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 IPR2021-00244

U.S. Patent No. 9,603,708

PETITION FOR *INTER PARTES* REVIEW

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1002	Declaration of William J. Drasler, Ph.D. ("Drasler")
1003	File History of U.S. Patent No. 9,603,708
1004	U.S. Patent No. 3,671,979 to Moulopoulos
1005	U.S. Patent No. 4,056,854 to Boretos
1006	U.S. Patent 4,994,077 to Dobben
1007	U.S. Patent Publication 2003/0055496 to Cai
1008	Reserved
1009	CoreValve System instructions (available at https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130021c.pdf)
1010	U.S. Patent Publication 2006/0259136 Nguyen
1011	Grube et al., "Percutaneous Aortic Valve Replacement for Severe Aortic Stenosis in High-Risk Patients Using the Second- and Current Third-Generation Self-Expanding CoreValve Prosthesis" *JACC* Vol. 50, No. 1, 2007; 50:69-76
1012	U.S. Patent No. 7,914,569 to Nguyen
1013	U.S. Patent No. 8,226,710 to Nguyen
1014	U.S. Patent No. 5,961,549 to Nguyen
1015	U.S. Patent No. 7,025,780 to Gabbay
1016	U.S. Patent No. 5,713,950 to Cox

1017	Sauren et al. "The Mechanical Properties of Porcine Aortic Valve Tissues" *J. Biomechanics* Vol. 16. No. 5. pp. 327-337. 1983
1018	Talman "Internal Shear Properties of Porcine Aortic Heart Valve Cusps" The University of Western Ontario, London, Ontario, Canada November 1999
1019	Weind, "Aortic valve cusp vessel density: Relationship with tissue thickness" *The J. Thorac. and Cardiovascular Surg.* February 2002
1020	U.S. Patent No. 5,957,949 to Leonhardt
1021	Sands et al., "An Anatomical Comparison of Human, Pig, Calf, and Sheep Aortic Valves", *Ann. Thorac. Surg.* 8(5):407-14 (November 1969)
1022	U.S. Patent Publication US 2009/0030503 to Ho
1023	U.S. Patent No. 6,129,758 to Love
1024	U.S. Patent No. 7,381,219 to Salahieh
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1030	Simionescu et al., "Mapping of glutaraldehyde-treated bovine pericardium and tissue selection for bioprosthetic heart valves" Journal of Biomedical Materials Research, Vol. 27, 697-704 (1993)
1031	Feinstein et al. "Percutaneous Pulmonary Valve Placement in a 10-Month-Old Patient Using a Hand Crafted Stent-Mounted Porcine Valve" Catheterization and Cardiovascular Interventions 67:644–649 (2006)

1032	*Speyside Medical, LLC v. Medtronic Corevalve, LLC and Medtronic, Inc.*, Case 1:20-cv-00361-LPS, Dkt. No. 19, Amended Complaint
1033	U.S. Patent Publication No. 2006/0235512 to Osborne et al.
1034	U.S. Patent Publication No. 2004/0236411 to Sarac et al.
1035	U.S. Patent No. 6,989,027 to Allen et al.
1036	*Speyside Medical, LLC v. Medtronic Corevalve, LLC and Medtronic, Inc.*, Case 1:20-cv-00361-LPS, Dkt. No. 35, Scheduling Order
1037	Reserved
1038	Reserved
1039	Reserved
1040	Website capture dated July 9, 2007 of "Publication Details," "Percutaneous pulmonary valve placement in a 10-month-old patient using a hand crafted stent-mounted porcine valve", available at https://web.archive.org/web/20070709195701/http://med.stanford.edu/profiles/frdActionServlet?choiceId=showPublication&pubid=132830&fid=4396
1041	Collection of printouts from the following URLs: • https://web.archive.org/web/20040103082651/http://circ.ahajournals.org/cgi/content/full/106/24/3006 • https://web.archive.org/web/20040224074417/http://circ.ahajournals.org/cgi/reprint/106/24/3006.pdf • https://web.archive.org/web/20031013145957/http://circ.ahajournals.org/content/vol106/issue24/index.shtml • https://web.archive.org/web/20030701173919/http://circ.ahajournals.org:80/cgi/content/abstract/106/24/3006 including at pages 1 to 3 Cribier et al., Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis ("Cribier")
1042	Reserved

