UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC, and

MEDTRONIC, INC.

Petitioners,

v.

SPEYSIDE MEDICAL, LLC,

Patent Owner.

Case IPR2021-00243

U.S. Patent No. 9,445,897

PETITION FOR *INTER PARTES* REVIEW

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LIST OF EXHIBITS

Exhibit ("Ex.")	Description
1001	U.S. Patent No. 9,445,897 ("'897")
1002	Declaration of William J. Drasler ("Drasler")
1003	File History of U.S. Patent No. 9,445,897 ("'897FH")
1004	U.S. Patent No. 5,957,949 to Leonhardt ("Leonhardt")
1005	U.S. Patent Pub. No. 2004/0181238 to Zarbatany ("Zarbatany")
1006	International Patent No. WO 2012/023980 to Thomas ("Thomas")
1007	U.S. Patent No. 7,985,213 to Parker ("Parker")
1008	*Speyside Medical, LLC v. Medtronic Corevalve, LLC,* C.A. No. 20-361 (LPS), ECF No. 35 (D. Del. Oct. 15, 2020)
1009	U.S. Patent Pub. No. 2009/0088836 to Bishop ("Bishop")
1010	*Speyside Medical, LLC v. Medtronic Corevalve, LLC,* C.A. No. 20-361 (LPS), ECF No. 19 (D. Del. Jun. 12, 2020)
1011	Donald S. Baim & William M.D. Grossman, GROSSMAN'S CARDIAC CATHETERIZATION, ANGIOGRAPHY, AND INTERVENTION (Donald S. Baim et al. eds., 6th ed. 2000) ("Baim")
1012	Vogt et al., *Implantation: tips and tricks – the cardiologist's view*, EUROPEAN HEART JOURNAL SUPPLEMENTS (2004) ("Vogt")
1013	[RESERVED]
1014	U.S. Patent No. 4,056,854 to Boretos ("Boretos")
1015	U.S. Patent Pub. No. 2007/0185558 to Hartley ("Hartley")
1016	U.S. Patent Pub. No. 2009/0024089 to Levine ("Levine")
1017	[RESERVED]

1018	U.S. Patent No. 6,425,916 to Garrison ("Garrison")
1019	U.S. Patent No. 3,671,979 to Moulopoulos ("Moulopoulos")
1020	U.S. Patent Pub. No. 2007/0213761 to Murphy ("Murphy")
1021	U.S. Patent Pub. No. 2011/0257733 to Dwork ("Dwork")
1022	[RESERVED]
1023	U.S. Patent Pub. No. 2011/0319989 to Lane ("Lane")
1024	[RESERVED]
1025	Sven Ivar Seldinger, *Catheter Replacement of the Needle in Percutaneous Arteriography: A new technique*, 39 Acta Radiologica 368 (1953) ("Seldinger")
1026	U.S. Patent Pub. No. 2008/0140189 to Nguyen ("Nguyen-189")
1027	AU Patent Pub. No. AU622897 to Sylvanowicz ("Sylvanowicz")
1028	U.S. Patent Pub. No. 2010/0256487 to Hawkins ("Hawkins")
1029	U.S. Patent Pub. No. 2011/0245911 to Quill ("Quill")
1030	Makoto Ando, *Short Operation Time: An Important Element to Reduce Operative Invasiveness in Pediatric Cardiac Surgery*, 80 ANN. THORAC. SURG. 631 (2005) ("Ando")
1031	U.S. Patent Pub. No. 2010/0004730 to Benjamin ("Benjamin")
1032-1039	[RESERVED]
1040	Google Scholar Citation results before 2012 for "Short operation time: an important element to reduce operative invasiveness in pediatric…" Ando, available at: https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=15851841334398837535&scipsc=&as_ylo=&as_yhi=2011
1041	Google Scholar Citation results before 2012 for "Catheter replacement of the needle in percutaneous ateriography: a new technique," Seldinger, available at:

	https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=6852151206197362331&scipsc=&as_ylo=&as_yhi=2011
1042	Google Scholar Citation results before 2012 for "Implantation: tips and tricks—the cardiologist's view" Vogt, available at: https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=2892462605629800573&scipsc=&as_ylo=&as_yhi=2011
1043	Google Books result Donald S. Baim & William M.D. Grossman, GROSSMAN'S CARDIAC CATHETERIZATION, ANGIOGRAPHY, AND INTERVENTION (Donald S. Baim et al. eds., 6th ed. 2000), available at: https://www.google.com/books/edition/_/9glsAAAAMAAJ?hl=en&gbpv=0
1044	Declaration of Crena Pacheco
1045	U.S. Patent No. 7,211,041 to Mueller ("Mueller")
1046	European Patent No. EP 1 890 721 to Williams ("Williams")
1047	Google Scholar Citation results before 2012 for "MD Grossman's Cardiac Catheterization," Baim, available at: https://scholar.google.com/scholar?hl=en&as_sdt=2005&sciodt=0%2C5&cites=13412578385609891210&scipsc=&as_ylo=&as_yhi=2011
1048	Affidavit of Elizabeth Rosenberg dated September 22, 2020
1049	The Annals of Thoracic Surgery: The First 50 Years, available at: https://www.annalsthoracicsurgery.org/article/S0003-4975(15)00691-8/pdf
1050	Website capture dated February 6, 2009 of "The Seldinger Technique: 50 Years On", available at https://web.archive.org/web/20090206145449/http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)66878-X/fulltext
1051	ZCJ Higgs, *The Seldinger Technique: 50 Years On*, 366 The Lancet 9494 at 1407-09 (Oct. 15, 2005)
1052-1054	[RESERVED]
1055	Affidavit of Duncan Hall dated December 23, 2020

Pursuant to §§311-319 and §42.1 Medtronic CoreValve LLC and Medtronic, Inc. ("Petitioners") petition for *inter partes* review ("IPR") of claims 1-4, 6-10, 16-22, and 24 ("Claims") of U.S. Patent 9,445,897 ("'897") (Ex. 1001), assigned to Speyside Medical, LLC ("PO").[1] There is a reasonable likelihood that at least one challenged claim is unpatentable as explained herein. Petitioners request review and cancellation of these Claims.

I. INTRODUCTION

The '897 is directed to a method of transluminally delivering a prosthetic heart valve to replace a native valve via a preassembled transcatheter delivery device. The delivery device includes an introducer catheter "preassembled" over a delivery catheter, and a retractable sheath that holds the prosthetic valve. The preassembled delivery device is inserted into one of the patient's access vessels and advanced through vasculature to a location within the heart proximate a damaged valve where the prosthesis may be deployed by retracting the sheath. '897, 26:55-27:30; cl. 1.

[1] Section cites are to 35 U.S.C. (pre-AIA) or 37 C.F.R. as context indicates. All emphasis/annotations added unless noted. Annotations added to the figures herein generally quote the language of the Claims for reference. All citations herein are exemplary and not meant to be limiting.

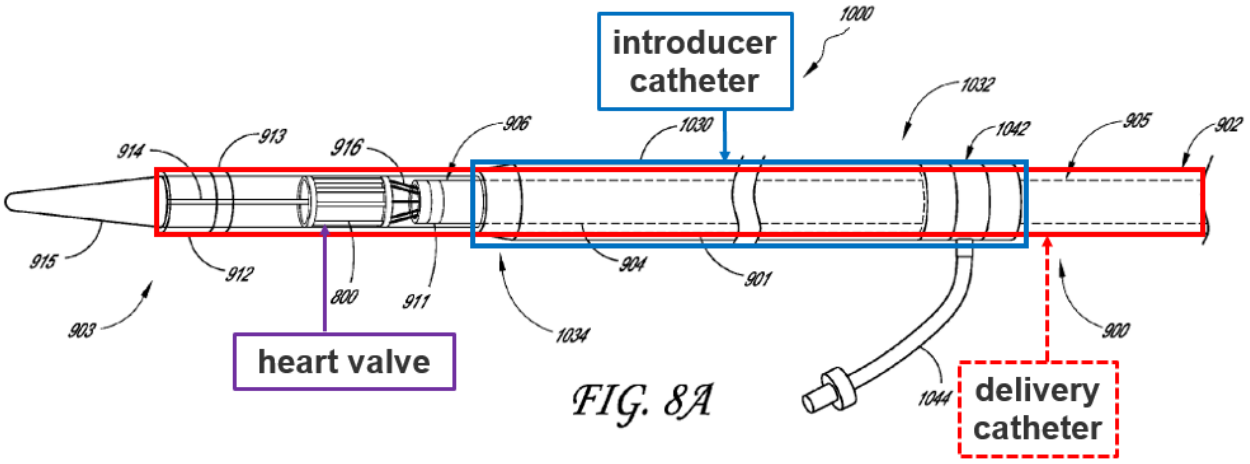


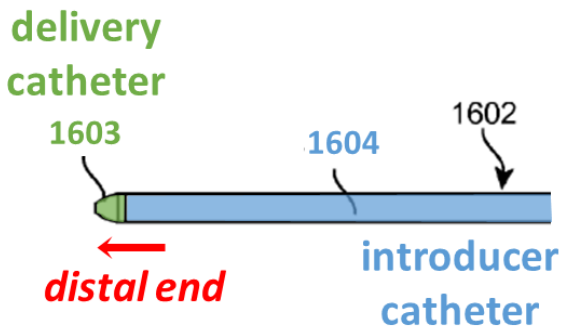
FIG. 8A

'897 concedes that transcatheter valve replacement via vasculature was known in the art. '897, 1:58-6, 2:14-21, 5:53-58. U.S. Patent Pub. No. 2009/0088836 (Ex. 1009), which PO admits is prior art (*id.*), teaches loading a delivery catheter with the prosthesis collapsed inside a sheath, advancing the delivery system, and deploying the prosthesis. Ex. 1009 ¶¶[0358]-[0429]; *see also* Boretos (Ex. 1014; issued 11/8/77), 1:45-63; Moulopoulos (Ex. 1019; issued 6/27/72), 1:43-61.

Claim 1's purported point is novelty is that the introducer catheter and the delivery catheter are "pre-assembled" and that "during advancement" an outer diameter of a distal end of the delivery catheter is "greater than" an inner diameter of a distal end of the introducer catheter. Ex. 1003 ("'897FH"), 2769-70. But such features were well-known. Drasler ¶¶35-41.

For example, **Lane** (Ex. 1023) teaches inserting into a patient flexible sheath 1602 comprising concentrically nested catheters: sheath catheter 1604, bell catheter

1624, hub catheter 1622, and guidewire catheter 1621 (from outermost to innermost). Lane ¶[0122]. The catheters are preassembled before introduction into the patient because guidewire catheter 1621's tip 1603 is too large to be inserted through sheath catheter 1604 (or any of the other catheters). Tip 1603 of guidewire catheter 1621 abuts the distal edge of sheath catheter 1604 because tip 1603's outer diameter is larger than the inner diameter of sheath catheter 1604. Lane ¶[0123], Fig. 16 (excerpted below).



Lane further discloses loading a prosthesis into the delivery device, advancing the device proximate to one of the heart's valves, and deploying the prosthesis. Lane ¶¶[0115]-[0130]. Additionally, **Zarbatany** (Ex. 1005), which is incorporated by reference into **Lane**, discloses introducing a delivery device into a patient's femoral vein. Zarbatany ¶[0088].

As further examples, **Hartley** (Ex. 1015) discloses a nose cone dilator with a tapered tip that can be directly inserted into an access vessel for accessing and dilating the vessel. Hartley ¶¶[0037], [0038]. **Nguyen-189** (Ex. 1026) discloses

introducing a delivery device into a patient's femoral artery and delivering it through the aorta to the aortic valve. Nguyen-189 ¶¶[0038], [0232]. And **Thomas** (Ex. 1006) teaches transluminal delivery of a replacement heart valve via a delivery device with a steerable portion 40 that can adjust the prosthesis's angular position. Thomas ¶[0066]. **Thomas** further discloses that outermost catheter 30b need only extend up to distal sheath 24, which encapsulates the prosthesis for delivery. Thomas ¶¶[0040], [0043], Fig. 3A.

As demonstrated herein, the prior art renders obvious the Claims, which are directed **to** an obvious combination of prior art elements combined according to known methods to yield predictable results. The claimed elements and the claimed arrangement of elements are rendered obvious by **Lane** (including **Zarbatany**) or in view of **Hartley**. **Nguyen-189** provides additional teachings for dependent claims 3-4. And **Thomas** provides additional teachings for dependent claims 16, 18-22, and 24. At most, the combination amounts to nothing more than a "predictable use of prior art elements according to their established functions." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

The USPTO did not consider **Lane**, **Zarbatany**, **Hartley**, **Thomas,** or **Nguyen-189** or any other reference providing analogous disclosures during '897's prosecution.

Petitioners request that the Board institute trial and find the Claims unpatentable.

II. MANDATORY NOTICES (§42.8)

A. Real Party-In-Interest

Pursuant to §42.8(b)(1), Petitioners identify Medtronic CoreValve LLC and Medtronic, Inc. as real parties-in-interest. No other party had access to or control over the present Petition, and no other party funded or participated in preparation of the present Petition.

B. Related Matters

The '897 is currently the subject of a district court litigation: *Speyside Medical, LLC v. Medtronic CoreValve LLC et al.*, No. 20-cv-00361 (D. Del., filed March 13, 2020). Medtronic has filed IPR petitions against the other patents asserted in that district court litigation: IPR2021-00239 (U.S. Patent No. 8,377,118); IPR2021-00240, IPR2021-00241, and IPR2021-00310 (U.S. Patent No. 9,510,941); IPR2021-00242 (U.S. Patent No. 10,449,040); and IPR2021-00244 (U.S. Patent No. 9,603,708).

C. Lead and Back-Up Counsel and Service Information

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Petitioners consent to electronic service of documents to the email addresses of the counsel identified above.

III. PAYMENT OF FEES

The undersigned authorizes the Office to charge the fee required by §42.15(a) and any additional fees that might be due to Deposit Account No. 18-1945, under Order No. 102760-0209-651.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioners certify the '897 is available for IPR. Petitioners are not barred or estopped from requesting IPR challenging the claims of the '897 on the grounds identified herein.

B. Identification of Challenge

Pursuant to §42.104(b), Petitioners request IPR of the Claims, and that the Board cancel the same as unpatentable. The '897 matured from U.S. Patent Application No. 13/777,745 ("'745 Application") filed 2/26/2013 and claims priority to provisionals filed 5/1/2012 and 9/28/2012.[2]

1. The Specific Art on Which the Challenge Is Based

Petitioners rely upon the following prior art:

Prior Art	Ex.	Patent / Publication	Filing Dates	Issued / Published	Prior Art Under at Least §102
Lane	1023	US2011/0319989	4/28/2011	12/29/2011	(a), (e)
Zarbatany	1005	US2004/0181238	3/14/2003	09/16/2004	(a), (b), (e)
Hartley	1015	US2007/0185558	1/17/2007	08/09/2007	(a), (b), (e)
Nguyen-189	1026	US2008/0140189	12/6/2007	06/12/2008	(a), (b), (e)
Thomas	1006	WO2012/023980	8/17/2011	02/23/2012	(a), (e)

[2] Petitioners take no position as to the priority claims' propriety as the art presented herein pre-dates the earliest possible filing date. Drasler ¶¶42-43. Petitioners reserve the right to challenge these priority claims.

Additional references relied on herein to show the knowledge and understanding of those of those of ordinary skill in the art, including Baim (Ex. 1011), Vogt (Ex. 1012), Seldinger (Ex. 1025), and Ando (Ex. 1030), were publicly accessible. *See* Ex. 1040; Ex. 1041; Ex. 1042; Ex. 1043; Ex. 1045; Ex. 1046; Ex. 1047; Ex. 1048, 5-7, 17; Ex. 1049; Ex. 1050; Ex. 1051; Ex. 1055, 5; Drasler ¶¶228-237.

2. Statutory Grounds on Which the Challenge Is Based

Petitioners respectfully request cancellation of the Claims on the following grounds:

§103 Grounds	Claim(s)	Prior Art
1	1-4, 6-10, 16-17	Lane
2		Lane in view of Hartley
3	3, 4	Lane in view of Nguyen-189
4		Lane in view of Hartley and Nguyen-189
5	16, 18-22, 24	Lane in view of Thomas
6		Lane in view of Hartley and Thomas

As further discussed in §X.A.1, **Lane** incorporates **Zarbatany** by reference in its entirety for transseptal techniques. To the extent it is argued that **Zarbatany** is not properly incorporated into **Lane**, the Claims are also obvious in further view of **Zarbatany.** *See* §X.A-D. Like **Lane**, **Zarbatany** is in the same field as '897 and

reasonably pertinent to '897's alleged problem(s), *e.g.*, of transluminally repairing heart valves. Zarbatany, Title, Abstract ¶¶[0009], [0013]-[0015], [0087]-[0091]. Further, **Lane** explicitly discloses that its delivery device is compatible with **Zarbatany's** techniques. Lane ¶[0138]. As taught in **Lane**, **Zarbatany** advantageously provides additional details for how to deliver **Lane's** delivery device transseptally. *Id.* A POSITA thus would have found it routine and straightforward to apply **Zarbatany's** teachings discussed in §X.A-D in implementing **Lane's** prosthesis delivery method and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶61.

3. How the Claims Are Unpatentable

Petitioners provide the information required under §§42.104(b)(4)-(5) in §X.

V. '897 OVERVIEW

'897 generally refers to methods of positioning a cardiovascular prosthetic implant within a patient's heart using a catheter delivery device. '897, Abstract, 2:32-41. '897 concedes that transcatheter valve replacement via percutaneous methods, including "delivery mechanism[s] utilizing the vasculature pathways" such as catheterization, are known. '897, 1:57-61, 2:14-28. '897 purportedly solves "vascular complications such as aortic dissection" by "reduc[ing the] ratio of the

diameter of the delivery device for the heart valve." '897, 2:19-28, 24:30-33; Drasler ¶44.

Combined delivery system 1000 for delivering implant 800 includes introducer catheter 1030 (annotated blue) positioned at least partially over the delivery catheter 900 (annotated red). '897, 23:66-24:2, 24:2-4, Fig. 8A (below).

