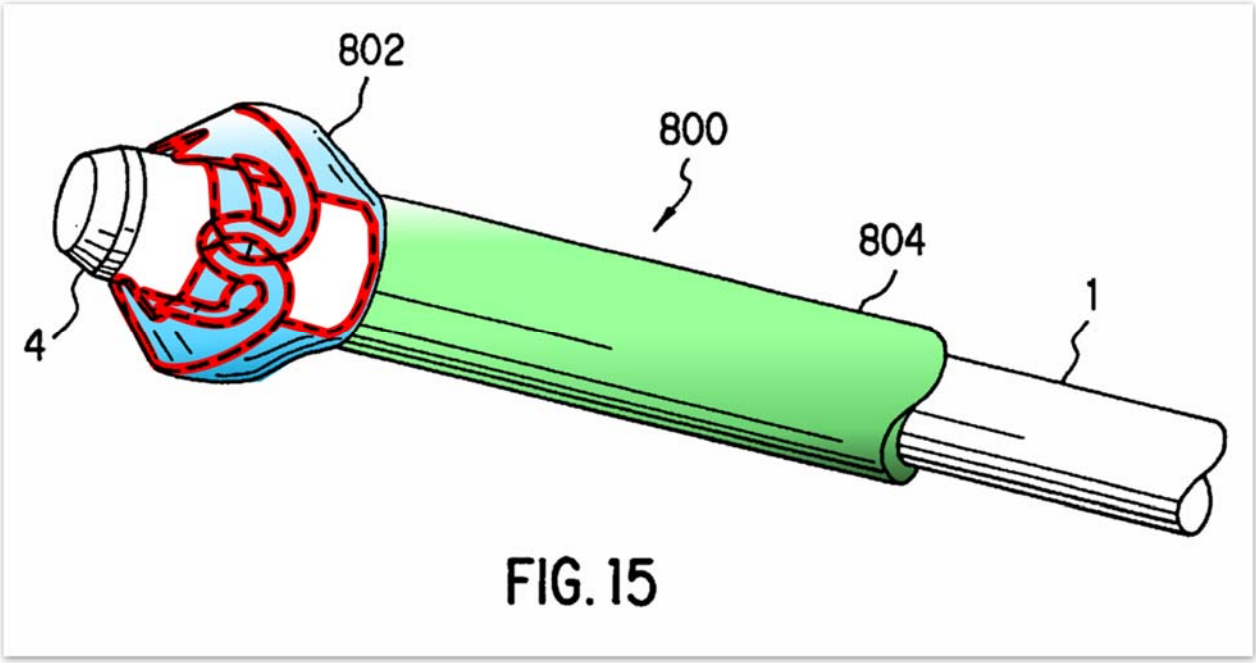
St.Goar, Fig. 83 (annotated); Aklog, 201.

Further, St.Goar even discloses that graspers "may serve as a grasping device ***and as an implantable fixation device***." St.Goar, 38:16–22. St.Goar likewise refers to its clips as "implantable fixation device[s]" and, thus, a POSITA would have understood that the techniques used to deliver St.Goar's graspers, including Garrison's retractable outermost sheath, would have a reasonable expectation of success with covering and delivering St.Goar's clips. Aklog, 203-205.

Third, using a retractable protective sheath with cardiac implants was also known. US Patent 6,428,548 ("Durgin") (Ex. 1033), for example, discloses an endoscopic surgical clip that is biased closed and used to compress body tissue. Durgin at Abstract, 6:40–45. Durgin discloses the use of a "retractable cover"—a sheath—to cover the clip to prevent injury to the patient's body tissue as the clip is being inserted:

> FIG. 15 illustrates a third embodiment for an intubation mechanism 800 that could be utilized with the present invention. Intubation mechanism 800 is comprised of a ***retractable cover 802*** which is attached to a tubular member 804. Cover 802 is movable by moving tube 804 between a first position where ***cover 802 covers surgical clip 10 and a second position where cover 802 is not disposed over surgical clip 10***. By covering surgical clip 10 with cover 802, the ***walls of the lumen are protected from potential injury from surgical clip 10***.