1043	Reserved
1044	U.S. Patent 6,666,886 to Tranquillo et al.
1045	Reserved
1046	Reserved
1047	Google Scholar Citation results before 2010 for "Mapping of glutaraldehyde-treated bovine pericardium and tissue selection for bioprosthetic..." Simionescu, , available at: https://scholar.google.com/scholar?hl=en&num=20&as_sdt=0,33&sciodt=0,33&as_yhi=2009&cites=7782136079815852160&scipsc=
1048	Reserved
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1051	Reserved
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1055	U.S. Patent 6,652,578 to Bailey
1056	U.S. Patent 7,556,646 to Yang et al.
1057	Google Scholar Citation results before 2010 for "Percutaneous aortic valve replacement for severe aortic stenosis in high-risk patients using...", available at https://scholar.google.com/scholar?start=0&hl=en&as_sdt=5,33&sciodt=0,33&as_yhi=2009&cites=4967945984212370976&scipsc=
1058	Google Scholar Citation results before 2010 for "An anatomical comparison of human, pig, calf, and sheep aortic valves," available at https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=11530397156136016418&scipsc=&as_ylo=&as_yhi=2009

1059	U.S. Patent 7,141,064 to Scott et al.
1060	WO Application Publication No. 2011/115612 to Schankereli
1061	Declaration of Jennifer McCarthy
1062	Affidavit of Elizabeth Rosenberg dated December 1, 2020
1063	The Annals of Thoracic Surgery: The First 50 Years (available at https://www.annalsthoracicsurgery.org/article/S0003-4975(15)00691-8/pdf)
1064	Affidavit of Duncan Hall dated December 23, 2020
1065	Declaration of Crena Pacheco

Pursuant to §§311-319 and §42.1, Medtronic CoreValve LLC and Medtronic, Inc. ("Petitioners") petition for *inter partes* review ("IPR") of claims 21 and 22 ("Claims") of U.S. Patent 9,603,708 ("'708") (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 of the Claims, and judgment finding them unpatentable under §103.

I. INTRODUCTION

The purported invention of the '708 patent is the reduction in size of delivery catheter components to deliver a natural tissue valve. Specifically, the claims require an 18 French catheter (a measurement of catheter diameter/circumference, which correlates to 0.236 inches in diameter) or smaller, and the implant itself must comprise natural tissue leaflets with a thickness of "at least about 0.011 inches." Aside from these dimensional limitations, the claim recites nothing more than standard catheter and prosthetic valve components well-known in the art at the time of the '708 patent filing.

[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 Challenged Claims for reference. All citations herein are exemplary and not meant to be limiting.

The ’708 patent claims are directed to a method and device for the minimally invasive deployment of cardiovascular prosthetic implants. In this field, it was well-known to use an elongated, narrow catheter (purple below) to deploy replacement heart valve (red below) at the implantation site (as the Claims require), and a wide variety of cardiovascular prosthetic implants were similarly well-known, including natural tissue valves attached to support structures (as the Claims require). ’708, Figs. 5A, 2A; Drasler ¶¶35-37. The ’708 admits, for example, that valves constructed of donor leaflets or other biological materials such as pericardium were known. ’708, 2:15-22.