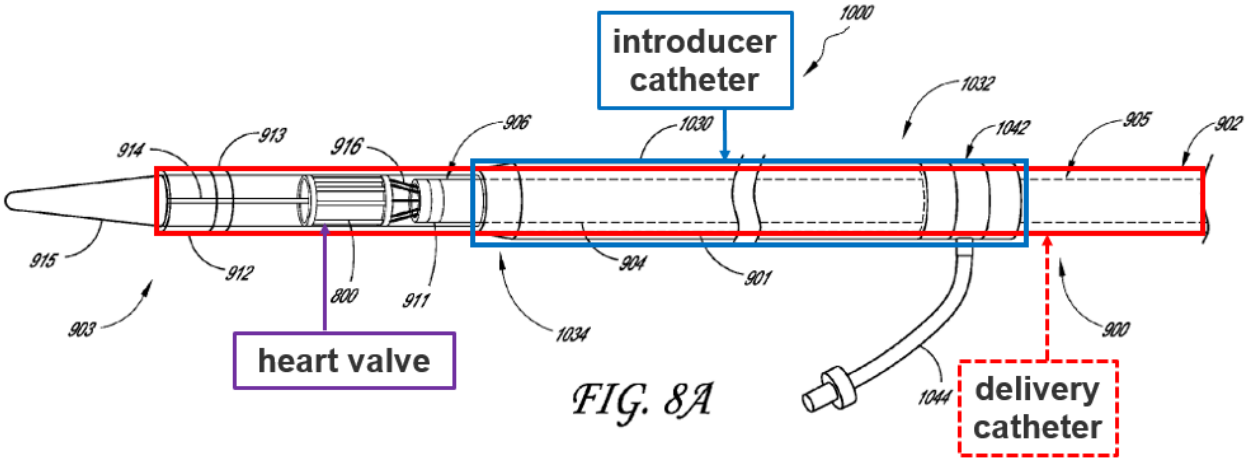


FIG. 8A

Delivery catheter 900 comprises outer tubular member 901 (annotated red) and inner tubular member 904 (annotated orange) extending through outer tubular member 901. '897, 19:53-61, Fig. 8A (below). Outer tubular member 901's distal end comprises a sheath jacket 912 housing implant 800 in a retracted state for delivery to the implantation site. '897, 19:61-67. Sheath jacket 912's outer diameter may be "too large to be inserted through the introducer catheter 1030." '897, 22:46-54; 24:10-18, Fig. 8A (below).

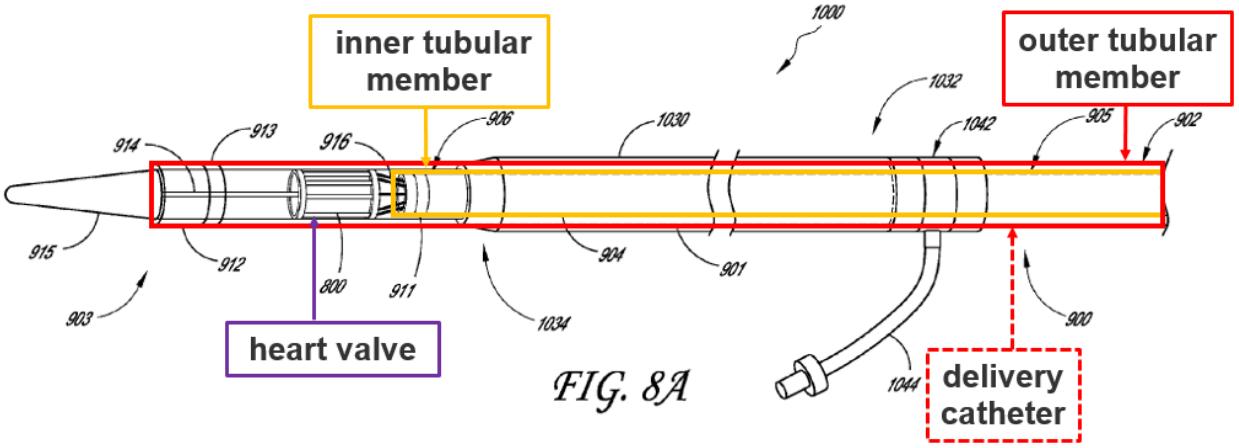


FIG. 8A

As such introducer catheter 1030 may be preassembled over delivery catheter 900, creating "a reduced diameter combined delivery system 1000," and may extend during delivery from the access site to a position proximate a native valve. '897, 24:10-29, 27:2-5; Drasler ¶45.

Introducer catheter 1030 comprises seal assembly 1042 (annotated yellow) with "a hemostasis seal/valve…to minimize blood loss during percutaneous procedures." '897, 24:39-41, 24:58-62, Fig. 8A (below); Drasler ¶46.

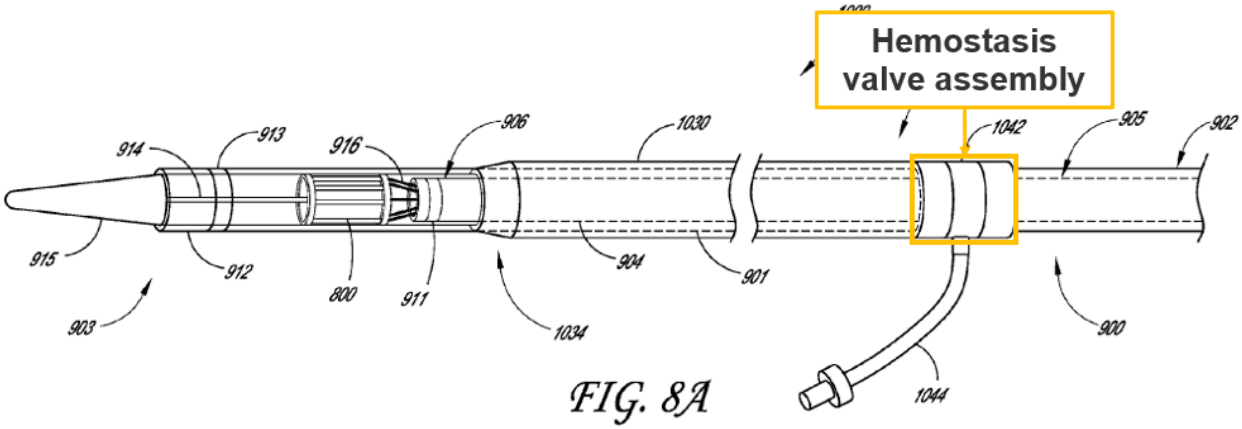


FIG. 8A

To deliver the prosthesis, guidewire tip 915 and sheath jacket 912 are inserted directly into an access vessel, *e.g.*, femoral artery, over a guidewire to dilate the access vessel. '897, 21:48-51; 24:29-33; 26:58-63. Delivery system 1000 advances through the vasculature to position the valve at the deployment site. '897, 26:63-27:5; 27:6-10; Drasler ¶47.

Once positioned, the implant is exposed by retracting outer tubular member 901 while holding inner tubular member 904 stationary. '897, 27:11-15. In alternative embodiments, "the implant can also be revealed by pushing the inner tubular member 904 distally while holding the outer tubular member 901 stationary." '897, 27:15-18, 27:18-21; 27:34-44. In some embodiments, implant 800 is partially deployed and "PFL tubes 916" "move the implant 800 proximally and distally, or…tilt the implant 800 and change its angle relative to the native anatomy." '897, 27:41-44, 28:43-53; 22:3-4; 23:28-31; 28:4-7. Once properly positioned, implant 800 can be fully deployed. '897, 28:51-52; Drasler ¶48.

After deploying implant 800, "delivery catheter 900 is retracted proximally until a proximal end of the sheath jacket 912 abuts the distal end 1034 of the introducer catheter 1030." '897, 29:45-48. Guidewire tubing 914 is retracted proximally "until the guidewire tip 915 closes the distal end of the outer tubular member," forming a smooth transition between the guidewire tip 915 and introducer catheter 1030, purportedly preventing distal end 1034 of introducer catheter 1030

from damaging the blood vessel as introducer catheter 1030 is removed from the patient. '897, 29:48-56. Introducer catheter 1030 and delivery catheter 900 can then be "removed from the patient simultaneously." '897, 29:56-58; Drasler ¶49.

VI. '897 PROSECUTION HISTORY

The Examiner rejected claim 19 (issued claim 1) and dependent claims 20-24 (issued claims 2-6) as anticipated by U.S. Pub. No. 2011/0257733 ("Dwork") (Ex. 1021; published 10/20/2011). '897FH, 2437-2439. Dependent claim 25 (issued claim 7) was rejected as being obvious over Dwork in view of Benjamin (Ex. 1031). *Id*. In its 06/25/2015 response, Applicant argued that Dwork's delivery device is advanced through a "separate introducer sheath" and amended claim 19 to recite additional limitations, including "advancing an introducer catheter positioned over and together with a delivery catheter" and "an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter." '897FH, 2465-2467 (underline showing amendments).

The Examiner's rejection of 09/23/2015 and maintained the prior rejections. '897FH, 2504-12. On 01/22/2016, Applicant further amended claim 19 to recite: "advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter" and "during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter." '897FH, 2541, 2716. Applicant argued

that Dwork's introducer sheath 202 is inserted through the incision 206 first and the "delivery device 40 is ***then*** inserted into the bodily lumen via the introducer device 200" and, thus, Dwork does not disclose preassembly. '897FH, 2546 (emphasis original). Applicant further argued that Dwork's introducer sheath 202 has an inner diameter "greater than a distal portion of the delivery device 40." *Id.*

In the 01/19/2016 interview, Applicant acknowledged that the "novelty of the present invention was that the introducer catheter and the delivery catheter were pre-assembled or preloaded during manufacture." '897FH, 2722. And in the 04/27/2016 interview, Applicant agreed to "examiner's amendments to clarify that the outer diameter of the distal end of the delivery catheter being greater than an inner diameter of a distal end of the delivery [*sic*] [introducer] catheter DURING ADVANCEMENT and not that a distal tip can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter during advancement." '897FH, 2737 (emphasis original). The Examiner then allowed the claims. '897FH, 2764-71. The Examiner stated that the closest prior art of record, Dwork, "fails to teach a preassembled configuration and teach teaches away from preassembly" and that Dwork "also fails to teach" during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter "since the delivery catheter of

Dwork is deployed through the introducer catheter." '897FH, 2769-70. The patent issued on August 31, 2016; Drasler ¶¶50-55.

VII. THE BOARD SHOULD NOT EXERCISE ITS DISCRETION TO DENY INSTITUTION

A. §325(d) Does Not Apply.

Considering the two-part framework discussed in *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH,* IPR2019-01469, Pap. 6, *8-9, the Board should not exercise its §325(d) discretion to deny institution.

The grounds raised by this Petition are not the same or substantially the same as the art and arguments raised during '897's prosecution.

Grounds 1-6: Neither the art nor the arguments in Grounds 1-6 are the same or substantially the same as those considered during prosecution (step-one of *Advanced Bionics*). **Lane**, **Zarbatany**, **Hartley**, **Thomas**,[3] and **Nguyen-189** were

[3] **Thomas** was cited as one of 111 references in an Information Disclosure Statement but was never cited in a rejection. '897FH, 350, 900; *Vizio, Inc. v. Nichia Corp.*, IPR2017-00551, Paper 9, *7-8 (no evidence that references cited in IDS were applied against the challenged claims or that examiner considered particular disclosures cited by Petitioner); *Microsoft Corp. v. Parallel Networks, LLC*, IPR2015-00486, Paper 10, *14-15 (same).

not considered during prosecution. Nor are these references cumulative. For example, **Lane** and **Thomas** each teach at least one limitation that the Examiner erroneously believed missing from the prior art: preassembling an introducer catheter over the delivery catheter. *See* §X. Similarly, **Hartley** teaches a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel. *Id.* And **Nguyen-189** teaches inserting a prosthesis into a femoral artery and delivering it through the aorta. *Id.* Necessarily, the Office also has not previously considered the expert testimony submitted herewith with regard to these combined teachings. Ex. 1002.

Where the "Examiner did not expressly consider" **Lane**, **Zarbatany**, **Hartley**, **Thomas**, and **Nguyen-189**, it is difficult, if not impossible, to explain "why the Examiner allowed the claims" or "how the Examiner might have considered the arguments presented in the Petition." *Bowtech, Inc. v. MCP IP, LLP*, IPR 2019-00379, Pap. 14, *20 (declining to exercise § 325(d) discretion). Even if the Examiner had considered substantially the same art as that relied on herein, the Examiner would have erred in allowing the claims based upon the mistaken analysis explained above. *See* §VI. For these additional reasons, an exercise of § 325(d) discretion is not appropriate here.

B. §314(a) Does Not Apply.

Co-pending district court proceedings also do not warrant the exercise of discretion under § 314(a) based on the six factors considered in *Apple Inc. v. Fintiv* IPR2020-00019, Pap. 11. **1:** Petitioners intend to seek a stay of the related District of Delaware (D. Del.) proceeding pending the outcome of this IPR, and Nos. IPR2021-00244, IPR2021-00239, IPR2021-00240, IPR2021-00241, IPR2021-00310, and IPR2020-00242 concerning the other asserted patents. **2:** Trial is scheduled for October 2022, more than three months after a final written decision will issue in this IPR. Ex. 1008. **3:** To date, the court has not issued any substantive orders related to '897, and while Petitioners have moved to dismiss pending claims and Infringement contentions were served on 12/4/20, invalidity contentions have not yet been served, depositions have not begun, and claim construction briefing has not yet begun. *Id.* **4:** The same grounds, arguments and evidence could not be presented in litigation after the earlier-expected final written decision. Moreover, the Petition challenges at least one claim not at issue in the litigation. **5**: The litigation and PTAB parties are the same. **6**: The merits of this Petition are particularly strong as shown herein, and the Petition presents arguments not substantially the same as those previously before the Office.

The Board should not exercise its discretion to deny institution.

VIII. LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art ("POSITA"), at the time the '897 or its parent applications were filed, would have had a minimum of either a medical degree and experience working as an interventional cardiologist or a Bachelor's degree in bioengineering or mechanical engineering (or a related field) and approximately two years of professional experience in the field of prosthetic cardiovascular implants. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education. Drasler ¶¶31-34.

IX. CLAIM CONSTRUCTION

Claim terms subject to IPR are to be construed using the *Phillips* standard. §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Only terms necessary to resolve the controversy need to be construed. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Because the prior art asserted herein discloses embodiments within the indisputable scope of the claims, the Board need not construe the outer bounds of the claims, while the district court may need to do so in addressing other issues, e.g., infringement. All claim terms should be construed according to their plain and ordinary meaning as would be understood by a POSITA in view of the specification. Drasler ¶56.

A. Preambles

Regardless of whether the preambles are limiting, the prior art discloses the preambles. *See* §X; Drasler ¶57.

X. GROUNDS OF UNPATENTABILITY

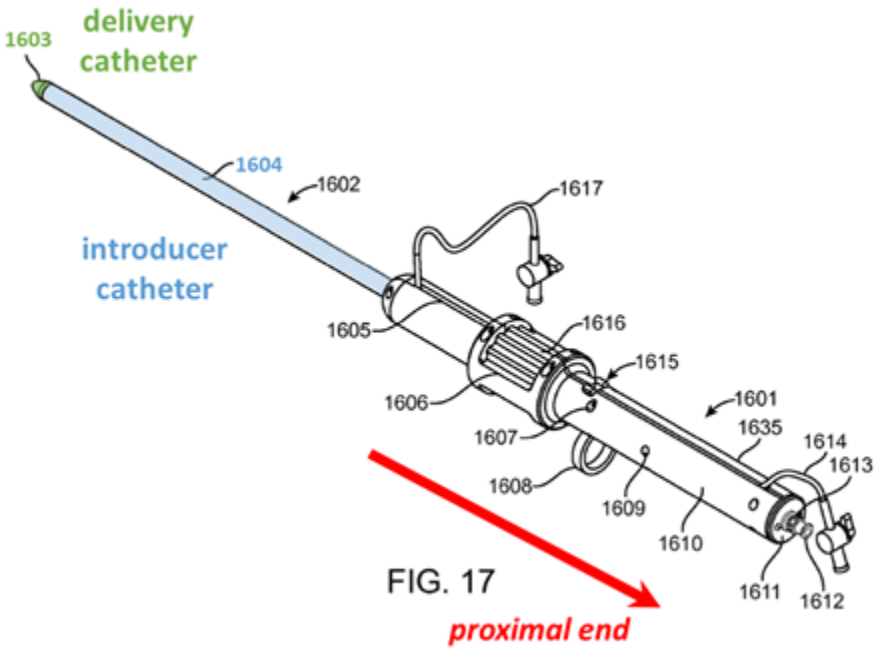
Although the '897 purports to have invented implanting a replacement heart valve device using a particular delivery device (an introducer catheter preassembled over a delivery catheter), such methods were known in the art. As explained below, the Claims are unpatentable as obvious. Drasler ¶¶1-243.

The prior art renders the Claims unpatentable. This Petition is supported by the Declaration of Dr. William Drasler, which describes the scope and content of the prior art at the time of the alleged '897 invention. Drasler (Ex. 1002) ¶¶1-243.

A. Ground 1: Claims 1-4, 6-10, and 16-17 Are Rendered Obvious by Lane

1. Overview of Lane

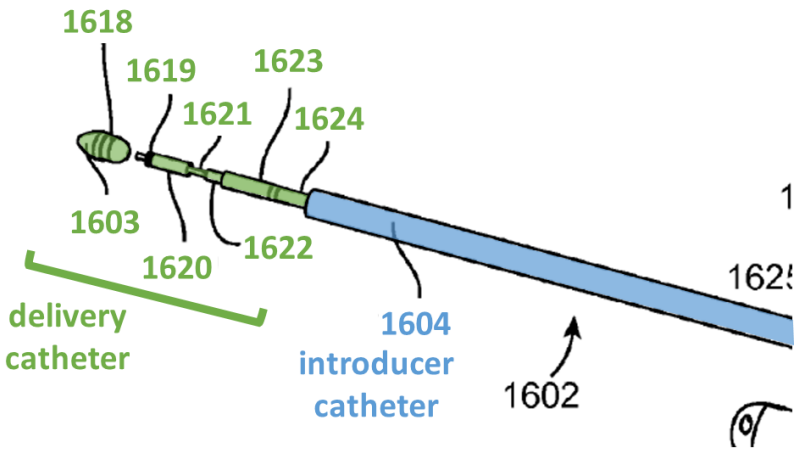
Lane discloses a delivery device for implanting a prosthetic valve in a native valve. Lane, Abstract, ¶¶[0014], [0087], [0091]-[0096], [0115]-[0145], Fig. 17 (below).



The delivery device may deliver the prosthesis—for mitral valve replacement, such delivery is "typically" either transseptal (which includes transluminal delivery via the "vena cava") and/or transapical. Lane ¶¶[0024], [0115], [0131], [0138], Figs. 22A-22G, 23A-G. The delivery device of Figures 16-21 (*see also* ¶¶[0115]-[0130]) may be used in transapical or transseptal delivery methods with appropriate modifications to the delivery mechanism. Lane ¶[0115]. Additionally, the transapical delivery methods of Figures 22A-22G (*see also* ¶¶[00131]-[0137]) and the transseptal delivery methods of Figures 23A-23G (*see also* ¶¶[0138]-[0143]) "may use any of the prosthetic valves" and "delivery devices described" in the reference (including Figures 16-21) "if modified appropriately." Lane ¶¶[0131], [0138]. Therefore, a POSITA would have understood, and at a minimum found it

obvious, that teachings from the transseptal and/or transapical delivery embodiments also apply to the delivery device disclosed in Figures 16-21 (and corresponding ¶¶[0115]-[0130]). Drasler ¶¶62-63.