Durgin, 12:53-65; Aklog, 206. Durgin's clip is shown below, with the green being the "retractable cover" and the red the clip:



Durgin, Fig. 15 (annotated); Aklog, 206.

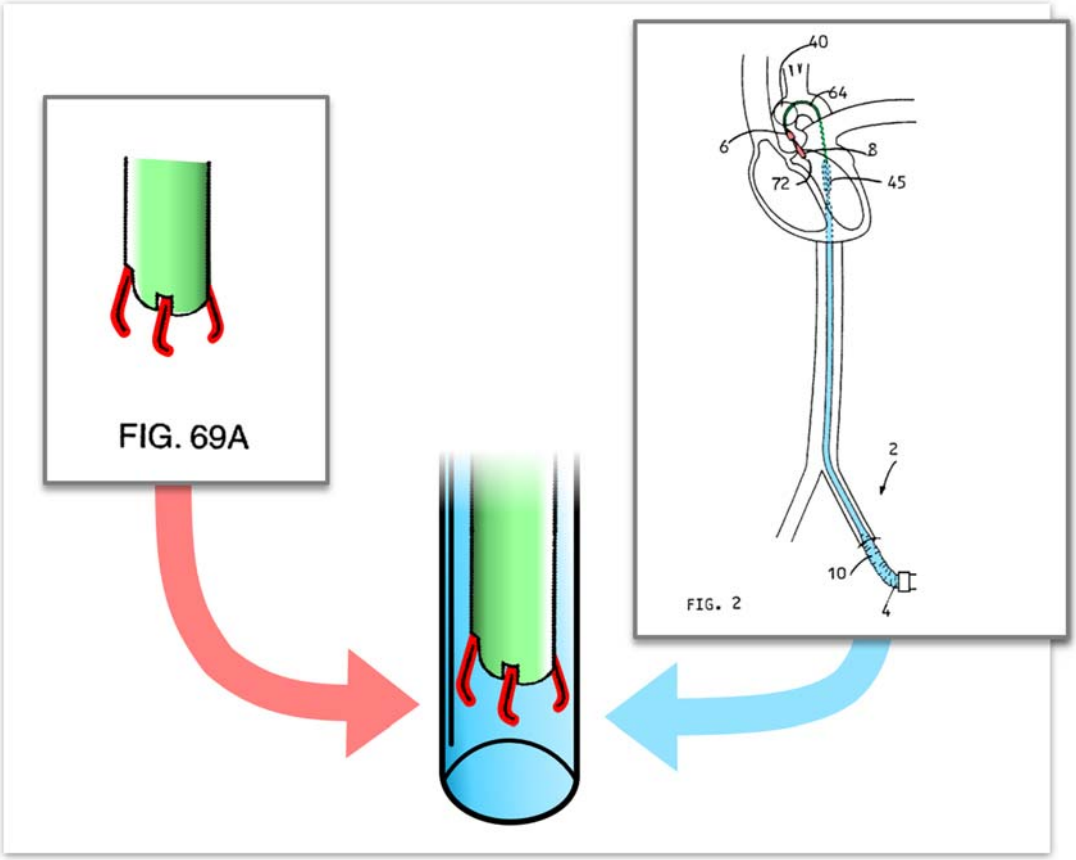
Although Durgin's preferred embodiment discloses a surgical clip, Durgin contemplates that "[t]here are also vascular applications for the surgical clip and delivery system. Miniaturization of the surgical clip and the delivery system could permit vascular repair," including as a "implant attachment." Durgin, 19:43–47; Aklog, 207.

For these reasons, a POSITA would have had more than a reasonable expectation of success to combine St.Goar's Figure 73 clip with an outermost sheath that covers the clip and is retractable therefrom. Aklog, 208.