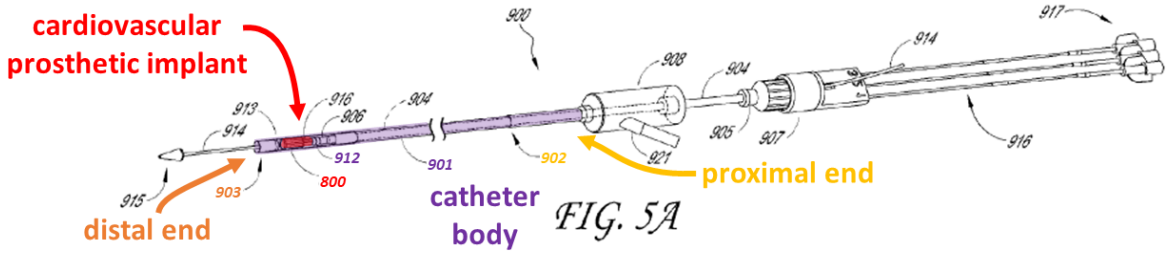


FIG. 5A

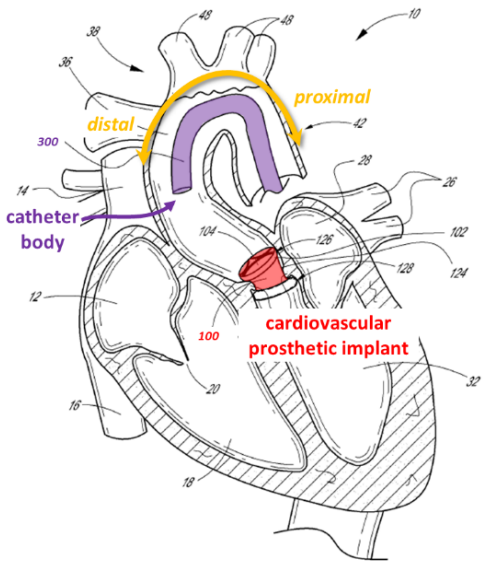


FIG. 2A

Indeed, the '708 describes the construction of cardiovascular prosthetic implants—attaching a valve to a support structure—as "conventional" and using methods that "are generally know[n] and accepted in the valve device industry." '708, 15:8-23. Moreover, the '708 admits that this was a well-developed field, describing "early efforts" over fifty years ago to deliver cardiovascular prosthetic implants via catheter. '708, 3:14-25, citing U.S. Pat. Nos. 3,671,979 (Ex. 1004) and 4,056,854 (Ex. 1005). The '708 also describes "[m]ore recent iterations," in which "tissue valves carried by expandable…stent[s]" are delivered via catheter in a collapsed state and later expanded at the implantation site. '708, 3:25-31.

PO similarly acknowledged the breadth and depth of the prior art, and the commensurate narrowness of the purported invention during prosecution. E.g., Ex.

1003 ("'708FH"), 2061 ("The differences between the prior art…and the present application was discussed. Specifically the small size of the catheter, 18 French…."). Consistent with this, the Examiner allowed the Claims only on the basis of the two dimensional limitations. '708FH, 2746, 2769 ("catheter has a distal end with a diameter of 18 French or less…and natural valve leaflet with a thickness of about 0.[0]11 inches"). But, as discussed herein, it was already well-known to use a catheter of 18 French or less to deliver a cardiovascular prosthetic implant comprising natural tissue valve leaflets with a thickness of at least about 0.011 inches. Drasler ¶¶38-39. And even if these dimensional limitations were not already well-known, a change in size or scale is not patentable. MPEP 2144.04 IV.

For example, **Salahieh** (Ex. 1024) teaches delivering a cardiovascular prosthetic implant (red below) comprising porcine valve leaflets using a delivery catheter (purple below) with a diameter of no more than 17 French.

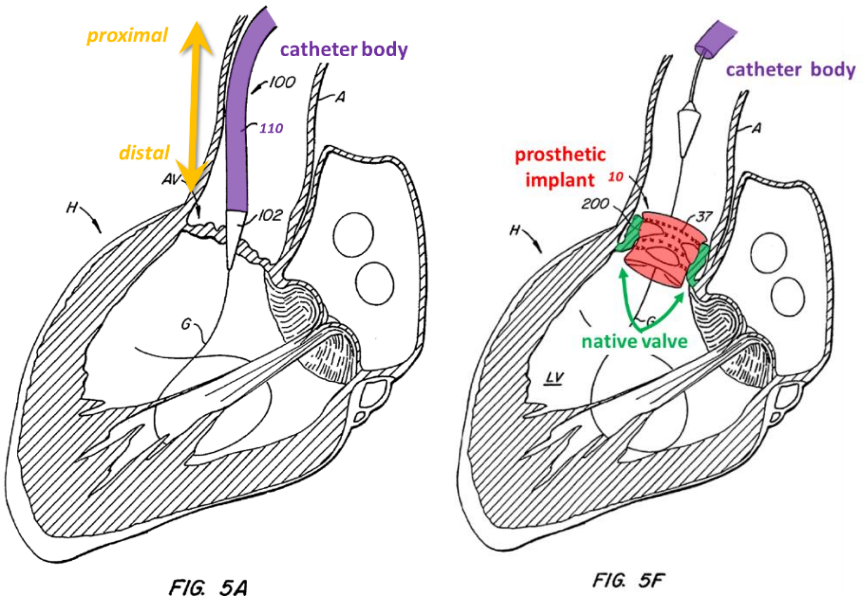


FIG. 5A FIG. 5F

Salahieh, Figs. 5A, 5F. Similarly, **Leonhardt** (Ex. 1020) teaches delivering a cardiovascular prosthetic implant (red below) comprising a native porcine valve with leaflets (blue below) using a delivery catheter (purple below) of a size ranging from 12 French to 20 French.