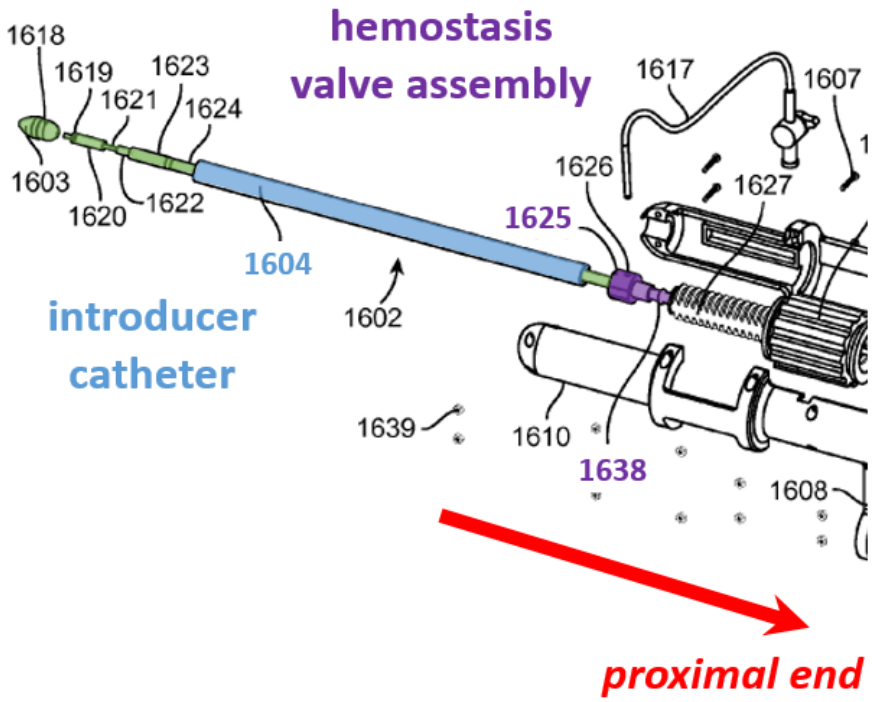
The delivery device comprises flexible sheath 1602 with four "concentrically nested catheters." Lane ¶¶[0115], [0122], Fig. 17 (above), Fig. 18 (excerpted below).



Guidewire catheter 1621 is "innermost." It begins at tip 1603 and provides "a channel through which a guide-wire" can be passed. Lane ¶[0122]. Hub catheter 1622, connected to hub 1620, is concentrically nested over guidewire catheter 1621. *Id*. Hub 1620 comprises hub slots 1619 for engaging the prosthesis. Lane ¶[0128]. Bell catheter 1624 is concentrically nested over hub catheter 1622 and "hous[es]" hub 1620. Lane ¶[0122]. Sheath catheter 1604 is "outermost," concentrically nested over the other three catheters, and "translates axially" relative to the stationary hub catheter 1622 and hub 1620. Lane ¶[0122], Fig. 18 (showing a gap between sheath

catheter 1604 and handle); Drasler ¶64. Sheath catheter 1604 is moved axially relative to this embodiment's stationary hub catheter via rotation of thumbwheel 1616, as further confirmed by discussion of the embodiment illustrated in Figures 16-19B. Lane ¶¶[0115], [0117] ("The handle 1601 provides housing for a thumbwheel 1616….[that] internally mates with a threaded insert (1627 in FIG. 18) that actuates the sheath catheter 1604"), [0123] ("As the thumbwheel 1616 is rotated, the screw insert 1627 will translate, and the sheath catheter 16[0]4 can be retracted or advanced by virtue of attachment."), [0127] ("manipulation of the thumbwheel 1616 will provide translational control of the sheath catheter 1604."), [0128] ("As seen in FIG. 19B, the pin lock 1608 is removed from the handle 1601 in order to allow further translation of the sheath catheter 1604."); Drasler ¶64.

The proximal end of sheath catheter 1604 "is in mating connection" with hemo-port 1625 and o-ring 1638 for "creating a hemostatic seal" between sheath catheter 1604 and bell catheter 1624 to prevent blood leakage. Lane ¶¶[0118], [0122], [0123], Fig. 18 (excerpted below).



Sheath catheter 1604's distal edge abuts shoulder 1618 of tip 1603 during advancement and removal of the delivery device. Lane ¶[0123], Fig. 16. Therefore, tip 1603's outer diameter is equal to or greater than sheath catheter 1604's inner diameter. This allows tip 1603 "to remain secure," "aligned" with sheath catheter 1604, and "creates piercing stiffness" to "assist[] in the dilation of an incision in the heart wall muscle" by the tip as shown in Figures 23A-23B. Lane ¶¶[0049], [0122], [0123]. For example, tip 1603 travels over a guidewire that has passed through a "transseptal puncture 2306" through the atrial septum "so that the device" may be "passed through the atrial wall." Lane ¶¶[0138], [0139], Figs. 23A-23B. Tip 1603 would remain snug against the puncture site as it passes through. Drasler ¶65.

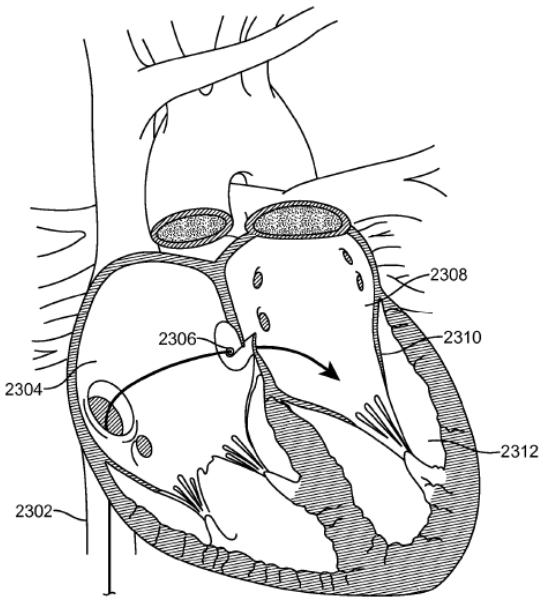


FIG. 23A

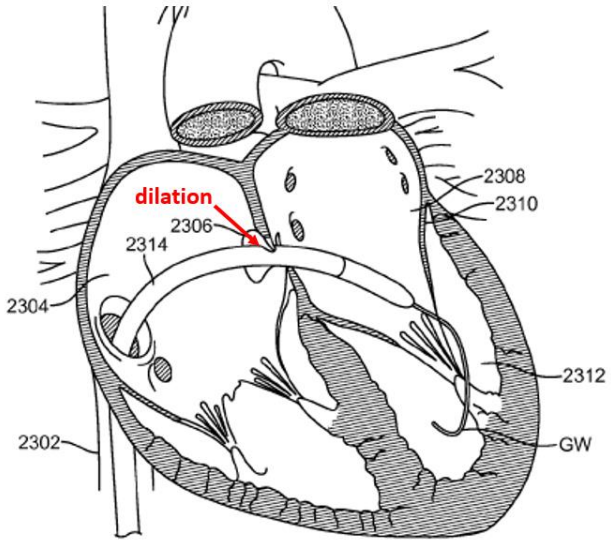


FIG. 23B

At the delivery device's distal end, the prosthesis engages hub 1620 via hub slots 1619. Lane ¶¶[0128], [0129], Fig. 20 (below, prosthesis not shown).

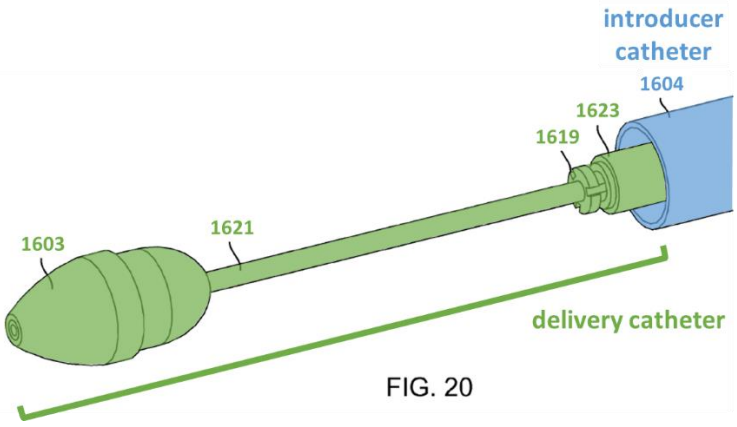


FIG. 20

The prosthesis is "releasably held" in hub slots 1619, which are retracted under tip 1623, which is a "bumped up" portion of bell catheter 1624. Lane ¶¶[0122], [0129]. During delivery, sheath catheter 1604 extends over the collapsed prosthesis to distal

tip 1603, as shown in Fig. 17. Lane ¶[0123], Fig. 17. The delivery device delivers the prosthesis in such a collapsed configuration to the heart valve being replaced. Lane ¶¶[0091], [0131], [0138], Figs. 22A-22G, Figs. 23A-23G. Once the delivery device is proximate the heart valve being replaced, the prosthesis is deployed either by retracting sheath catheter 1604 or advancing the prosthesis. Lane, Fig. 21 (below).

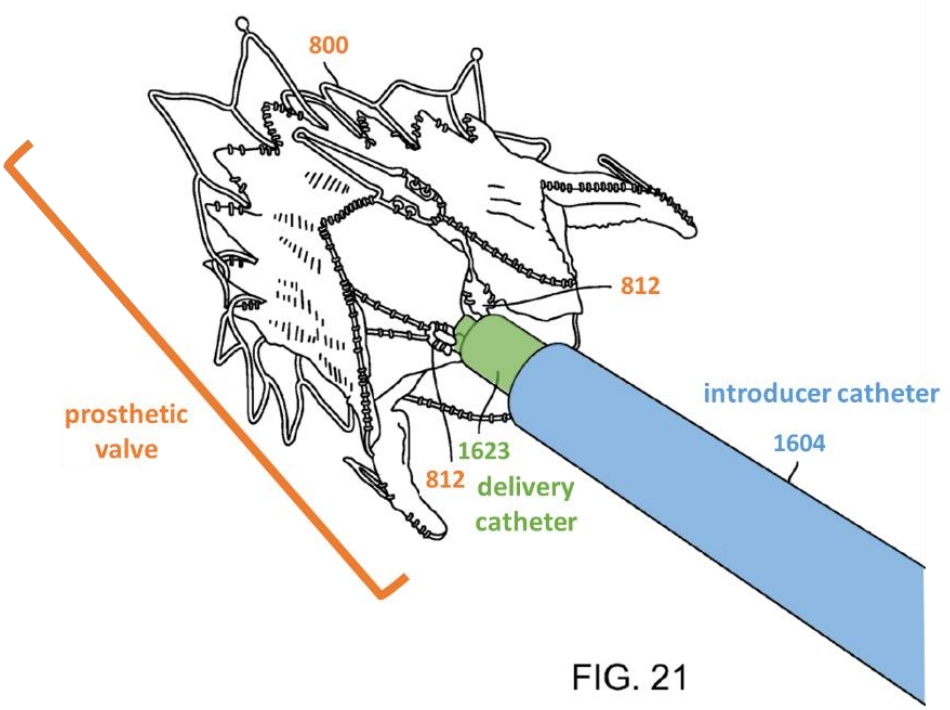


FIG. 21

When deploying the prosthesis by retracting sheath catheter 1604, guidewire catheter 1621 "is stationary" and "the larger diameter section 1623 of the bell catheter 1624 is also fully retracted, which completely frees" the prosthesis from the delivery system. Lane ¶¶[0117], [0122], [0127], [0128]; Drasler ¶¶65-68.

The prosthesis may be oriented, aligned, adjusted, and/or repositioned to the desired location. Lane ¶¶[0140], [0138], Fig. 23C. A POSITA would have understood, and at minimum found it obvious, that for proper orientation at the desired location, angular axial adjustment (as opposed to lateral axial movement) of the prosthesis would be accomplished by **Lane's** adjustment mechanisms to advantageously properly place the device. Drasler ¶70.

After deploying the prosthesis, the delivery device is "retracted and removed." Lane ¶¶[0031], [0143]. Just as the concentric catheters are inserted into the patient simultaneously allowing tip 1603 to remain "secure and aligned" with sheath catheter 1604 "during delivery" (*e.g.*, in Figs. 16-17, 23B (excerpted below)), a POSITA would have understood, and at minimum found it obvious, that the catheters would be retracted out simultaneously, such that after deployment tip 1603 is retracted and its shoulder again "abut[s]" sheath catheter 1604 to advantageously prevent tip 1603 from catching on a blood vessel wall during removal. *E.g.*, Lane ¶¶[0115], [0122]-[0123]; Drasler ¶¶71-72. It was well-known that smooth transitions and contiguous surfaces without sharp edges were beneficial for transluminal implants—to avoid catching on the inside of blood vessels during delivery and removal. Baim (Ex. 1011, published 2000), 28-29; Vogt (Ex. 1012, published 2004), 10; Murphy (Ex. 1020, published 9/13/07), ¶¶[0040], [0086]; Drasler ¶72.

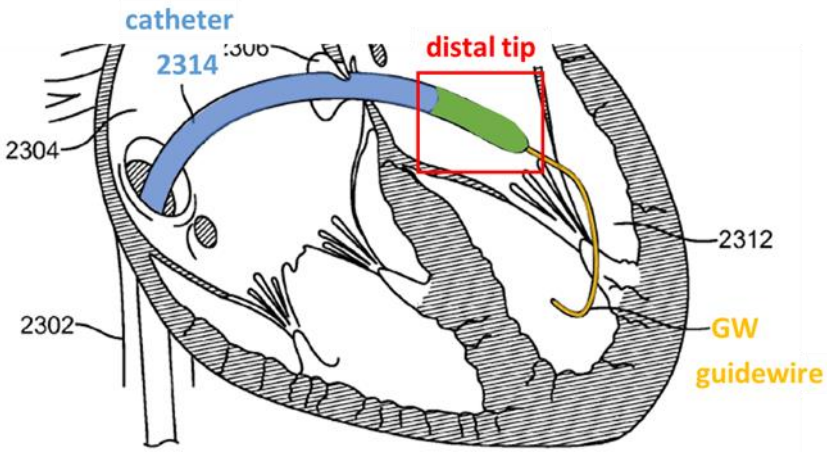


FIG. 23B

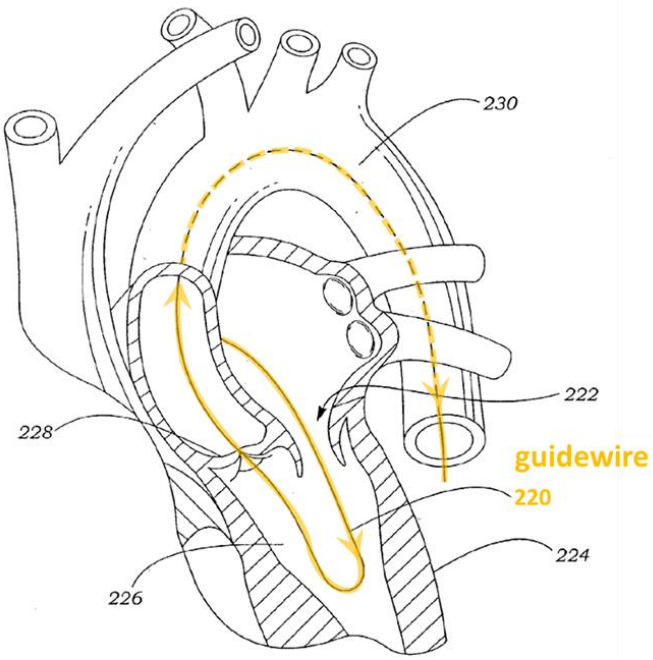
Lane, Fig. 23B (excerpted). Additionally, simultaneous removal of **Lane's** catheters 1604, 1624, 1622, and 1621 provides an overall smaller device profile extending through the access site. Removing hub catheter 1622, then bell catheter 1624, and then sheath catheter 1604 last would require sheath catheter 1604's diameter to be large enough to allow the other catheters and distal tip 1603 to pass through sheath catheter 1604, thereby increasing the overall profile of the delivery device and requiring a larger diameter access site. Drasler ¶72. Removing catheters simultaneously would advantageously save the physician time and improve patient outcomes. Ando (Ex. 1030; published 2005), 8, 11; Drasler ¶¶72-73.

Furthermore, a POSITA would have further understood, and at minimum found it obvious, that after the prosthesis has been deployed distal tip 1603 would be retracted until distal tip 1603 closes sheath catheter 1604's distal end to prevent

any components from catching on a blood vessel during removal of the catheters for similar reasons as above. Lane, Figure 23B; Baim, 28-29; Vogt, 10; Murphy ¶¶[0040], [0086]; Drasler ¶73. Especially when the prosthesis was deployed by advancing hub catheter 1622, the distal tip 1603 would be retracted by pulling guide-wire catheter 1621. Drasler ¶73.

Lane additionally incorporates by reference "[t]ransseptal techniques" for repairing a heart valve taught by **Zarbatany**. Lane ¶[0138]. **Zarbatany** discloses inserting the delivery device directly into an access vessel through an "entry" point/port for transseptal delivery. Zarbatany ¶[0088]. First, a guidewire is introduced through an endoluminal entry point (*e.g.*, "formed in a femoral vein" by a needle) and advanced "through the circulatory system" to the heart, where it traverses the "aortic valve 228 into the aorta 230" to "emerge at the left femoral artery through an endoluminal exit point." Zarbatany ¶[0088], Fig. 25 (below).

Fig. 25



The endoluminal entry/exit points are "dilated to permit entry of a catheter" directly into the vessel. *Id*.; Drasler ¶¶74-75.[4]

[4] **Zarbatany** refers to endoluminal entry/exit "point[s]" and endoluminal entry/exit "port[s]"—"entry" referring to where the guidewire entered the femoral vein and "exit" referring to where the guidewire exited the femoral artery. Zarbatany ¶[0088]. A POSITA would have understood that the entry/exit "point[s]" and "port[s]" refer to the same endoluminal openings through which the delivery device is introduced into and removed from vasculature and that endoluminal entry/exit "port[s]" are distinct from ports in the delivery device itself. Zarbatany ¶[0073] (disclosing "a first needle port 58A"); Drasler ¶76.

In light of **Zarbatany's** disclosures that an endoluminal entry/exit point is dilated to permit entry of a catheter and **Lane's** teaching that tip 1603 dilates heart wall tissue, a POSITA would have understood, and at minimum found it obvious, to dilate the entry/exit point and thus the access vessel with **Lane's** tip 1603 to advantageously avoid needing to separately dilate the insertion point. Zarbatany ¶[0088]; Lane ¶¶[0049], [0122]-[0123], [0132], [0139], Figs. 23A-23G; Drasler ¶77. As taught in **Hartley**, it was well-known to include the dilator on the end of the catheter to advantageously eliminate the need for a separate dilation of the access tract. Hartley ¶¶[0002], [0018], [0037] (nose cone dilator 11 with tapered end 19 for "accessing and dilating a vascular access site"), [0047], Fig. 1 (showing "tapered end 19"); *see also* Levine (Ex. 1016; published 1/22/2009) ¶¶[0005] (advancing delivery device "without first dilating the access tract" would "result in vessel…damage"), [0047] (elimination of repeated predilations reduces trauma, blood loss, patient discomfort, loss of vessel access); Drasler ¶78. Indeed, PO's infringement contentions in district court assert that a catheter inserted into the blood vessel dilates the vessel wall. Ex. 1010 (Am. Compl.), 24-25. Even if it is argued that a more tapered tip is required to dilate, **Lane** discloses such a shape and it would have been obvious to apply such a shape to insert the catheter more easily into the blood vessel, which would continue to function in the same manner as tip 1603 (*e.g.*, to penetrate and dilate the apex of the heart). Lane ¶[0113], [0115], Figs. 15A-C

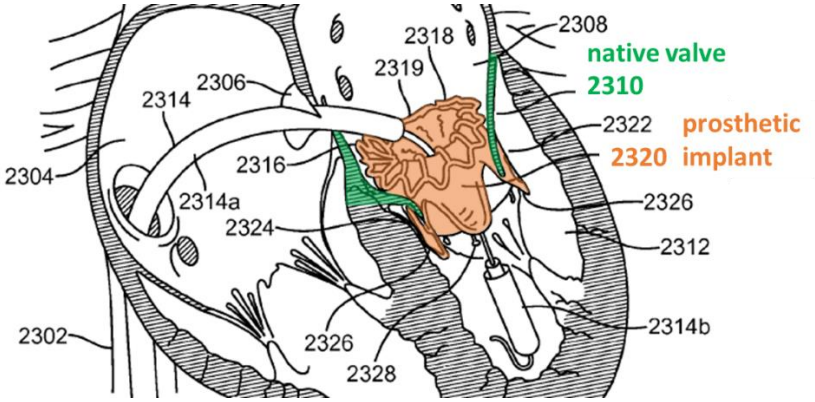
(showing tapered "flexible tip 1110"); *see also* Hartley ¶¶[0002], [0018], [0047], Fig. 1; Drasler ¶79.