C. Claim 14 Is Rendered Obvious by St.Goar's Figures 73 and 69 Clips in View of Garrison

Claim 14 has identical limitations to features recited in 1[pre], 1[a], 1[b], claim 2, and claim 5, and is therefore rendered obvious by St.Goar's Figure 73 clip in view of the knowledge of a POSITA and Garrison for the same reasons discussed above with respect to claim 5 in Ground 3. Aklog, 209.

Furthermore, claim 14 is broader than claim 5 (see Section VI.F above), and is also rendered obvious in view of St.Goar's Figure 69 clip in view of the knowledge of a POSITA and Garrison. Combining St.Goar's Figure 69 clip's delivery catheter (942) with a retractable outermost sheath, such as that disclosed in Garrison would have resulted in the configuration below:



St.Goar, Fig. 69A (modified); Garrison, Fig. 2 (cropped, annotated); Aklog, 210.

A POSITA would have been motivated to modify St.Goar's Figures 73 and 69 clips and corresponding delivery catheters to incorporate a retractable outermost sheath, as disclosed in Garrison for the same reasons discussed for claim 5 above. Section VII.B above; Aklog, 212.

In sum, claim 14 would have been obvious to a POSITA over St.Goar in view of Garrison.

IX. NO KNOWN SECONDARY CONSIDERATIONS EXIST

Should Patent Owner proffer any evidence of secondary considerations in its Preliminary Response, that evidence should not be considered for institution purposes, or Abbott should be given leave to file a reply with rebuttal evidence. *See Garmin Int'l, Inc. v. Wis. Archery Prods., LLC*, IPR2018-01137, Paper 11 at 29 (Dec. 11, 2018). Abbott should be permitted a fair opportunity to rebut Edwards' specific allegations, as it cannot predict them beforehand.

X. THE BOARD SHOULD INSTITUTE TRIAL NOTWITHSTANDING THE PENDING DISTRICT COURT LITIGATION

The '767 patent is the subject of an infringement action brought by Edwards alleging that Abbott's MitraClip infringes the '767 patent. Edwards may argue that the Board should decline to institute trial because instituting *inter partes* review would be duplicative of the validity challenges raised in the district court action.

If so, the Board should not decline to institute trial based on the ongoing district court action, and Abbott should have an opportunity to address Edwards's specific arguments in light of the situation at that time.

Briefly, although the district court set a pretrial conference for March 12, 2021, it has not set a trial date yet. And even the pretrial conference date is subject to being pushed back. Recently, in another patent case before the same district court, the district court moved the pretrial conference date, resulting in a six-month push-back, from June 28, 2019 to December 17, 2019. Exs. 1048-50, *Pavo Sols., LLC v. Kingston Tech. Co.*, No. 8-14-cv-01352 (C.D. Cal.) Dkts. 148, 167, 309. Likewise, in the parallel district court case between the parties here, the district court continued the *Markman* hearing scheduled for November 12, 2019 to February 4, 2020. Ex. 1007. So, whether a trial occurs in district court before the Final Written Decision may issue here is entirely speculative. Further, though Abbott has asserted invalidity defenses against the '767 patent in the district court, this petition includes specific grounds not included in Abbott's invalidity contentions in the district court: the St.Goar and Garrison combination in Ground 3 was not presented in Abbott's invalidity contentions and will ***not*** be adjudicated in district court. Thus, instituting trial in this proceeding in this petition will not duplicate the district court litigation.

XI. CONCLUSION

The Board should institute *inter partes* review on the grounds presented in this petition.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this petition complies with the word count limitation of 37 C.F.R. § 42.24(a)(1)(i) because the petition contains a total of 13,921 words, which is the sum of 13,775 words calculated by Microsoft Word's word-count feature and 146 words hand-counted in the figures. This total excludes the cover page, signature block, and the parts of the petition exempted by 37 C.F.R. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this petition for *Inter Partes* Review of US Patent No. 6,719,767 and all Exhibits and other documents filed together with this petition were served on the official correspondence address for the patent shown in PAIR and a courtesy copy to Edwards Lifesciences Corp. and Edwards Lifesciences LLC's current litigation counsel:

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