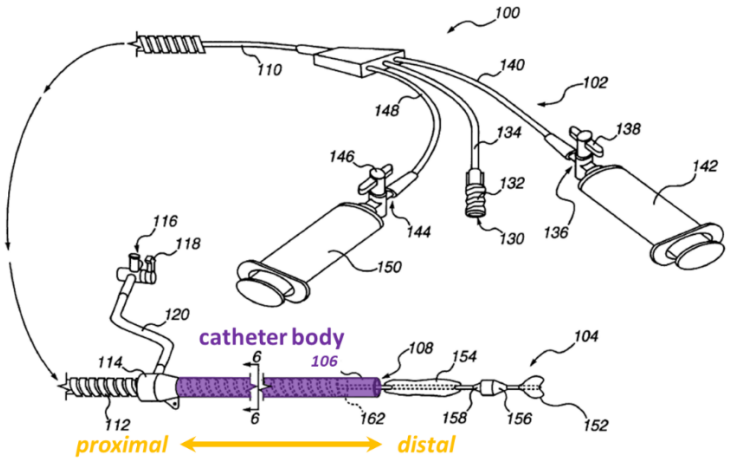


FIG. 5

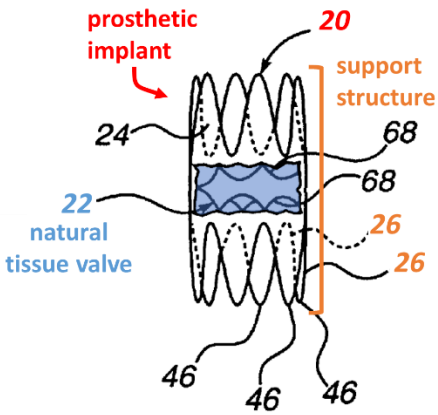
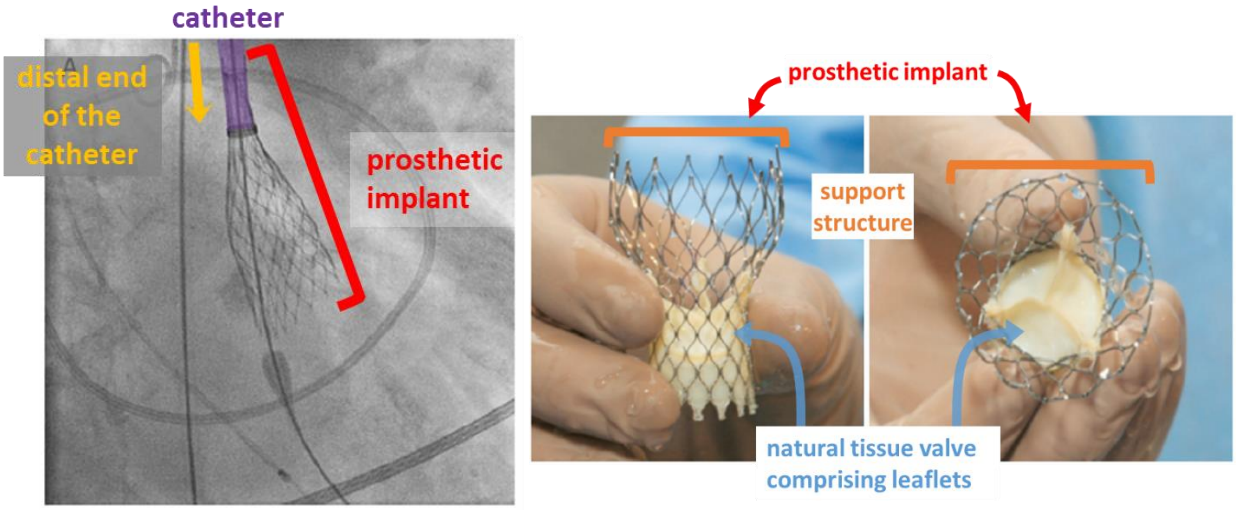


FIG. 4

Leonhardt, Figs. 4-5. And **Sands** (Ex. 1021) teaches that native porcine valves naturally have a leaflet thickness between 0.70 mm (.0276 inches) and 0.8 mm (0.0315 inches).

Moreover, under PO's broader interpretation of the claims, which does not require a natural valve leaflet, additional art also renders the claims unpatentable. For example, **Grube** (Ex. 1011) discusses the CoreValve device, which delivers a natural tissue cardiovascular prosthetic implant (red below) with a natural tissue valve comprising leaflets (blue below) using a delivery catheter (purple below) with a profile of 18 French.