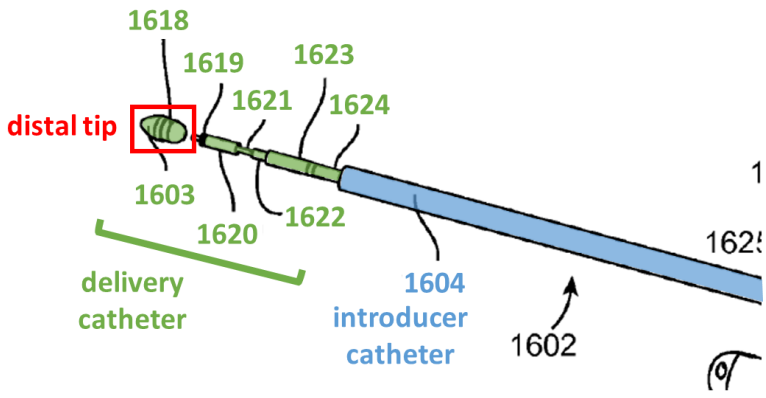
Lane teaches that its prosthesis and delivery device can treat aortic valves. Lane, ¶¶[0014], [0087]. Given **Lane's** disclosure, a POSITA would have understood to deliver **Lane's** device and prosthesis via the well-known retrograde femoral arterial method—transitting the aortic arch and aorta for delivery at or near the aortic valve—to advantageously avoid puncturing the atrial septum, which is required by **Zarbatany's** transseptal approach. Drasler ¶80; Lane ¶¶[0014], [0138]-[0139] (citing Zarbatany for *transseptal* techniques); Garrison, 7:28-38; *see also* Leonhardt (Ex. 1004; issued 9/28/1999), 9:64-10:11; Dwork ¶[0003]; Nguyen-189 ¶¶[0038], [0232]; Drasler ¶80.

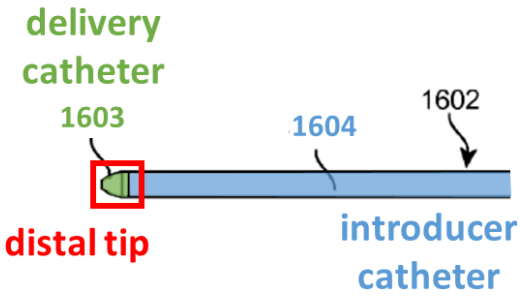
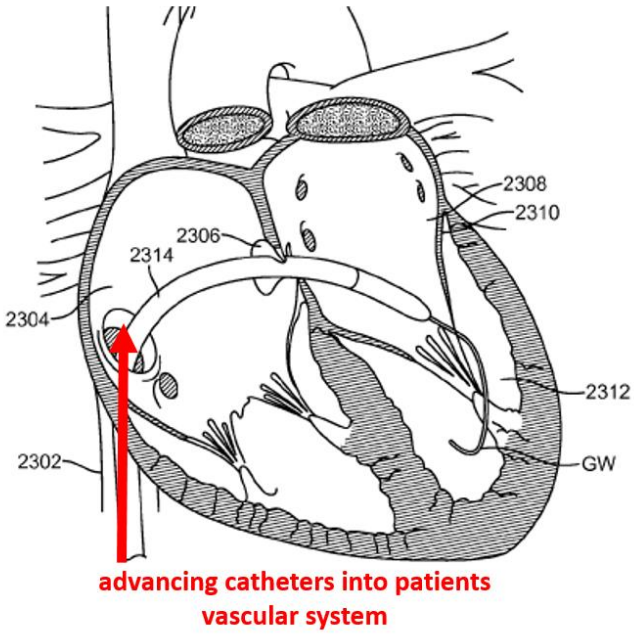
Lane is in the same field of endeavor as '897—implantable cardiac prosthetic devices—and reasonably pertinent to the alleged problem(s) identified in '897 of a need for percutaneously implanting a valve. '897, Abstract, 2:21-29, 2:31-35; Lane, ¶¶[0003], [0015]; Drasler ¶81.

2. Claim Chart

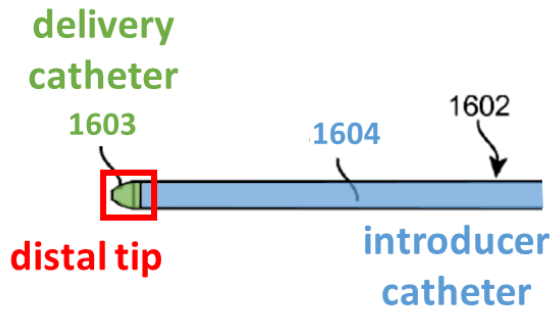
9,445,897	Lane US2011/0319989
[1.pre] A method of positioning a prosthetic implant within a heart, the method comprising:	**To the extent the preamble is limiting, Lane discloses a method of positioning a prosthetic implant** (*e.g.*, "positioning of the prosthesis") **within a heart** (*e.g.*, "anchoring the prosthetic cardiac valve to a patient's heart")**.** ***E.g.*, Lane:**

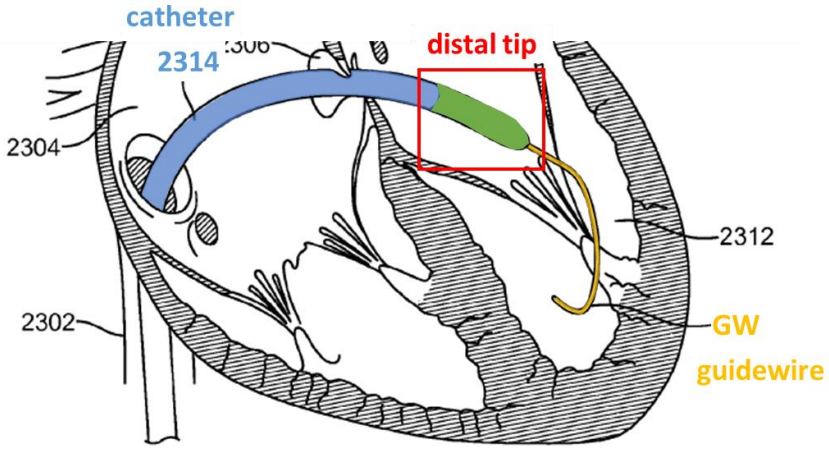
9,445,897	Lane US2011/0319989
	Lane discloses "positioning" a "valve prosthesis" within "a patient's heart" as a "replacement for the native" valve. • Fig. 23G  • ¶[0031] ("…once satisfactory ***positioning of the prosthesis*** has been achieved...catheter delivery system [is] withdrawn…***leaving…valve prosthesis in place as a functional replacement*** for the native mitral valve...") • Abstract ("…***anchoring***…prosthetic cardiac valve to a patient's heart.") • ¶[0117] ("…handle 1601 provides location for the control mechanisms used to ***position and deploy a prosthetic mitral valve***.") • ¶¶[0014], [0026]-[0029], [0142], 23A-G. Drasler ¶¶82-84.
[1.1] advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery	**Lane discloses advancing together a delivery catheter** (*e.g.*, together the "guide-wire catheter 1621", "hub catheter 1622", and "bell catheter 1624") **and an introducer catheter** (*e.g.*, "sheath catheter 1604") **that is preassembled over the delivery catheter** (*e.g.*, "guide-wire catheter 1621", "hub catheter 1622", and "bell catheter 1624" are "concentrically nested" within "sheath catheter 1604" before insertion because

9,445,897	Lane US2011/0319989
catheter into a patient's vascular system,	distal tip 1603 "abut[s] against" distal edge of sheath catheter 1604) **into a patient's vascular system** (*e.g.*, inserted into the access vessel during "transseptal" delivery)**.** ***E.g.*, Lane:** **Lane** discloses advancing the delivery apparatus comprising four "concentrically nested" catheters: 1604, 1624, 1622, and 1621 (from outermost to innermost). Lane ¶[0115], [0122], [0138], Fig. 18. As discussed in §X.A.1, because distal tip 1603 cannot pass through and instead "abut[s] against" the sheath catheter 1604's distal edge, sheath catheter 1604 is preassembled over the other three catheters outside the patient. Lane ¶[0123]; Drasler ¶¶87-88. Sheath catheter 1604, which "provides housing for a…valve," acts as the introducer catheter as no other catheter is used outside 1604 to introduce the device into the patient; while the remaining three catheters are the delivery catheter for the prosthesis, which is held "concentrically above the guide-wire catheter 1621" and by slots 1619 "under tip 1623 of bell catheter 1624." Lane ¶¶[0122], [0127], [0129], Fig. 21; Drasler ¶87. • Fig. 18 (excerpted)  • Fig. 16

9,445,897	Lane US2011/0319989
	 • Fig. 2B  FIG. 23B • ¶[0115] ("The delivery apparatus is…comprised of…a ***tip 1603 that can smoothly penetrate the apex of the heart***, and a flexible sheath 1602…comprised of ***concentric catheters*** that are designed to translate axially...") • ¶[0122] ("…***flexible sheath 1602 is comprised of four concentrically nested catheters***…innermost catheter is a ***guide-wire catheter 1621*** that runs internally

9,445,897	Lane US2011/0319989
	throughout the entire delivery system, beginning at the tip 1603…next…is…***hub catheter 1622***…in mating connection with…hub 1622 [*sic* 1620]…next…is…***bell catheter 1624***, which provides housing to the ***hub 1620***…bell catheter 1624 is bumped up to a larger diameter 1623 on the distal end…to encapsulate…hub 1620…***outermost…catheter is…sheath catheter 1604 which provides housing for a prosthetic mitral valve***…and which is able to penetrate…apex of the heart…by ***supporting and directing a tip 1603 and assisting in…dilation of an incision in…heart wall muscle***.") • ¶[0123] ("…to provide adequate stiffness to dilate heart wall tissue, ***the distal edge of the sheath catheter 1604 will abut against a shoulder 1618 located on the tip 1603***. This communication ***allows the tip 1603 to remain secure and aligned with the sheath catheter 1604 during delivery***, and creates piercing stiffness.") • ¶[0127] ("…***to effect the deployment of a heart valve… user must withdraw the sheath catheter 1604 from contact with the shoulder 1618 of the tip 1603*** until it passes the larger diameter section 1623 of the bell catheter 1624. ***A heart valve…will reside concentrically above the guide-wire catheter 1621***…") • ¶[0129] ("The ***valve may be releasably held by the slots*** by disposing the commissure tabs or tabs 812 of the prosthetic valve into slots 1619 and then ***retracting the slots 1619 under tip 1623 of bell catheter 1624***… …***prosthetic valve may be released from…delivery catheter by advancing…slots distally relative to…bell catheter*** so that…loading anchors or tabs 812 may self-expand out of and away from slots 1619.") • ¶[0138] ("FIG. 23A illustrates…***transseptal pathway***…taken with the delivery device ***passing up***

9,445,897	Lane US2011/0319989
	the vena cava 2302 into the right atrium 2304.") • ¶¶[0047], [0091], Figs. 20, 21; *see also* [1.2]. Drasler ¶¶85-88.
[1.2] the delivery catheter comprising a prosthetic valve and a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter,	**Lane discloses the delivery catheter comprising a prosthetic valve** (*e.g.*, "valve…releasably held by…bell catheter 1624") **and a distal tip** (*e.g.*, distal "tip 1603" connected to "guidewire catheter 1621")**.** ***E.g.*, Lane:** The inner catheters—1621, 1622, and 1624—comprise the "delivery catheter" and include a prosthetic "valve." *See* [1.1]; Lane ¶[0129]. "[T]ip 1603," connected to guidewire catheter 1621, is the delivery catheter's distal tip. Lane ¶¶[0115], [0122], [0123]. "Tip 1603" is inserted into the access vessel before sheath catheter 1604 for delivery of the valve to the implantation site transluminally, *e.g.*, "up the vena cava" for "transseptal[]" delivery. Lane ¶¶[0091], [0138]. • Fig. 16  • Fig. 23B

9,445,897	Lane US2011/0319989
	 FIG. 23B • ¶[0049] ("…tissue penetrating ***distal tip may be adapted to pass through and expand an incision*** in the patient's heart.") • ¶[0091] ("The prosthetic valve…has a collapsed configuration…***adapted to loading on a shaft such as a delivery catheter for transluminal delivery to the heart***, or on a shaft for transapical delivery through the heart wall.") • ¶¶[0115], [0122], [0123], [0129], [0138] (*see* [1.1]) • *See also* ¶¶[0006], [0115], Figs. 20, 23A-23G. **Zarbatany, which is incorporated by reference by Lane** (*see* §X.A.1)**, discloses inserting a catheter directly into the access vessel** (*e.g.*, "endoluminal entry" in "femoral vein" "is dilated to permit entry of a catheter therethrough") **such that the distal tip dilates the access vessel for the introducer catheter** (*e.g.*, "dilate[]" the access vessel for the "catheter")**.** ***E.g.*, Zarbatany:**

9,445,897	Lane US2011/0319989
	Zarbatany discloses inserting a catheter into a patient through an "entry" point/port in a "femoral vein," to transluminally delivery the valve to the heart. Zarbatany ¶[0088]. The entry point/port is "dilated to permit entry of a catheter." *Id*. As discussed in §X.A.1, a POSITA would have understood, and at minimum found it obvious, to use **Lane's** tip 1603 to dilate the access point to the access vessel and therefore the access vessel itself, *e.g*., during insertion into the vessel. Drasler ¶94. Similar to the manner in which tip 1603 is used to dilate an incision in the heart muscle, this would advantageously eliminate the need for a separate dilation of the vessel before insertion of the catheter. *See* §X.A.1; Lane ¶¶[0122], [0049], Figs. 23A-23G; Drasler ¶94. Alternatively, a POSITA would have also been motivated to use a more tapered tip, such as 1110, to dilate the vessel as discussed in §X.A.1. Lane ¶¶[0113], [0147], Figs. 15A-15C; Drasler ¶94. Because **Zarbatany** teaches a "protective sheath" is optional, a POSITA would have understood, or it would have been obvious, to insert the catheter directly such that it dilates the access vessel to enter the vessel, meaning **Lane's** sheath catheter 1604 remains the introducer catheter. Zarbatany ¶[0088]; Drasler ¶95. • ¶[0069] ("While the guide catheter, therapy catheter, and fastener catheter cooperatively enable a surgeon to deliver a suture to a repair site in vivo, the ***various components of the present invention may be used individually***. For example, the therapy catheter, the fastener catheter, or both may be coupled to a guidewire and advanced to a repair site in vivo without the use of the guide catheter.") • ¶[0088] ("…guidewire…is ***introduced into…patient through an endoluminal entry point***…formed in a femoral vein or right jugular vein…guidewire 220 traverses…aortic valve 228 into…aorta 230 and is made

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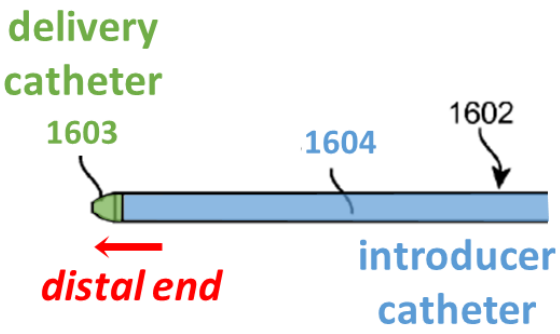
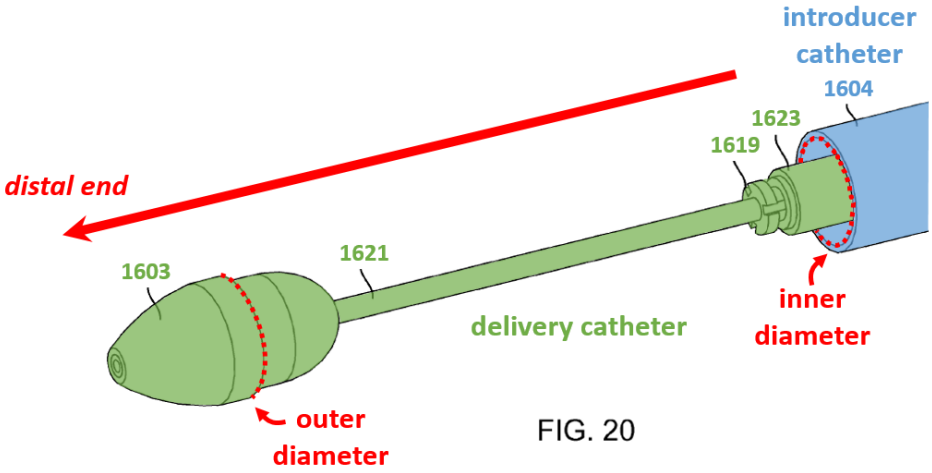
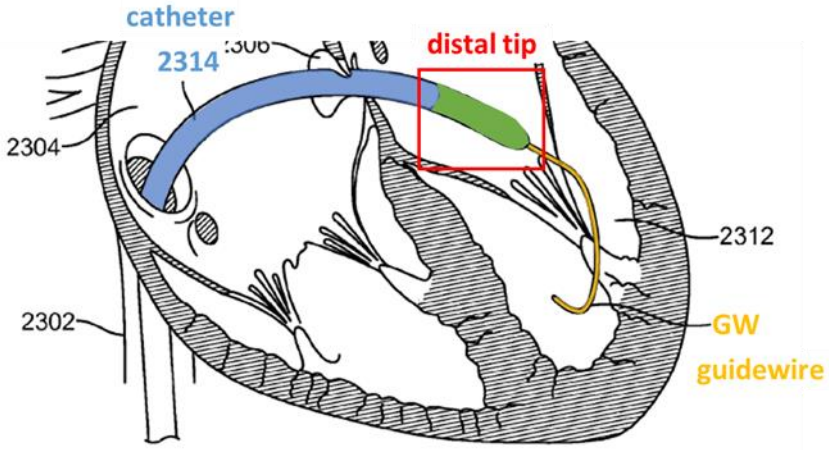
	to emerge at…***left femoral artery through an endoluminal exit point***. Once…guidewire 220 is positioned…***endoluminal entry or exit port is dilated to permit entry of a catheter therethrough…***") • ¶¶[0009], [0070], [0073]. Drasler ¶¶89-95.
[1.3] wherein during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter,	**Lane discloses wherein during advancement** (*e.g.*, "during delivery")**, an outer diameter of a distal end of the delivery catheter** (*e.g.*, outer diameter of distal "tip 1603" of "guidewire catheter 1621") **being greater than an inner diameter of a distal end of the introducer catheter** (*e.g.*, "the distal edge of the sheath catheter 1604…abut[s] against…tip 1603" of "guidewire catheter 1621")**.** ***E.g.*, Lane:** During advancement, tip 1603's proximal shoulder 1618 "will abut against" the distal edge of sheath catheter 1604 such that tip 1603 (the distal end of the delivery catheter) cannot be withdrawn into sheath catheter 1604. Lane ¶[0123]. Therefore, tip 1603's (at delivery catheter's distal end) outer diameter is greater than sheath catheter 1604's (the introducer catheter) inner diameter (*see* Figs. 16, 23B). *Id.*; *see also* Figs. 19A-20; Drasler ¶98. • Fig. 16