Grube, 71 (Fig. 1), 74 (Fig. 2A). And **Nguyen** (Ex. 1010)**,** describing the same delivery catheter and implant, discloses a cardiovascular prosthetic implant comprising leaflets formed of a porcine pericardium with a thickness of between

0.012 and 0.014 inches. Salahieh's delivery system could also be used with Nguyen's cardiovascular prosthetic implant.

As demonstrated herein, the prior art renders obvious the Claims, which are directed to a simple combination of well-known prior art elements combined according to known methods to yield predictable results. The claimed elements and the claimed arrangement of elements are rendered obvious separately by (1) **Salahieh** in view of **Sands** and (2) **Leonhardt** in view of **Sands** under both parties' constructions of "natural tissue valve comprising [] leaflets." In addition, under PO's broader construction, the Claims are rendered obvious by (3) **Grube** in view of **Nguyen** and (4) **Salahieh** in view of **Nguyen**. 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 **Grube**, **Nguyen**, **Leonhardt**, **Sands**, or any other reference providing analogous disclosures during the '708's prosecution. Neither **Salahieh** nor its family members was considered during prosecution. To the extent the Examiner considered an unrelated patent application publication by nearly the same inventors that discloses using a delivery catheter smaller than 18 French, the art and arguments are not the same or substantially the same as the Examiner did not consider any disclosure of natural tissue valve leaflets of at least about 0.011 inches. *See* §VII.A.

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 ’708 is currently the subject of a district court litigation: *Speyside Medical, LLC v. Medtronic CoreValve LLC et al.*, No. 20-361-LPS (D. Del., filed March 13, 2020). Medtronic is filing IPR petitions against the other patents asserted in that district court litigation: IPR2021-00243 (USP 9,445,897); IPR2021-00242 (USP 10,449,040); IPR2021-00239 (USP 8,377,118); IPR2021-00240, IPR2021-00241, and IPR2021-00310 (USP 9,510,941).

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. 102760-0209-652.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioners certify the '708 is available for IPR. Petitioners are not barred or estopped from requesting IPR challenging the claims of the '708 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 '708 matured from 13/110,780 ("'780 Application"), and claims priority to provisional applications 61/346,390, filed 5/19/2010 and 61/411,862 (Exs. 1026-1027), filed 11/9/2010.

1. The Specific Art on Which the Challenge Is Based

Petitioners rely upon the following prior art:

Name	Exhibit	Patent / Publication	Priority Date	Issued / Published	Prior Art Under at Least §102
Salahieh	1024	U.S. 7,381,219	12/23/2003	06/03/2008	(a), (b)
Sands	1021	Sands, An Anatomical Comparison of Human, Pig, Calf, and Sheep Aortic Valves, ANNALS OF THORACIC SURGERY, vol. 8, no. 5 (Nov. 1969)		11/05/1969	(a), (b)
Leonhardt	1020	U.S. 5,957,949	05/01/1997	09/28/1999	(a), (b)
Grube	1011	Grube, Results After CoreValve Implantation, JACC Vol. 50, No. 1, 2007		07/03/2007	(a), (b)
Nguyen	1010	U.S. 2006/0259136	05/13/2005	11/16/2006	(a), (b)

Grube was publicly accessible to POSITAs and interested researchers both through the Journal of the American College of Cardiology (JACC) as well as the University of Rochester Library well before 2010. Ex. 1011; Ex. 1061 (Grube was available at the University of Rochester Library by July 2008 and in a volume and issue indexed by title and subject matter); Ex 1022 ¶[0061] (citing Grube in a patent application published 1/29/2009); Drasler ¶¶177-183 (both the JACC and the University of Rochester Library were well-known and accessible sources for a

POSITA and an interested researcher); Ex. 1057 (showing numerous articles citing Grube by the alleged priority date). Indicia of publication on Grube's face, including its publishers, JACC and Elsevier, further indicate the public accessibility of Grube by 2007. *Giora George Angres, Ltd. v. Tinny Beauty & Figure, Inc.*, 1997 WL 355479, at *7 (Fed. Cir. June 26, 1997) (unpublished) (finding "no reason to suspect that [a reference published by an established publisher] was not publicly available, including to one skilled in the art"); *Microsoft Corp. v. IPA Techs., Inc.*, IPR2018-00794, Pap. 11, *10-11 (finding that "indicia of publication appearing on the face of [reference] are particularly persuasive of public availability"); *Arista Networks v. Cisco Sys.*, IPR2016-00303, Pap. 53, *21-22 (finding evidence of publication "by a well-known commercial publisher" "in the business of publishing and selling … papers" "suggest[s] public dissemination."). Indeed, for established publishers, "absent some indication that the reference was not publicly available, demonstrating a date of publication is alone sufficient for showing accessibility to the public." *Microsoft*, Pap. 11, *10-11; *Arista*, Pap. 53, *22 ("[I]t serves the interest of justice to allow the Petitioners to rely on the copyright date of technical references published by a well-known publisher….").

Similarly, **Sands** was publicly accessible to POSITAs and interested researchers both through the ANNALS OF THORACIC SURGERY as well as the University of Rochester Library well before 2010. Ex. 1021 (Sands was available at

the University of Rochester Library by January 1970); Ex. 1023, 5:52-59 (citing Sands in a patent issued 10/10/2000); Drasler ¶¶177-183 (both the ANNALS OF THORACIC SURGERY and the University of Rochester Library were well-known and accessible sources for a POSITA and an interested researcher); Ex. 1058 (showing numerous articles citing Sands by the alleged priority date); Ex. 1025 (indicating the Annals of Thoracic Surgery had a circulation of 2,733 in 1969 at time of Sands publication). Indicia of publication on Sands' face, including its publishers, the Annals of Thoracic Surgery, which has been published regularly for more than fifty years, further indicate the public accessibility of Sands by 1969. Ex. 1025, at 1; Ex. 1063.

Additional references relied on herein to show the knowledge and understanding of those of ordinary skill in the art, including Simionescu (Ex. 1030), Weind (Ex. 1019), Feinstein (Ex. 1031), Sauren (Ex. 1017), and Talman (Ex. 1018), were also publicly accessible. *See* Ex. 1040; Ex. 1044, 2; Ex. 1047, 1-3; Ex. 1062, 4-5, 7-8, 10-11, 13-16, 18, 21-22, 24, 27-29, 31-32; Ex. 1064, 7-8; Ex. 1041, 1-16; Drasler ¶¶184-190.

2. Statutory Grounds on Which the Challenge Is Based

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

§103 Grounds	Claims	Prior Art
1	21-22	Salahieh in view Sands
2		Leonhardt in view of Sands
3		Grube in view of Nguyen
4		Salahieh in view of Nguyen

3. How the Claims Are Unpatentable

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

V. '708 PATENT

The '708 Claims generally refer to a delivery catheter and a method for deploying a cardiovascular implant using a delivery catheter. '708, Abstract, 1:16-20. The claimed method is generally directed to: (1) translumenally (through the vasculature) advancing a delivery catheter (annotated purple below) to a position proximate a patient's native valve, (2) deploying a cardiovascular prosthetic implant (annotated red below) from the tip of the delivery catheter, inside the patient, and (3) removing the catheter from the patient, as illustrated in Fig. 2A below. Drasler ¶42.

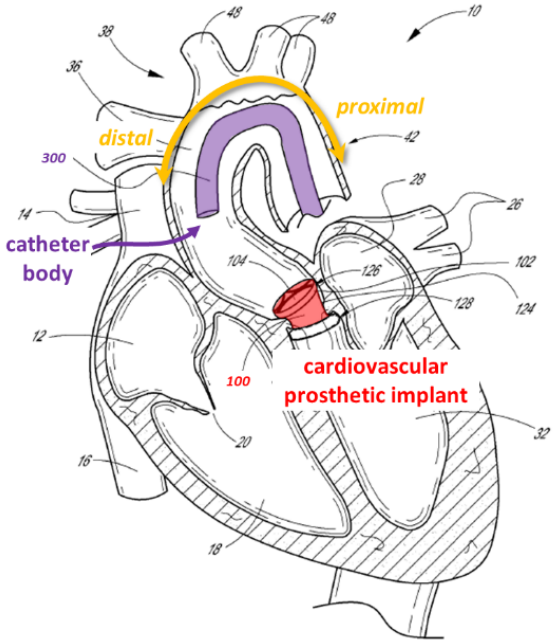


FIG. 2A

The delivery catheter comprises an "elongate, flexible catheter body [(annotated in purple)] having a proximal and a distal end" (annotated respectively in yellow and orange), as shown in Fig. 5A below.[2] '708, 1:60-61, 19:57-60, Fig. 5A. The '708 teaches a "low crossing profile delivery catheter," wherein the catheter body has a reduced "outer diameter of 18 French or less" at the distal end (*i.e.*, the

[2] Proximal and distal have their plain and ordinary meaning of referring to closer and farther away from the user, respectively. '708, 6:8-17 ("[I]n general, distal means closer to the heart while proximal means further from the heart…."); Drasler ¶43.

deployment portion) to facilitate "transluminal[] advance[ment]" of the catheter carrying a cardiovascular prosthetic implant to the placement site.