9,445,897	Lane US2011/0319989
	 • Fig. 20  FIG. 20 • Fig. 23B

9,445,897	Lane US2011/0319989
	 FIG. 23B • ¶¶[0122], [0123] (*see* [1.1]) • *See also* ¶[0113], Fig. 19A. Drasler ¶¶96-98.
[1.4] the introducer catheter comprising a hemostasis valve assembly at a proximal end of the introducer catheter;	**Lane discloses the introducer catheter comprising a hemostasis valve assembly** (*e.g.*, "o-ring 1638…creating a hemostatic seal" in contact with hole 1625 and 1626 to allow "fluid purging" through the "first hemo-port") **at a proximal end of the introducer catheter** (*e.g.*, "proximal end of the sheath catheter 1604 is in mating contact with…an o-ring 1638")**.** ***E.g.*, Lane:** Hemostasis valve assembly comprising o-ring 1638 at sheath catheter 1604's proximal end is designed to "compress against the bell catheter 1624, creating a hemostatic seal." Lane ¶[0123]. The o-ring is in contact with hole 1625 and 1626 to allow fluid purging. Lane ¶[0122]. This is consistent with '897, which recites that "seal assembly 1042" positioned at

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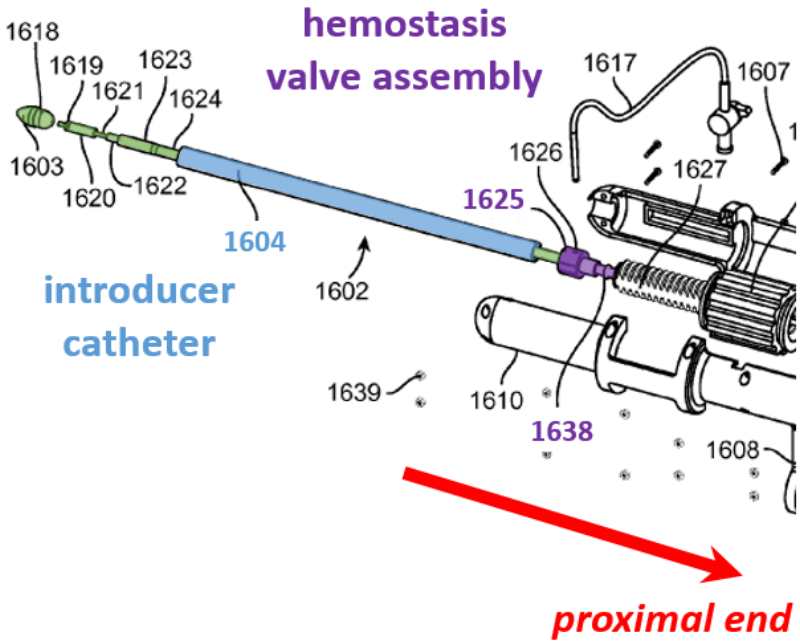
	introducer catheter 1030's proximal end forms "a seal around the delivery catheter 900." '897, 24:39-41, 24:52-62. • Fig. 18  • ¶[0122] ("The sheath catheter 1604 is in ***mating connection with the first hemo-port 1625*** at the proximal end, and ***hemostasis*** between the sheath catheter 1604 and the bell catheter 1624 ***can be achieved*** by purging the first hemostasis tube 1617.") • ¶[0123] ("…***the proximal end of the sheath catheter 1604*** is in mating contact with…an ***o-ring 1638***, which is entrapped between…hemo-port 1625 and…threaded insert 1627…to ***compress against…bell catheter 1624, creating a hemostatic seal***.") • *See also* ¶[0073]. Drasler ¶¶99-101.

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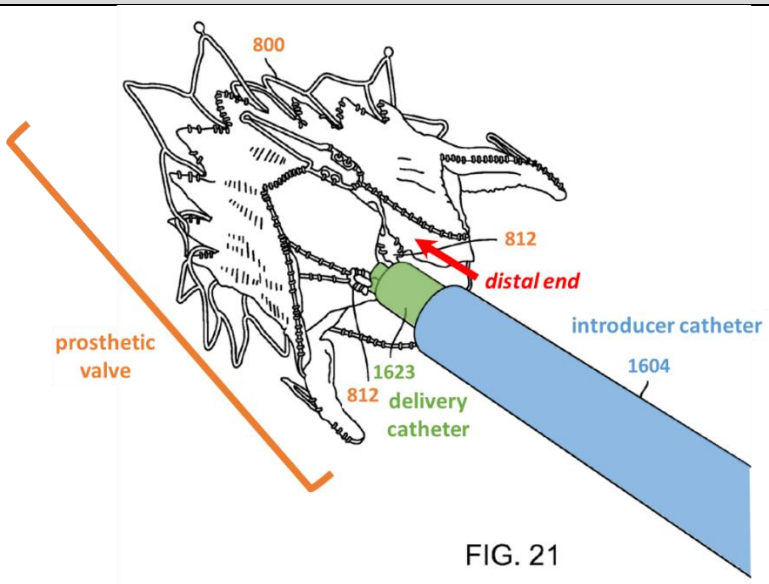
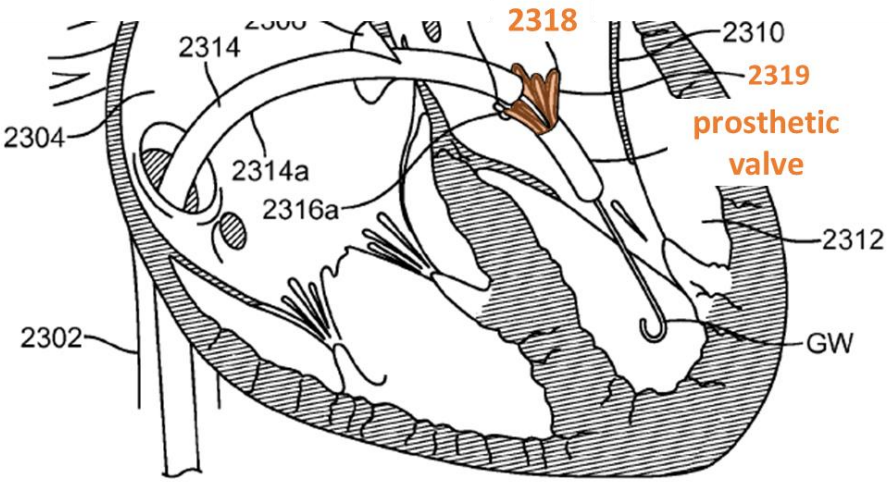
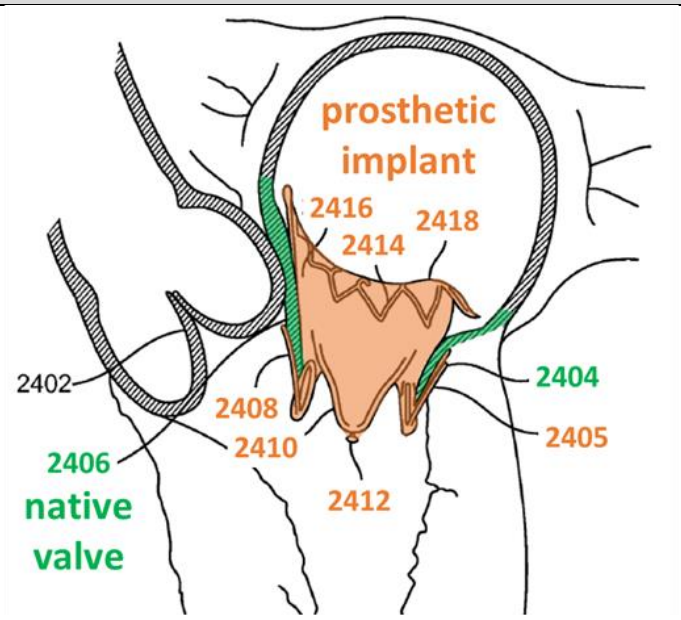
[1.5] translumenally advancing the prosthetic valve to a position proximate a native valve of the heart, the prosthetic valve being at least partially disposed within the distal end of the delivery catheter during advancement of the introducer catheter; and	**Lane discloses translumenally advancing the prosthetic valve** (*e.g.*, advancing the "valve prosthesis" transluminally to the heart) **to a position proximate a native valve of the heart** (*e.g.*, "positioning" a "valve prosthesis" as a "replacement for the native" heart valve)**, the prosthetic valve being at least partially disposed within the distal end of the delivery catheter during advancement of the introducer catheter** (*e.g.*, "valve…releasably held by the slots…and then retracting the slots 1619 under tip 1623 of bell catheter 1624")**.** ***E.g.*, Lane:** **Lane** discloses advancing the delivery device with the prosthetic valve to a position proximate a native valve transluminally through vascular pathways (e.g., "up the vena cava") for "transseptal[]" delivery. Lane ¶¶[0029], [0091], [0138], [0143], Figs. 23G, 24; Drasler ¶105; *see* [1.pre], [1.2]. A POSITA would have understood "transseptal" delivery refers to transluminal delivery. Drasler ¶105. The prosthesis is held at the delivery catheter's distal end by slots 1619 "under tip 1623 of bell catheter 1624." Lane ¶¶[0127], [0129]; *see* [1.1]. The prosthesis is thus partially disposed within the delivery catheter's distal end during advancement until it is released after the delivery catheter has reached the implantation site. Lane ¶¶[0031], [0129]; *see* [1.pre]. • Fig. 21

9,445,897	Lane US2011/0319989
	 FIG. 21 • Fig. 23C  FIG. 23C • Fig. 24

9,445,897	Lane US2011/0319989
	 • ¶[0029] ("Complete retraction of the outer catheter delivery sheath…allows the ***anchoring tabs to proximate their anchoring location***.") • ¶[0076] ("Fig. 21 illustrates engagement of the delivery device in Fig. 16 with the prosthetic valve of Fig. 8A") • ¶[0091] ("FIG.8A illustrates…a prosthetic mitral valve 800[,which] has a collapsed configuration…adapted to loading on a shaft such as a delivery catheter ***for transluminal delivery to the heart***….") • ¶[0031] (*see* [1.pre]) • ¶[0091] (*see* [1.2]) • ¶¶[0127], [0129], [0138] (*see* [1.1]) • ¶[0143] ("The ***prosthetic valve*** is now ***implanted*** in the patient's heart and ***takes over the native mitral valve***.")

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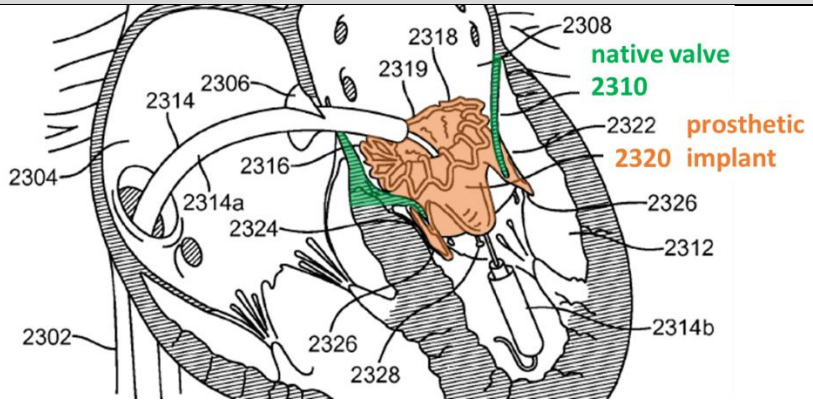
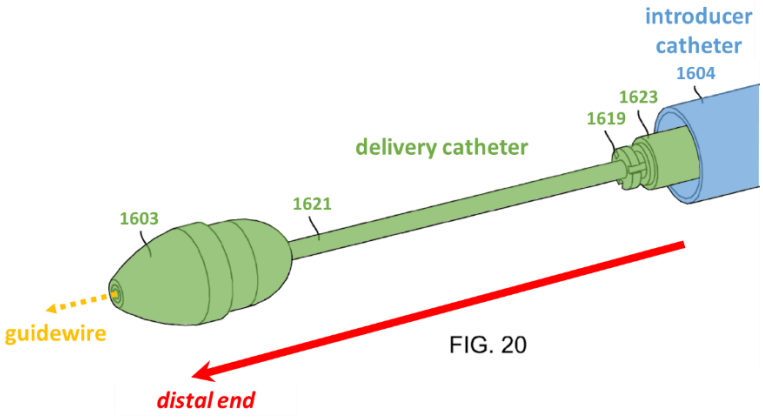
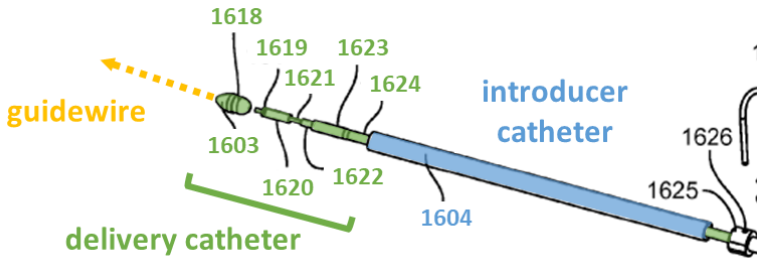
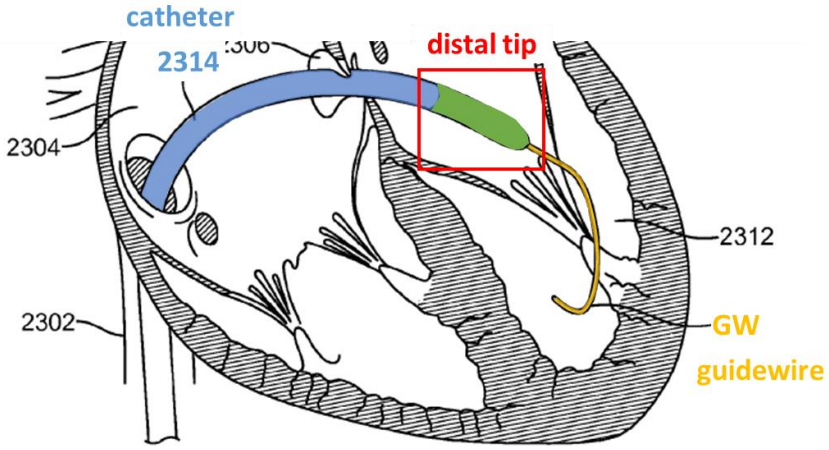
	• *See also* ¶¶[0140], [0142]-[0145], Figs. 16, 20, 23G. **Zarbatany, incorporated by reference in Lane** (*see* §X.A.1)**, discloses translumenally advancing the prosthetic valve to a position proximate a native valve of the heart** (*e.g.*, "advancing a [] catheter through a circulatory pathway to a location in the heart proximate to a heart valve…"). ***E.g.*, Zarbatany:** *See* [1.2]. In addition, as discussed in §X.A.1, a POSITA would have understood, and at minimum found it obvious, that **Lane's** delivery device enters a patient through an "endoluminal entry point" in a "femoral vein" and is advanced transluminally "to a location in the heart proximate to a heart valve" in view of such teachings in **Zarbatany**. Drasler ¶¶108-109. • ¶[0018] ("…method of repairing tissue within…heart of a patient…includes ***advancing a guide catheter through a circulatory pathway to a location in the heart proximate to a heart valve***…") • ¶[0088] (*see* [1.2]) • ¶¶[0019], [0049], [0089], [0091], Abstract. Drasler ¶¶102-109.
[1.6] deploying the prosthetic valve.	**Lane discloses deploying the prosthetic valve** (*e.g.*, "prosthetic valve may be released from the delivery catheter")**.** ***E.g.*, Lane:** *See* [1.5]. • Fig. 23G

9,445,897	Lane US2011/0319989
	 • ¶[0117] (*see* [1.pre]) • ¶[0129] (*see* [1.1]) ¶[0143] ("The ***prosthetic valve is now implanted in the patient's heart*** and takes over the native mitral valve.") • *See also* ¶¶[0026]-[0029], [0031], [0140], [0143]. Drasler ¶¶110-111.
[2] The method of claim 1, wherein the step of advancing the introducer catheter preassembled over the delivery catheter comprising the prosthetic valve into the patients vascular system comprises advancing the introducer catheter and delivery	***See* [1].** **Lane discloses that the step of advancing the introducer catheter preassembled over the delivery catheter comprising the prosthetic valve into the patients vascular system comprises advancing the introducer catheter and delivery catheter over a guidewire** (*e.g.*, *see* [1.1], "delivery device 2314 is passed over a guidewire GW"). ***E.g.*, Lane:** *See* [1.1]-[1.2]. In addition, **Lane** discloses a guidewire running through the innermost concentric guidewire catheter 1621 of the delivery system, such that the delivery device (including the delivery

9,445,897	Lane US2011/0319989
catheter over a guidewire.	and introducer catheters) (Lane ¶[0115]) is advanced/"passed" over the guidewire. • Fig. 20  FIG. 20 • Fig. 18  • Fig. 23B

9,445,897	Lane US2011/0319989
	 FIG. 23B • ¶[0047] ("…delivery system…comprises…***inner guidewire shaft***…***adapted to slidably receive a guidewire***.") • ¶[0122] (*see* [1.1]) • ¶[0139] ("In FIG. 23B a delivery device 2314 ***is passed over a guidewire GW*** through the vena cava 2302 into the right atrium 2306.") • ¶¶[0115], [0116]. • *See also* [1.2] (discussing Zarabatany's guidewire) Drasler ¶¶112-116.
[3] The method of claim 1, wherein the step of advancing the introducer catheter preassembled over the delivery	***See* [1].** **Lane discloses the step of advancing the introducer catheter preassembled over the delivery catheter comprising the prosthetic valve into the patient's vascular system comprises inserting the introducer catheter into a vessel.**