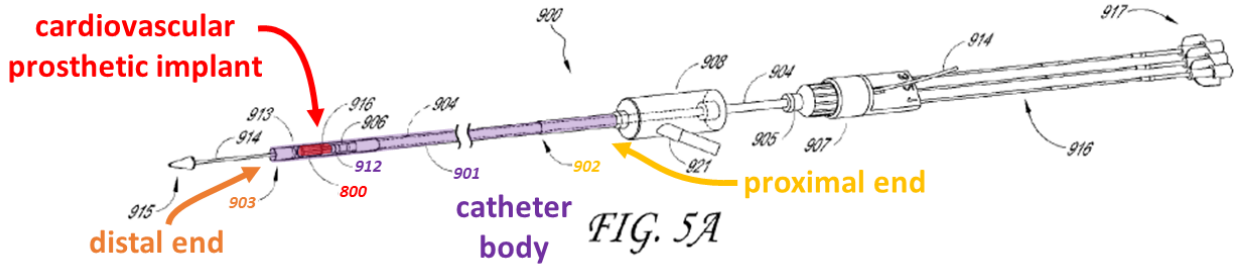


FIG. 5A

'708, Fig. 5A, 19:57-66 ("With reference to FIGS. 5A and 5B, the catheter 900 comprises an outer tubular member [9]01 having a proximal end 902 and a distal end 903….The distal end 903 of the outer tubular member 901 comprises a sheath jacket 912."), 19:57-66. The '708 describes as "particularly advantageous" maintaining a low crossing profile delivery catheter while deploying a valve made of tissue with a "thickness equal to or greater than about 0.011 inches." '708, 19:6-12, 19:17-23. As illustrated above, the "cardiovascular prosthetic implant 800" (annotated in red) is loaded within the catheter body's distal end prior to introduction into the patient. '708, Fig. 5A, 19:15-17, 30:7-8. The cardiovascular prosthetic implant comprises a "support structure" coupled to a "natural tissue" valve. '708, 4:24-27, 14:38-45, 15:34-36. The natural tissue valve encompasses "native valves such as pig…valves" and valves "constructed with flexible tissue leaflets" where the leaflets comprise animal tissue such as porcine pericardial tissue. '708, 15:21-22,

15:24-28, 15:34-40. As discussed herein, in either case, the valve's leaflets have a thickness equal to or greater than about 0.011 inches. '708, 4:24-27, 14:38-45, 15:34-46. Drasler ¶¶43-44.

The delivery catheter loaded with the cardiovascular prosthetic implant is inserted into the patient at a "vascular access" site, which is "most often through the femoral artery," and advanced transluminally to the implantation site. '708, 23:45-52. The implant is then deployed. '708, Abstract, 23:57-66, Fig. 5A. After the implant is deployed within the patient, "the catheter is removed from the patient." '708, 4:34-36; Drasler ¶45.

VI. '708 PROSECUTION HISTORY

In Application 13/110,780, which matured into the '708, the originally filed claims were generally directed to a "delivery catheter for deploying a cardiovascular prosthetic implant" and a "method for deploying a cardiovascular prosthetic implant" from the delivery catheter comprising the steps of (1) translumenally advancing the catheter to a position proximate a native valve of a patient, (2) deploying the cardiovascular prosthetic implant within the patient, and (3) removing the catheter from the patient. '708FH, 48-50; Drasler ¶¶40-41, 46.

The Applicant filed a terminal disclaimer to three U.S. Patents: Nos. 8,012,201, 7,556,645, and 7,320,704 to overcome a nonstatutory obviousness-type

double patenting rejection directed towards the elected invention. '708FH, 354-365, 596-597; Drasler ¶47.