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catheter comprising the prosthetic valve into the patient's vascular system comprises inserting the introducer catheter into a femoral artery.	*See* [1.1]-[1.2], [1.5]. As discussed in §X.A.1, a POSITA would have understood, and at minimum found it obvious, to advance the prosthesis through the well-known retrograde arterial approach in which case the catheter would be inserted via the femoral artery, given **Lane's** disclosure of transluminal delivery and **Zarbatany's** (incorporated by reference in Lane) disclosure of direct venous access to advantageously avoid puncturing the atrial septum for transseptal delivery. Lane ¶¶[0087], [0091], [0138]; Zarbatany ¶[0088]; Drasler ¶¶117-121.
[4] The method of claim 1, wherein the step of translumenally advancing the prosthetic valve to a position proximate the native valve of the heart comprises advancing the prosthetic valve through an aorta.	***See* [1].** **Lane discloses the step of translumenally advancing the prosthetic valve to a position proximate the native valve of the heart comprises advancing the prosthetic valve through an aorta** (*e.g.*, advancing "prosthetic valve" to replace the "aortic valve")**.** ***E.g.*, Lane:** *See* [1.2], [1.5], [3]. In addition, **Lane** discloses replacing the aortic valve by delivering the prosthesis transluminally. Lane, ¶¶[0087], [0091], [0138]. As discussed in §X.A.1, a POSITA would have understood, and at minimum found it obvious, to transluminally advance the prosthesis through the well-known retrograde arterial approach via the aorta, to reach the native aortic valve, in which case the guidewire would be inserted via the femoral artery, along the iliac artery, up the descending the aorta, around the aortic arch and to the aortic valve. Drasler ¶¶125-126. • ¶[0087] ("the device and methods disclosed herein ***may also be used to treat other cardiac valves*** such as…

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	aortic valve....") • *See also* ¶¶[0132], [0139]. Drasler ¶¶122-126.
[6] The method of claim 1, wherein the distal end of the delivery catheter is inserted directly into an access vessel.	***See* [1].** **Lane discloses that the distal end of the delivery catheter is inserted directly into an access vessel** (*e.g.*, inserting the distal end of the catheters 1621, 1622, and 1624 including tip 1623 into the access vessel, *see* [1.2])**.** ***See* [1.2].** **Zarbatany, incorporated by reference in Lane** (see §X.A.1)**, discloses inserting a catheter directly into the access vessel** (*see* [1.2]). ***See* [1.2].** Drasler ¶¶127-129.
[7] The method of claim 1, further comprising removing the delivery catheter and introducer catheter together from the patient.	***See* [1].** **Lane discloses removing the delivery catheter and introducer catheter together from the patient** (*e.g.*, "delivery system is retracted and removed")**.** ***E.g.*, Lane**: *See* [1.1]. In addition, the entire "delivery system," including catheters 1621, 1622, and 1624 (delivery catheter) as well as 1604 (introducer catheter), is "retracted and removed" simultaneously after the prosthesis is deployed (*see e.g.*, Fig. 16). Lane ¶¶[0031], [0047], [0123] (tip 1603 abuts catheter 1604 during delivery). As discussed in §X.A.1, a POSITA

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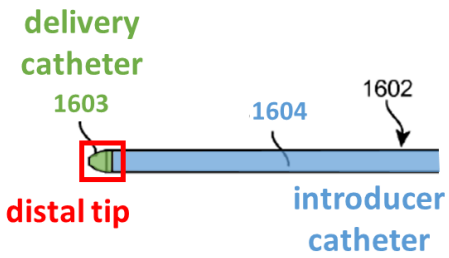
	would have understood, and at minimum found it obvious, to do so given that tip 1603 cannot pass through catheter 1604 (*see* [1.3]) and, if tip 1603 did not abut catheter 1604 during removal, shoulder 1618 (*see* Fig. 19A) would inadvertently catch on blood vessel. Drasler ¶133. • Fig. 16  • ¶[0031] ("Once final deployment is complete, ***the delivery system is*** retracted and ***removed***.") • ¶[0047] ("…***delivery system…comprises*** an inner guidewire shaft…and a hub shaft…delivery system also comprises a bell shaft…a sheath…and a handle near a proximal end of the ***delivery system***.") • ¶[0115] (*see* [2]) • ¶¶[0122]-[0123] (*see* [1.1]) • *See also* Figs. 19A-20. Drasler ¶¶130-133.
[8] The method of claim 1, wherein deploying the prosthetic valve comprises retracting the delivery catheter	***See* [1].** **Lane discloses that deploying the prosthetic valve comprises retracting the delivery catheter to expose the prosthetic valve** (*e.g.*, "larger diameter section 1623 of the bell catheter 1624 is also fully retracted, which completely frees the heart valve")**.**

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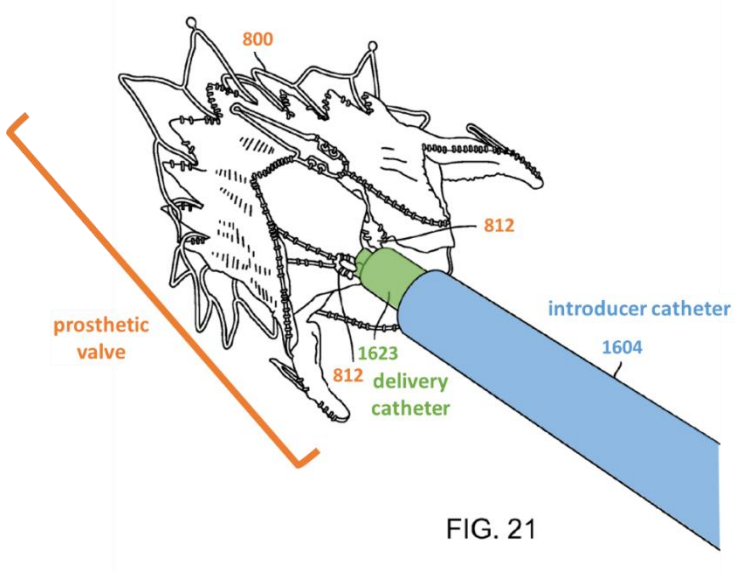
to expose the prosthetic valve.	***E.g.*, Lane:** *See* [1.1], [1.5]-[1.6]. In addition, bell catheter 1624, which is part of the delivery catheter, is retracted to expose hub 1620 and hub slots 1619 and free the heart valve—allowing it to expand. • Fig. 21  FIG. 21 • ¶[0124] ("…***bell catheter 1624 can be retracted*** or advanced with respect to the hub 1620.") • ¶[0128] ("…the ***larger diameter section 1623 of the bell catheter 1624 is also fully retracted, which completely frees the heart valve***…from the delivery system…[and] hub slots 1619 become uncovered which allows***…heart valve anchor…fully expand***.") • ¶¶[0031], [0047], [0049], [0122], [0129]. Drasler ¶¶134-137.

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[9] The method of claim 8, wherein deploying the prosthetic valve comprises holding the prosthetic valve stationary as the delivery catheter is retracted.	***See* [8].** **Lane discloses that deploying the prosthetic valve comprises holding the prosthetic valve stationary as the delivery catheter is retracted** (*e.g.*, after "valve prosthesis is…anchored," "bell catheter 1624 is also fully retracted")**.** ***E.g.*, Lane:** *See* [8]. In addition, as the "first general deployment step," the atrial skirt of the prosthesis is "anchored against" the "surface of the heart"—thus holding the prosthesis stationary as the bell catheter 1624 is retracted to release the prosthesis. • ¶[0026] ("***In the first…deployment step***…atrial skirt region of…valve prosthesis is permitted to expand…and ***anchored*** against…adjoining atrial surface of the heart.") • ¶[0031] (*see* [1.pre]) • ¶[0128] (*see* [8]) • ¶[0129] (*see* [1.1]) • *See also* ¶¶[0122], [0124]. Drasler ¶¶138-141.
[10] The method of claim 1, wherein the delivery catheter comprises an outer tubular member and an inner	***See* [1].** **Lane discloses that the delivery catheter comprises an outer tubular member** (*e.g.*, "bell catheter 1624") **and an inner tubular member** (*e.g.*, "guide-wire catheter 1621" and "hub catheter 1622") **extending through the outer tubular member** (*e.g.*, "guide-wire catheter 1621…runs internally

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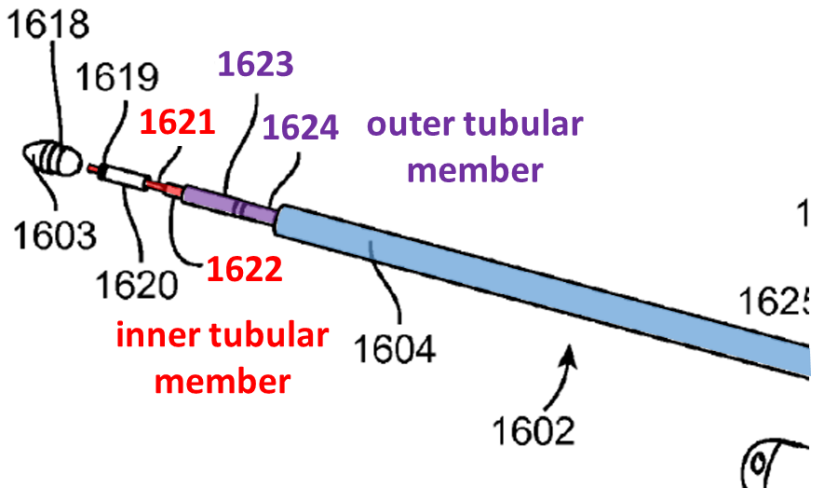
tubular member extending through the outer tubular member.	throughout the entire delivery system", "hub catheter 1622" is "concentrically nested" within bell catheter 1624)**.** ***E.g.*, Lane:** *See* [1.1]. In addition, guide-wire catheter 1621 and hub catheter 1622 are "concentrically nested" within bell catheter 1624. • Fig. 18 (excerpted)  • ¶[0122] (*see*[1.1]) Drasler ¶¶142-144.
[16.1] The method of claim 1, wherein deploying the prosthetic valve comprises: partially deploying the prosthetic valve;	***See* [1].** **Lane discloses deploying the prosthetic valve comprises: partially deploying the prosthetic valve** (*e.g.*, "partially radially expand" the "prosthetic valve")**.** ***E.g.*, Lane:** *See* [1.5]-[1.6].

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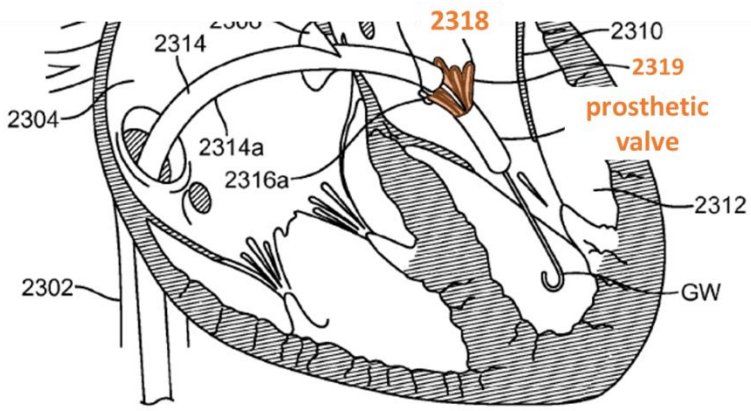
	In addition, the prosthetic valve "partially radially expand[s]" as part of deployment and these teachings were applicable to "transseptal" delivery embodiments as discussed in §X.A.1. • Fig. 23C  FIG. 23C • ¶[0140] ("In FIG. 23C, the outer sheath 2214a of the delivery device 2214 is retracted proximally relative to the prosthetic mitral valve 2319. Alternatively, a distal portion 2314b of the delivery device 2214 may be advanced distally relative to the prosthetic valve 2319 …which allows the atrial skirt region 2318 to begin to ***partially radially expand*** outward and flare open….") • ¶¶[0026]-[0029], [0031]. Drasler ¶¶145-149.
[16.2] adjusting an angular position of the prosthetic valve; and	**Lane discloses adjusting an angular position of the prosthetic valve** (*e.g.*, "rotate[]" "delivery device" to "align the alignment element" of the "prosthetic cardiac valve")**.** ***E.g.*, Lane:**

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	See* [16.1].** In addition, after partially expanding the prosthesis, the delivery device may be "rotated" and the position of the prosthesis otherwise adjusted to "align" the prosthesis. Lane ¶¶[0026], [0029], [0046], [0140], [0141]. As discussed in §X.A.1, a POSITA would have understood that "rotat[ing]," "orient[ing]," "adapt[ing]," and "adjusting" the prosthesis adjusts its angular axial position (*i.e.*, alignment of the device axis with the native valve axis (e.g., yaw / pitch)), and at minimum it would have been obvious to do so in order to "ensure accurate positioning" and to "orient the…valve into a desired position." Drasler ¶153. • ¶[0026] ("…catheter delivery sheath is ***first retracted only so far as to permit expansion of…alignment structure (so…it may be visualized to facilitate ***manipulation of the delivery system…to orient…prosthesis into…desired position***), and…once initial alignment of the prosthesis appears…satisfactory, further retracted to permit…expansion, positioning and anchoring of the remaining portions…") • ¶[0046] ("The prosthetic…cardiac valve may…comprise an ***alignment element…adapted to be aligned with*** an aortic root of…heart…") • ¶[0140] ("…***physician can…align the alignment element*** so that the radiopaque markers 2316a are disposed on either side of the anterior mitral valve leaflet. ***Delivery device 2214 may be rotated***…to help align the alignment element.") • ¶[0142] ("***Slight rotation and realignment of the prosthesis*** can occur at this time.…") • *See also* ¶¶[0029], [0092].

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	Drasler ¶¶150-153.
[16.3] fully deploying the prosthetic valve.	**Lane discloses deploying the prosthetic valve comprises: fully deploying the prosthetic valve** (*e.g.*, "fully expand" the prosthesis)**.** ***E.g.*, Lane:** ***See* [1.pre], [1.6], [8]-[9], [16.1]-[16.2].** In addition, after the prosthesis is appropriately positioned, bell catheter 1624 is retracted such that "commissures are released" allowing the valve to "fully expand." Lane ¶¶ [0031], [0128], [0138], [0143]; s*ee* [9], [16.1]-[16.2]. Drasler ¶¶154-156.
[17] The method of claim 1, further comprising simultaneously removing the introducer catheter and the delivery catheter.	***See* [1], [7].** Drasler ¶157.

B. Ground 2: Claims 1-4, 6-10, 16-17 Are Rendered Obvious by Lane in View of Hartley

To the extent it is argued that further disclosure of "a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter" (limitation [1.2]) is required, **Hartley** teaches inserting a nose cone dilator, with a tapered tip, connected to a catheter directly into an access vessel to dilate the vessel for the catheter—thus further rendering obvious claims 1-4, 6-10, 16-17 over **Lane** in view of **Hartley**. Drasler ¶¶158-162.

Hartley discloses a "nose cone dilator" on the front of a "delivery device" to directly enter and dilate an access vessel for "intraluminal or endovascular delivery" of a prosthetic stent. Hartley ¶¶[0002], [0010], Fig. 1 (below).

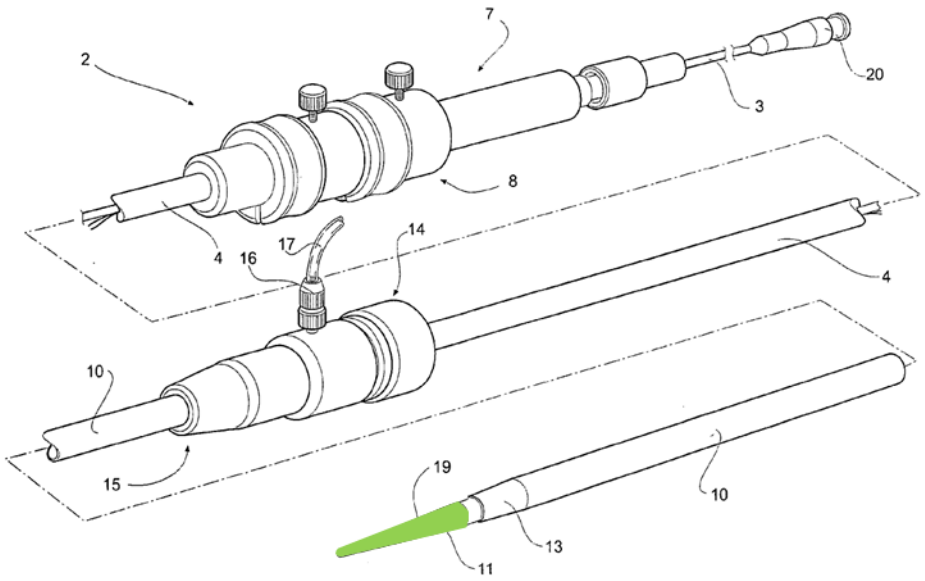


FIG 1

The nose cone dilator 11 has a tapered end 19 for "accessing and dilating a vascular access site." Hartley ¶[0037], Fig. 1. For example, after insertion of a wire guide into a vessel using the needle-based "Seldinger's technique" (*see* Seldinger (Ex. 1025; published 1953), 16, Figs. 1-f), nose cone dilator 11 may be inserted directly to dilate the access site and the vessel for advancement of the delivery device. Hartley ¶[0038]; *see also* Nguyen-189 ¶¶[0178], [0183]; Sylvanowicz (Ex. 1027; published 11/2/1989), 7:14-18, 3a; Hawkins (Ex. 1028; published 10/7/2010) ¶¶[0042], [0046], [0070]; Drasler ¶¶38-39, 159. To "assist in conformation with tortuosity of vessels into which the delivery device is deployed," nose cone dilator

has a "high flexibility." Hartley ¶¶[0013], [0018]. This avoids "unnecessary trauma" to walls of the vessels. Hartley ¶[0047].

It was known that advancing a delivery device over a guidewire "without first dilating the access tract" would result in "damage" and/or "loss of…access"/"severe bleeding" to the vessel. Levine ¶¶[0005], [0047]; Drasler ¶160. While a POSITA would have understood, and at minimum found it obvious, that tip 1603 dilates an entry point and the access vessel in view of **Lane** (including **Zarbatany**) (*see* §X.A.1), **Hartley** expressly discloses inserting a nose cone dilator on the end of a catheter into an access vessel to dilate the vessel on initial entry. Hartley ¶¶[0037], [0018]; Drasler ¶160. A POSITA would have been motivated to apply **Hartley's** teachings of the nose cone dilator with a tapered tip to **Lane's** distal tip 1603 to achieve the beneficial and predictable result of a distal tip that is directly inserted into an access vessel to dilate the vessel for sheath catheter 1604 advantageously eliminating the need for a separate dilation of the insertion point as discussed in §X.A.1. Drasler ¶160. Moreover, a POSITA would have been motivated to apply **Hartley's** teachings in light of the similarities with **Lane**—both references teach transluminally delivering a prosthesis to replace a heart valve using a delivery device with a distal tip. Hartley ¶¶[0002], [0003], [0037], [0038], [0047]; *see* §X.A.1; Drasler ¶160.

A POSITA would have had a reasonable expectation of success in applying **Hartley's** teachings regarding the nose cone dilator to **Lane's** distal tip 1603. Drasler ¶161. **Lane's** distal tip 1603 so modified with **Hartley's** teachings would remain operable, including for embodiments where it "assist[s] in the dilation of an incision in the heart wall muscle" similar to the manner in which **Lane's** tip 1110 is "easily introduced into the apex of the heart." Lane ¶¶[0113], [0122], [0132], [0139], [0147], Figs. 15A-15C; Drasler ¶161.

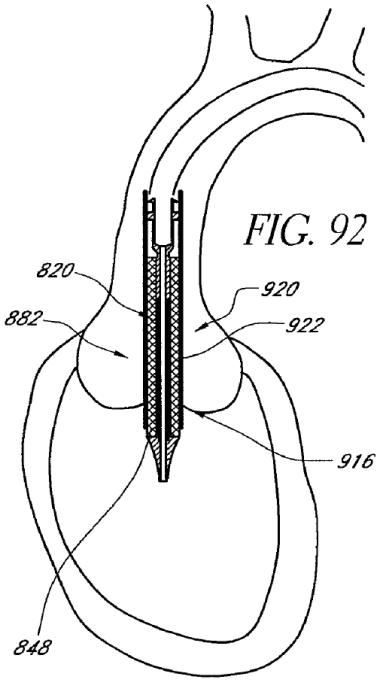
A POSITA would have found it routine, straightforward and advantageous to apply **Hartley's** teachings in implementing **Lane's** prosthesis delivery method and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality of delivering **Lane's** valve prosthesis by directly inserting modified distal tip 1603 into an access vessel to dilate the vessel for sheath catheter 1604. Lane ¶¶[0049], [0113], [0122]; Hartley ¶¶[0037], [0038]; Drasler ¶162.

C. Grounds 3, 4: Claims 3-4 Are Rendered Obvious by Lane in View of Nguyen-189 and Alternatively in Further View of Hartley

To the extent PO argues further disclosure of inserting the delivery device into a femoral artery is necessary for Claim 3 (*see* §X.A.2.[3]) and advancing the prosthesis through an aorta is necessary for Claim 4 (*see* §X.A.2.[4]), **Nguyen-189** teaches inserting a prosthesis into a femoral artery and delivering it through the

aorta—thus further rendering obvious claims 3-4 over **Lane** in view of **Nguyen-189** and alternatively in further view of **Hartley**. Drasler ¶¶163-167.

Nguyen-189 discloses a "prosthetic valve assembly" "intended to be percutaneously inserted and deployed using a catheter assembly" that may be "introduced in a retrograde manner through a peripheral artery (femoral artery)" "[w]hen replacing an aortic valve." Nguyen-189 ¶¶[0038], [0177], *see also id.* ¶¶[0046], [0183], [0229]. For "retrograde delivery," the catheter assembly advances through the "arterial vasculature" and "retrograde through the aorta to reach the aortic valve." Nguyen-189 ¶[0232], Fig. 92 (below); Drasler ¶164.



Transseptal delivery in **Lane** (including **Zarbatany**) requires a "transseptal puncture" through the atrial septum. Lane ¶[0138]; Zarbatany ¶[0088]; §X.A.1.

While a POSITA would have found it obvious to beneficially avoid puncturing the atrial septum by delivering the prosthesis to the aortic valve using a retrograde femoral arterial approach in view of **Lane** (including **Zarbatany**) (*see* §§X.A.1, X.A.2.[3]-[4]), **Nguyen-189** expressly discloses inserting a prosthesis through a femoral artery and delivering it through the aorta to the aortic valve. Nguyen-189 ¶¶[0038], [0232], Fig. 92; Drasler ¶¶165-166. A POSITA would have been motivated to apply **Nguyen-189's** retrograde femoral arterial approach teachings to **Lane's** prosthesis delivery to the aortic valve to achieve the beneficial and predictable result of not puncturing the arterial septum. Drasler ¶166. Moreover, a POSITA would have been motivated to apply **Nguyen-189's** teachings in light of the similarities with **Lane**—both references teach transluminally delivering a prosthesis to replace a heart valve using a catheter delivery device. Nguyen-189 ¶¶[0002], [0009], [0149], [0177], [0183]; *see* §X.A.1; Drasler ¶166.

A POSITA would have had a reasonable expectation of success in applying **Nguyen-189's** retrograde femoral arterial approach teachings to **Lane's** delivery method given that **Lane** discloses delivering the prosthesis transluminally. Lane ¶¶[0087], [0091], [0138]; Drasler ¶167. A POSITA would have found it routine, straightforward and advantageous to apply **Nguyen-189's** teachings in implementing **Lane's** prosthesis delivery method (both without and with **Hartley's** teachings applied) and would have known that such a combination (yielding the

claimed limitations) would predictably work and provide the expected functionality of delivering **Lane's** valve prosthesis through the femoral artery and aorta. Lane ¶¶[0087], [0091], [0138]; Nguyen-189 ¶¶[0038], [0232]; Drasler ¶167.

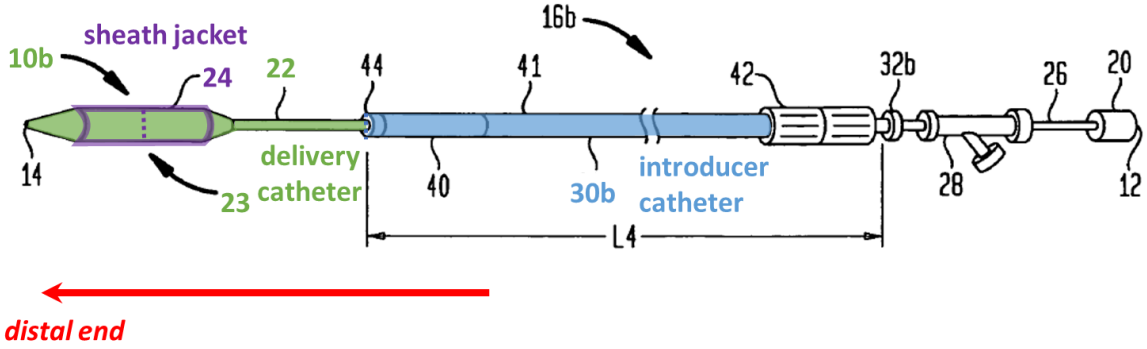
D. Grounds 5, 6: Claims 16, 18-22, 24 Are Rendered Obvious by Lane in View of Thomas and Alternatively in View of Hartley and Thomas

To the extent it is argued that additional disclosure of adjusting an angular position of the prosthesis is necessary for element [16.2] of Claim 16, **Thomas** teaches using "pull-wires" to bend the catheter, and therefore the prosthesis in the catheter, thereby adjusting its angular position. As to Claims 18-22 and 24, **Thomas** teaches a distal end of the delivery catheter that comprises a sheath jacket with an outer diameter greater than the inner diameter of the introducer catheter. Claims 16 and 18-22 and 24 are rendered obvious by **Lane** in view of **Thomas** and alternatively in view of **Hartley** and **Thomas.** Drasler ¶¶168-226.

1. Overview of Thomas

Thomas discloses delivery devices for "prosthetic heart valve replacement" using catheters delivered "transfemoral[ly]" (transluminally via the femoral artery or vein). Thomas ¶[0002], Fig. 3A (below); Drasler ¶169.

FIG. 3A



Delivery device 10b has a proximal end 12, a distal end 14, distal sheath 24, sleeve 30b, and steering actuator 42. Thomas ¶¶[0057], [0059].

Distal sheath 24, adjacent to distal tip 14, holds a collapsed prosthetic heart valve in compartment 23. Thomas ¶[0057], Fig. 3A. Distal sheath 24 "cannot be passed through" sleeve 30b because the distal sheath 24's diameter is larger than sleeve 30's inner diameter. Thomas ¶¶[0040], [0043].[5] Therefore, sleeve 30b is "pre-assembled" over outer shaft 22, which in turn is assembled over inner shaft 26. Thomas ¶¶[0040], [0057].

[5] **Thomas** discloses that "delivery device 10b is substantially the same as the delivery device 10a shown in Figs. 2A-B," and "delivery device 10a is substantially the same as the delivery device 10 shown in Figs. 1A-C." Thomas ¶[0056], [0049]. Thus, its teachings can be applied across different embodiments and at minimum it would have been obvious to do so. Drasler ¶170.

Blood can flow into gaps between components of the delivery device, therefore, sleeve 30b "preferably is designed to minimize bleeding and to minimize the friction force that must be overcome to deploy the valve into a patient." Thomas ¶¶[0037], [0039]. For example, sleeve 30's inner diameter may be "closely matched" to outer shaft 22's outer diameter to minimize blood flow into gap between the two components. Thomas ¶[0039]. To minimize friction, sleeve 30b may be constructed from a material that "produces low friction" when slid against outer shaft 22. Thomas ¶¶[0041]-[0042]. Sleeve 30b is "long and steerable" with steerable portion 40 having a pull-ring on its distal end and steering actuator 42 near its proximal end. Thomas ¶¶[0056], [0059]. Pull-wires extend longitudinally along sleeve 30b coupling the pull-ring and steering actuator 42. *Id.* Steering actuator 42 can "actively maneuver" steering portion 40 through vasculature such as the aortic arch by pulling a pull-wire to pull one side of the pull-ring and bending steerable portion 40. Thomas ¶¶[0061], [0065], [0066]. The steering mechanism thus adjusts the prosthesis's angular axial position (*e.g.*, pitch and yaw) within distal sheath 24. Drasler ¶¶171-172.

After delivery device 10b reaches the aortic valve, sleeve 30b is retracted proximally by about "the length of distal sheath 24" so that distal sheath 24 has room to retract and fully expose the valve contained in compartment 23. Thomas ¶[0066]. Delivery device 10b's position may be adjusted using the steering mechanism for

"acceptable placement of the heart valve in the proper location." Thomas ¶¶[0054], [0065], [0066].

Like **Lane** (*see* §X.A.1), **Thomas** is in the same field of endeavor as '897—prosthetic cardiovascular implants—and reasonably pertinent to the alleged problem(s) identified in the '897 of a need for a reduced diameter delivery device. '897, Abstract, 2:21-29, 24:4-21; Thomas, Abstract, ¶¶[0010], [0011], [0014], [0043]; Drasler ¶174. A POSITA would have been motivated to apply **Thomas's** teachings to **Lane** for at least the reasons discussed below. Drasler ¶¶173-174.

2. Claim 16

To the extent further disclosure of [16.2] ("adjusting an angular position of the prosthetic valve") is required, **Thomas** discloses that deploying the prosthesis comprises: adjusting an angular position of the prosthesis within distal sheath 24 (*e.g.*, "pull-wire extending along one side of the sleeve 30b…bends the steerable portion 40 of the sleeve 30b"). Thomas ¶¶[0059], [0065]-[0066], [0068], Fig. 3B; Drasler ¶175.

While **Lane** discloses "rotat[ing]," "orient[ing]," "adapt[ing]," and "adjust[ing]" the prosthesis for proper orientation, it does not *explicitly* disclose a mechanism for changing the prosthesis's angular position. Lane ¶¶[0026], [0029], [0046], [0140], [0141]; *see* §X.A.2.[16.2]; Drasler ¶176. **Thomas** discloses using pull-wires to change angular position of the prosthesis. Thomas ¶¶[0059], [0065]-

[0066], [0068], Fig. 3B; Drasler ¶176. A POSITA would have been motivated to apply **Thomas's** teachings of pull-wires to **Lane's** alignment mechanism to achieve the beneficial and predictable result of incorporating an additional control modality over alignment of the prosthesis for at least the following independent reasons. Drasler ¶176.

First, applying **Thomas's** teachings of pull-wires to **Lane's** alignment mechanism would have allowed manipulating the alignment element in pitch / yaw directions not *explicitly* disclosed by **Lane** to advantageously further **Lane's** objective of properly positioning and aligning the prosthesis (*see* §§X.A.1, X.A.2.[16.2]. Drasler ¶177. Facilitating this goal by adding a mechanism by which to better position the prosthesis, *i.e.*, by changing angular axial position, would have helped prevent the need for future surgeries to correct a misplacement. Quill (Ex. 1029; published 10/6/2011), ¶[0038]; Drasler ¶177.

Second, **Thomas's** steering mechanism advantageously helps "reduce friction acting on the catheter assembly…during advancement…through the vasculature." Thomas ¶[0059]. A POSITA would further have been motivated to apply **Thomas's** teachings of steering using pull-wires in implementing **Lane's** delivery device to reduce friction and minimize vasculature damage. Drasler ¶178.

Third, a POSITA would have been motivated to apply **Thomas's** teachings in light of the similarities to **Lane**—both references teach concentrically nested

catheters for transluminally delivering a prosthesis to replace a heart valve by pulling back a catheter sheath to expand the prosthesis, and repositioning the prosthesis. Thomas ¶¶[0002], [0054], [0057], [0065], [0066]; *see* §§X.A.1, X.A.2.[16.2], X.D.1; Drasler ¶179.

In light of the above, a POSITA would have found it routine, straightforward and advantageous to apply **Thomas's** pull-wire teachings in implementing **Lane's** prosthesis delivery method and would have known that such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Drasler ¶180.

3. Motivation to Apply Thomas's Teachings to Lane (Claims 18-22, 24)

While **Lane** teaches that outermost catheter 1604 must extend over the prosthesis (*see* §X.A.1), **Thomas** instead teaches that the outermost catheter need only extend up to a separate sheath jacket covering the prosthesis but advantageously does not need to be wide enough to cover the prosthesis. *See* §X.D.1. Specifically, **Thomas** teaches that outermost catheter 30b need only extend up to distal sheath 24, which encapsulates the prosthesis for delivery. Thomas ¶¶[0040], [0043], Fig. 3A. **Thomas** specifies that distal sheath 24 encapsulates the prosthesis such that "the inner diameter of the sleeve 30 will be much less than the diameter of the distal sheath 24." Thomas ¶[0040].

A POSITA would have been motivated to apply **Thomas's** teachings of distal sheath 24 to **Lane's** "concentrically nested" catheters to achieve the beneficial and predictable result of extending the "bumped up" portion bell catheter 1624 (with a larger diameter 1623) to cover the prosthesis's entire length—forming a "sheath jacket," while allowing sheath catheter 1604's diameter to advantageously be smaller. Drasler ¶¶181-182.

Reduction of sheath catheter 1604's diameter and profile would beneficially reduce friction against vasculature during delivery device advancement and removal. Dwork ¶¶[0007], [0039]; Parker (Ex. 1007; published 11/25/2004), 2:37-44 ("outer diameter of the delivery catheter is advantageously reduced to reduce bleeding at the access site and to navigate smaller diameter and tortuous vessels"); Baim, 28-29; Drasler ¶183. Reduction of sheath catheter 1604's diameter and profile would additionally mitigate the need for surgical procedures at the entry site. Thomas ¶[0010] ("too large of an introducer…may make it necessary to perform an additional surgical procedure to seal the entry point into the femoral artery"); Drasler ¶183.

And just as **Lane** teaches and renders obvious that sheath catheter 1604 covering the prosthesis abuts shoulder 1618 of tip 1603 during delivery and removal and to dilate the heart tissue (*see* §X.A.1), so too would a POSITA have been motivated to have modified section 1623 (forming the "sheath jacket" around the

valve prosthesis) to abut shoulder 1618 of tip 1603 and the proximal portion of the modified section 1623 abut the smaller diameter sheath catheter 1604 when **Thomas's** teachings are applied in order to maintain **Lane's** teachings of "creating piercing stiffness" for dilating the heart tissue and presenting a smooth surface for insertion and removal as illustrated below:

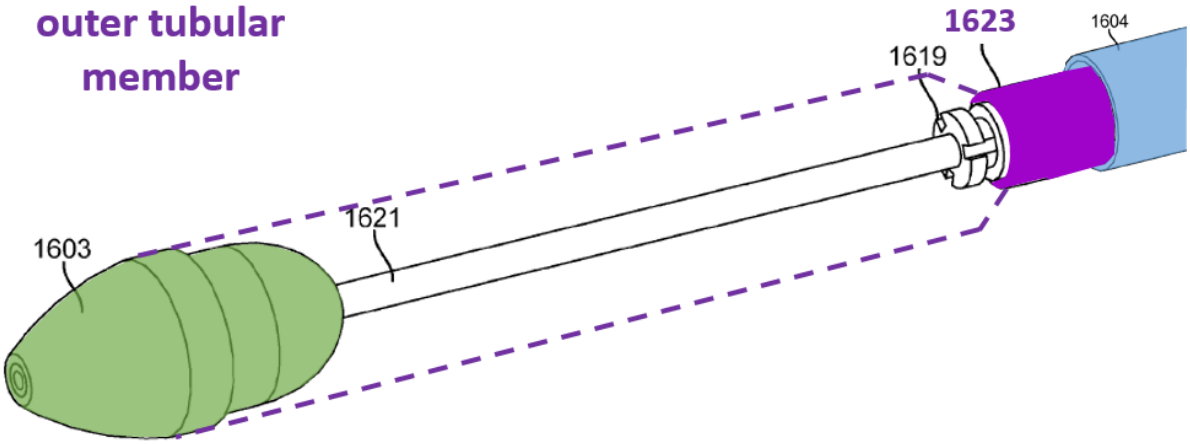


FIG. 20

Lane, Fig. 20 (modified with Thomas's teachings); Drasler ¶184. The reduced diameter sheath catheter 1604 cannot slide over the "sheath jacket." However, **Lane** teaches that sheath catheter 1604 is not fixedly attached to the device's handle. *See* §X.A.1. Therefore, to the extent the "sheath jacket" needs to be retracted to release the prosthesis, sheath catheter 1604 can also be retracted to accommodate retraction of the "sheath jacket." Drasler ¶185. **Thomas** similarly teaches retracting sleeve 30b by the length of distal sheath 24 to release the prosthesis. Thomas ¶[0066]; §X.D.1; Drasler ¶185.

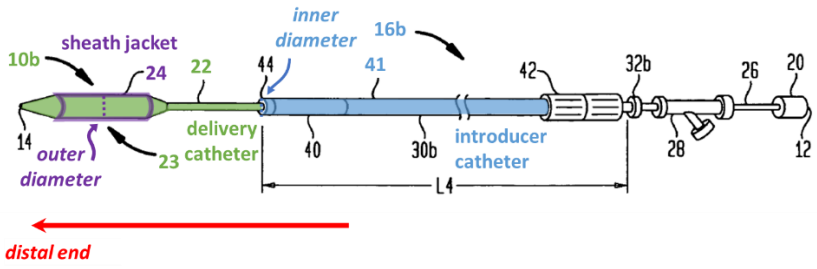
Consequently, after the prosthesis is deployed by retracting the "sheath jacket," a POSITA would have been motivated and found it obvious to retract both the "sheath jacket" and the distal tip such that the distal tip abuts the "sheath jacket's" distal end and the "sheath jacket" abuts the reduced-diameter catheter 1604's distal end during removal in order to create a smooth surface to, *e.g.*, prevent any components from catching on a blood vessel during deployment. *See* §X.A.1; Murphy, ¶¶[0040], [0086]; Baim, 28-29; Vogt, 10; Drasler ¶186.

A POSITA would have had a reasonable expectation of success in applying **Thomas's** teachings regarding distal sheath 24's diameter relative to sleeve 30b's diameter to **Lane's** bell catheter 1624. Drasler ¶187. Indeed, **Lane**, like **Thomas**, discloses encapsulating the prosthesis in the delivery device's distal end (*i.e.*, bell catheter 1624 or distal sheath 24). Lane ¶¶[0122], [0128], [0129]; Thomas ¶¶[0035], [0040]; Drasler ¶187. Indeed, encapsulating the prosthesis at the delivery device's distal end such that the portion of the delivery device proximal to the prosthesis has a smaller diameter was known in the art and a POSITA would have known such configurations could be used to encapsulate **Lane's** prosthesis by the distal end of extended bell catheter 1624 such that extended bell catheter 1624's outer diameter is greater than sheath catheter 1604's outer diameter. Dwork, ¶¶[0037], [0039], Figs. 3, 4; Drasler ¶187.

In light of these disclosures, modifying **Lane's** section 1623 to have an outer diameter greater, not less, than the inner diameter of the distal end of sheath catheter 1604 and extending section 1623 to cover the entire prosthesis (as taught in **Thomas** for sheath jacket 24) would be nothing more than reorganizing familiar elements (nested catheters of varying diameters) according to known techniques to yield predictable results ("sheath jacket" whose outer diameter is greater than the inner diameter of the distal end of the introducer catheter) to a POSITA. Drasler ¶188.

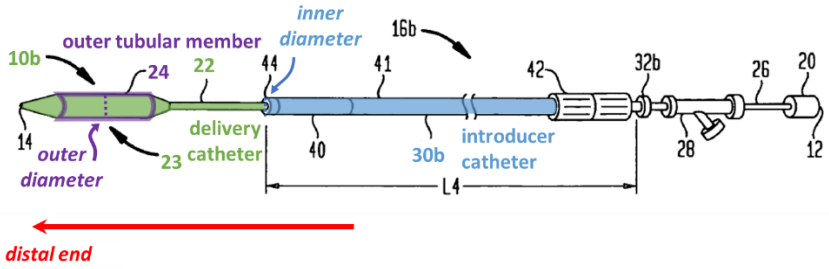
4. Claim Chart (Claims 18-22, 24)

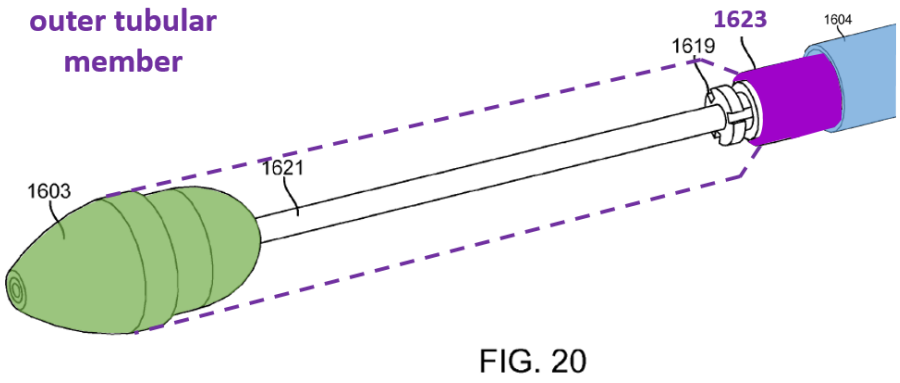
9,445,897	Lane in view of Thomas
[18] The method of claim 1, wherein the distal end of the delivery catheter comprises a sheath jacket, the sheath jacket having an outer surface that defines an outer diameter of the sheath jacket, the outer diameter of the sheath jacket being greater than the inner diameter of the introducer catheter at the distal end of the introducer catheter.	***See* §X.A.2.[1].** **Lane discloses the delivery catheter and the introducer catheter. *See* §X.A.2.[1.1].** **Thomas discloses that the distal end of the delivery catheter** (*e.g.*, distal end of delivery device 10b) **comprises a sheath jacket** (*e.g.*, "distal sheath 24")**, the sheath jacket having an outer surface that defines an outer diameter of the sheath jacket, the outer diameter of the sheath jacket being greater than the inner diameter of the introducer catheter** (*e.g.*, sleeve 30b) **at the distal end of the introducer catheter** (*e.g.*, "the inner diameter of the sleeve 30 will be much less than the diameter of the distal sheath 24" such that "distal sheath 24 cannot be passed through sleeve 30")**.** ***E.g.*, Thomas:** **Thomas** discloses a distal sheath 24 located on the delivery device's distal end and a sleeve 30b proximal to distal sheath 24. Thomas, Fig. 3A. Distal sheath 24's outer diameter is greater than sleeve 30's inner diameter such that "distal sheath

9,445,897	Lane in view of Thomas
	24 cannot be passed through sleeve 30." Thomas ¶¶[0040], [0043]. • Fig. 3A FIG. 3A  • ¶[0040] ("the ***inner diameter of the sleeve 30 will be much less than the diameter of the distal sheath 24***. Accordingly, the ***distal sheath 24 cannot be passed through sleeve 30*** during insertion of the delivery device 10 in a patient.") • ¶[0043] ("[T]he outer diameter of the sleeve 30…preferably is equal to or ***less than*** the outer diameter of the distal sheath 24.") • ¶¶[0049], [0056], [0059]. As discussed above in §X.D.3, a POSITA would have been motivated to apply **Thomas's** teachings regarding distal sheath 24's diameter being greater than sleeve 30's inner diameter to **Lane's** concentrically nested catheter delivery system so as to distally extend section 1623 of bell catheter 1624 such that it abuts shoulder 1618 of tip 1603, thereby providing a "sheath jacket" and reducing sheath catheter 1604's diameter. Drasler ¶¶189-193.
[19] The method of claim 18,	***See* §X.D.4.[18].**

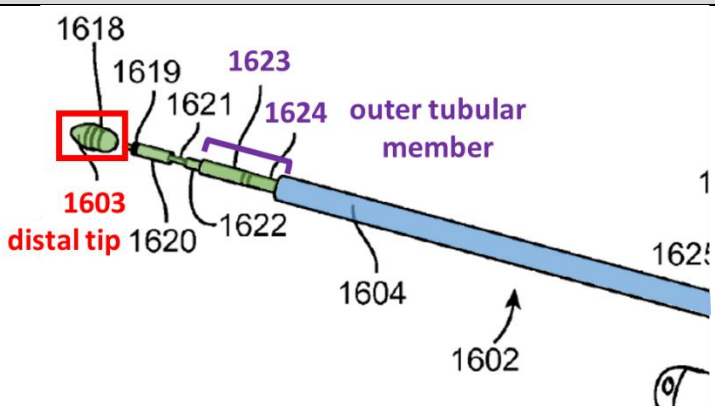
9,445,897	Lane in view of Thomas
further comprising, after deploying the prosthetic valve, retracting the delivery catheter until a proximal end of the sheath jacket abuts the distal end of the introducer catheter.	**Lane discloses deploying the prosthetic valve** (*e.g.*, "prosthetic valve may be released from…delivery catheter") **and retracting the delivery catheter** (*e.g.*, "larger diameter section 1623 of the bell catheter 1624 is also fully retracted")**.** *See* §§X.A.2.[1.6], [8], [9]. **Thomas discloses after deploying the prosthetic valve, retracting the delivery catheter** (*e.g.*, distal end of "delivery device 10b") **until a proximal end of the sheath jacket** (*e.g.*, "distal sheath 24") **abuts the distal end of the introducer catheter** (*e.g.*, sleeve 30b is "retracted" such that "distal sheath 24 will have sufficient room to retract")**.** *See* §X.D.4.[18]. In addition, starting from an initial position where the "proximal end of the distal sheath 24" is in "contact[]" with sleeve 30b, sleeve 30b is "retracted proximally" by "the length of the distal sheath 24." Thomas, ¶[0066]. Distal sheath 24 is then retracted by its entire length to "fully expose" the heart valve. *Id.* Because distal sheath 24 and sleeve 30b are both retracted by "the length of the distal sheath 24," they abut once more. *Id.*; Drasler ¶198. As discussed above in §X.D.3 and §X.D.4.[18], a POSITA would have been motivated to apply **Thomas's** teachings to **Lane** to distally extend section 1623 of bell catheter 1624 to provide a "sheath jacket." The "sheath jacket" would be part of the delivery catheter as a distal extension of bell catheter 1624. Drasler ¶199. A POSITA would have been motivated to apply **Thomas's** teachings of retracting the delivery catheter after deploying the prosthesis until a proximal end of distal sheath 24 abuts the distal end of sleeve 30b to **Lane's** "sheath jacket" and sheath catheter 1604 after fully releasing the prosthesis both in light of **Thomas's** teachings and also in light of **Lane's** teachings that render obvious the proximal end of section 1623 (the "sheath jacket") abutting the distal end of

9,445,897	Lane in view of Thomas
	sheath catheter 1604 during removal as discussed in above in §X.D.3. Thomas ¶[0066]; Drasler ¶199. • ¶[0050] ("…heart valve having a length of about 2" is positioned inside of the compartment 23…") • ¶[0056] ("The ***delivery device 10b is substantially the same as the delivery device 10a*** shown in FIGS. 2A and 2B…") • ¶[0066] ("…sleeve 30b is initially positioned with the steerable portion 40 ***contacting*** the proximal end of the distal sheath 24…After the distal sheath 24 has reached the annulus 6, the ***sleeve 30b can be retracted proximally***, preferably by about 2" or ***the length of the distal sheath 24…so that the distal sheath 24 will have sufficient room to retract and fully expose the compartment 23*** to deploy a self-expandable heart valve contained therein.") Drasler ¶¶194-199.
[20] The method of claim 1, wherein the delivery catheter comprises an outer tubular member and a guidewire tubing extending through the outer tubular member, the guidewire tubing being coupled to the distal tip of the delivery catheter, wherein during	***See* §X.A.2.[1].** **Lane discloses that the delivery catheter** (*see* §X.A.2.[1.1]) **comprises a tubular member** (*see* §X.A.2.[10], "bell catheter 1624") **and a guidewire tubing** (*e.g.*, "guide-wire catheter 1621") **extending through the tubular member** (*see* §X.A.2.[10], "guide-wire catheter 1621…runs internally throughout the entire delivery system")**, the guidewire tubing being coupled to the distal tip** (*e.g.*, "tip 1603") **of the delivery catheter** (*e.g.*, guide-wire catheter 1621 "begin[s] at the tip 1603")**, wherein during advancement, the distal tip closes a distal end of the introducer catheter** (*e.g.*, "distal edge of the sheath catheter 1604 will abut against a shoulder 1618 located on the tip 1603")**.** ***E.g.*, Lane:**

9,445,897	Lane in view of Thomas
advancement, the distal tip closes a distal end of the outer tubular member.	***See* §§X.A.2.[1.1], [10].** In addition, **Lane** discloses that guide-wire catheter 1621, which "begin[s] at" and is coupled to "tip 1603," is guidewire tubing extending through tubular member bell catheter 1624. • ¶¶[0122], [0123] (*see* §X.A.2.[1.1]), Fig. 18. **Thomas discloses the outer tubular member** (*e.g.*, "distal sheath 24")**.** ***E.g.*, Thomas:** *See* §X.D.4.[18]. • Fig. 3A FIG. 3A  • ¶[0040] (*see* [18]). As discussed above in §X.D.3 and §X.D.4.[18], a POSITA would have been motivated to apply **Thomas's** teachings to distally extend **Lane's** section 1623 of bell catheter 1624 to provide a "sheath jacket" such that bell catheter 1624 becomes the outer tubular member. Drasler ¶205. **Lane** discloses that during advancement, distal tip 1603 abuts sheath catheter 1604's distal edge (Lane, Figs. 16, 23B), *e.g.*, "to provide adequate stiffness to dilate heart wall tissue."

9,445,897	Lane in view of Thomas
	Lane ¶[0123]; *see* §X.A.2.[1.3]. As discussed above in §X.D.3, when **Thomas's** teachings are applied, the distal end of modified section 1623 of bell catheter 1624 abuts distal tip 1603 during advancement. • Lane, Fig. 20 (modified with Thomas's teachings)  FIG. 20 Drasler ¶¶200-206.
[21] The method of claim 20, further comprising distancing the distal tip from the outer tubular member.	***See* §X.D.4.[20].** **Lane discloses distancing the distal tip from the tubular member** (*e.g.*, "retract[ing]" "bell catheter 1624" from "tip 1603")**.** ***E.g.*, Lane:** **Lane** discloses retracting bell catheter 1624 (*see* §X.A.2.[8]), thereby distancing it from tip 1603. • Fig. 19A

9,445,897	Lane in view of Thomas



- ¶¶[0122], [0124], [0128], [0140], Fig. 23C.

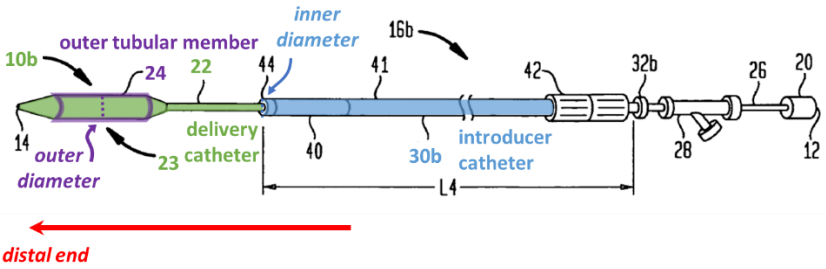
Thomas discloses the outer tubular member (*e.g.*, "distal sheath 24")**.**

***E.g.*, Thomas:**

See §X.D.3.[20].

- Fig. 3A

FIG. 3A



- ¶[0040] (*see* [18]).

As discussed above in §X.D.3 and §§X.D.4.[18], [20], a POSITA would have been motivated to apply **Thomas's** teachings to distally extend **Lane's** section 1623 to provide a "sheath jacket." §X.D.3, §§X.D.4.[18], [20]; Drasler ¶211. In the delivery system of **Lane** modified with **Thomas's** teachings, retracting bell catheter 1624 will distance modified

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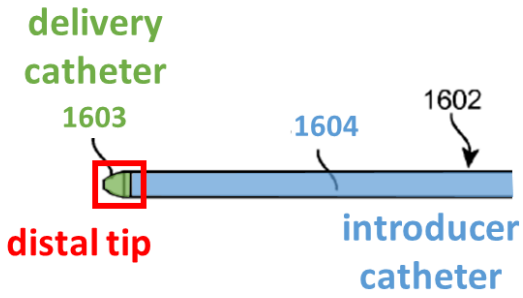
	section 1623 from distal tip 1603 because modified section 1623 is a part of bell catheter 1624. *See* §X.D.4.[18]. Drasler ¶¶207-212.
[22] The method of claim 21, wherein distancing the distal tip comprising retracting the outer tubular member while holding the guidewire tubing stationary.	***See* §X.D.4.[21].** **Lane discloses distancing the distal tip comprising retracting the tubular member** (*see* §X.A.2.[10], "bell catheter 1624 has been withdrawn") **while holding the guidewire tubing stationary** (*e.g.*, "guide-wire catheter 1621…is stationary")**.** ***E.g.*, Lane:** *See* §X.A.2.[9]. In addition, **Lane** discloses that in the embodiment where bell catheter 1624 is "retracted," guide-wire catheter 1621 is held "stationary." • ¶[0122] ("…***guide wire catheter 1621*** is…***stationary***.") • ¶[0128] ("Once the larger diameter section 1623 of the ***bell catheter 1624 has been withdrawn***, the hub slots 1619 become uncovered which allows the heart valve anchor…to fully expand") **Thomas discloses the outer tubular member** (*e.g.*, "distal sheath 24")**.** ***E.g.*, Thomas:** *See* §X.D.4.[20]. • ¶[0040] (*see* [18]).

9,445,897	Lane in view of Thomas
	As discussed in §X.D.3 and §X.D.4.[20], a POSITA would have been motivated to apply **Thomas's** teachings to distally extend **Lane's** section 1623 to provide a "sheath jacket"—an outer tubular member. Drasler ¶218. In the delivery system of **Lane** modified with **Thomas's** teachings, retracting bell catheter 1624 will retract modified section 1623 from distal tip 1603 because section 1623 is a part of bell catheter 1624. *See* §X.D.4.[20]. Guide-wire catheter 1621 will remain "stationary" while retracting bell catheter 1624. Lane ¶[0122]. Drasler ¶¶213-219.
[24] The method of claim 20, further comprising, after deploying the prosthetic valve, retracting the guidewire tubing until the distal tip closes the distal end of the outer tubular member.	***See* §X.D.4.[20].** **Lane discloses after deploying the prosthetic valve** (*see* §X.A.2.[1.6])**, retracting the guidewire tubing** (*see* §X.D.4.[20]; "guide-wire catheter 1621") **until the distal tip closes the distal end of the introducer catheter** (*e.g.*, "sheath catheter 1604")**.** ***E.g.*, Lane:** *See* §X.A.2.[1.6], §X.D.4.[20]. In addition, **Lane** discloses that guide-wire catheter 1621 is coupled to distal tip 1603 because it "begin[s] at the tip 1603." Lane ¶[0122], Fig. 18; *see* §X.A.2.[1.1]. **Lane** discloses advancing hub 1620 to deploy a valve. Lane ¶[0129]. In view **Lane's** disclosure of distally advancing a distal portion of the delivery catheter, a POSITA would have understood, and at minimum would have found it obvious, after deploying the prosthesis to retract the distal tip 1603, via guidewire tubing, until it closes the distal end of sheath catheter 1604, as discussed in §X.A.1. Drasler ¶¶72, 223. • Fig. 16

9,445,897	Lane in view of Thomas
	 • ¶[0129] (*see* [1.5]) **Thomas discloses the outer tubular member** (*e.g.*, "distal sheath 24")**.** ***E.g.*, Thomas:** *See* §X.D.4.[20]. • ¶[0040] (*see* [18]). As discussed above in §X.D.3 and §X.D.4.[20], a POSITA would have been motivated to apply **Thomas's** teachings to distally extend **Lane's** section 1623 to provide a "sheath jacket"—an outer tubular member. §X.D.3, §X.D.4.[20]; Drasler ¶225. In applying **Thomas's** teachings to **Lane**, distal tip 1603 will be retracted to close the distal end of modified section 1623 of the outer tubular member after deployment of the prosthetic valve, as discussed in §X.D.3. *See also* §X.A.1. Drasler ¶¶220-226.

XI. SECONDARY CONSIDERATIONS

There is no evidence in the prosecution history of the '897 or any related application that any arguments regarding secondary considerations exist, let alone

that any such evidence could overcome the strong showing of obviousness above or that there is a sufficient nexus to any of the Claims. *See generally* '897FH; Drasler ¶227. Indeed, as demonstrated by the prior art referenced herein, any purported solutions to problems or unexpected results in the '897 were already well known. Drasler ¶227. To the extent PO asserts the existence of any secondary considerations in its responses, Petitioners reserve the right to address any such evidence.

XII. CONCLUSION

Substantial, new, and noncumulative technical teachings have been presented for the '897's Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioners will prevail as to claims 1-4, 6-10, 16-22, and 24. *Inter partes* review of claims 1-4, 6-10, 16-22, and 24 is accordingly requested.

Dated: January 20, 2021

Respectfully submitted,

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and MEDTRONIC, INC.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 CFR §42.24(a) and (d), the undersigned hereby certifies that this Petition for Inter Partes Review complies with the type-volume limitation of 37 CFR §42.24(a)(i) because, exclusive of the exempted portions, it contains 13,926 words as counted by the word processing program used to prepare the paper.

Dated: January 20, 2021

/James L. Davis, Jr./
James L. Davis, Jr.
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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§42.6(e) and 42.105(b) on the Patent Owner by Fedex of a copy of this Petition for *Inter Partes* Review and supporting materials at the correspondence address of record for the '897 patent:

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Courtesy copies of the same documents were also served at the following email addresses of record for Speyside Medical, LLC's litigation counsel:

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Dated: January 20, 2021

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