Over the course of prosecution, the Examiner rejected all of the elected claims four separate times as anticipated and/or obvious over several prior art combinations. '708FH, 323-337, 600-610, 2063-2071, 2095-2103. After responding to a second Office Action, the Applicant was granted an Examiner Interview to discuss features of the claimed delivery catheter that differ over cited prior art, specifically the small size of the delivery catheter of 18 French or less. *Id.*, 2056-2057, 2061. However, the Examiner issued a third Office Action rejecting all of the claims over new §102(b) and §103(a) grounds, stating "[c]laim 21 is rejected…as being anticipated by U.S. Patent 4,994,077 to Dobben" and "unpatentable over U.S. Patent Publication 2006/0020334 to Lashinski et al. in view of U.S. Patent Publication 2003/0055496 to Cai et al." *Id.*, 2063-2071; Exs. 1006 (Dobben), 1007 (Cai). The Examiner pointed out an ***additional*** four prior art references that taught a similar catheter smaller than 18 French, including U.S. Patent Publication 2005/0137701 to Salahieh et al. '708FH, 2069. In a fourth Office Action, the Examiner maintained the prior art rejections pointing out that the claims required only that the tissue valve generally has a "thickness of at least 0.011 inches," not the valve's leaflets (*id.*, 2101), and that the claims did not require that the valve comprise "natural tissue material" (*id.*). *Id.*, 2095-2103; Drasler ¶48.

In response to the fourth Office Action, the Applicant amended independent claims 1 and 21 to limit the cardiovascular prosthetic implant to a "natural tissue valve" "comprising a leaflets" having a thickness of "at least about 0.011 inches." '708FH, 2120-2123. The Examiner then allowed the claims. *Id.*, 2740-2770, 2766-2770. The Examiner stated that the prior art of record "fails to teach or render obvious the delivery catheters and methods as claimed, specifically the fact the catheter has a distal end with a diameter of 18 French or less, a cardiovascular implant with an inflatable cuff ***and*** a natural valve leaflet with a thickness of at least about 0.[0]11 inches, where the implant is loaded in the distal end of the catheter." *Id.*, 2746, 2769 (emphasis added). The patent issued on March 28, 2017; Drasler ¶49.

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

A. §325(d)

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 '708's prosecution. The Examiner did not consider **Grube**, **Nguyen**, **Leonhardt**, **Sands**, or **Salahieh** or art with

substantially the same disclosures during '708's prosecution. Similarly, the Examiner did not consider the same or substantially the same arguments during prosecution as those contained herein. Specifically, although the Examiner considered references teaching a delivery catheter sized 18 French or less, including U.S. Patent Publication 2005/0137701 to Salahieh ("'701 Salahieh"),[3] ('708FH, 2069), which has a similar but not identical specification to the Salahieh relied on herein, the Examiner did not consider any reference or ground teaching "a natural valve leaflet with a thickness of at least about 0.[0]11 inches," let alone grounds teaching such a valve loaded into a catheter of 18 French or less. '708FH, 2746, 2769.

Although the Examiner did consider art with valve leaflets having a thickness of at least about 0.011 during prosecution, none of those references concerned a natural tissue valve. '708FH, 2065-66 (finding Dobben teaches "a tissue valve (36) having a thickness of at least about 0.011 inches"), 2097 (same), 2101 (noting then-pending claims required only the valve to be at least about 0.011 inches), 2067 (finding Cai teaches "a tissue valve of at least .011 inches"); Dobben (Ex. 1006), 2:44-68 (flap valve made of stainless steel wire and two nylon disks); Cai (Ex. 1007) ¶[0090] (polymer leaflets). Indeed, PO amended claim 21 to add the "natural" valve

[3] '701 Salahieh is not family to Salahieh, although it shares seven of eight inventors.

limitation to get around this very art. '708FH, 2124 ("a natural tissue valve comprising a leaflets having a thickness of at least about .011 inches coupled to the support structure.") (additions underlined). The Examiner then allowed the Claims at least in part on this amended limitation—"a natural valve leaflet with a thickness of at least about 0.11 inches." '708FH, 2746, 2769.

In contrast, as explained below, **Salahieh** in view of **Sands** (Ground 1), **Leonhardt** in view of **Sands** (Ground 2), **Grube** in view of **Nguyen** (Ground 3) and **Salahieh** in view of **Nguyen** (Ground 4) teaches those very limitations. *See* §§X.A, X.B, X.C, X.D.

Even if the art and arguments were substantially the same, the Examiner erred in a manner material to the patentability of the Claims. Where the "Examiner did not expressly consider" **Grube**, **Nguyen**, **Leonhardt**, **Sands**, or **Salahieh**, 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, LLC*, IPR2019-00379, 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. Specifically, to the extent the Examiner considered references teaching a delivery catheter sized 18 French or smaller ('708FH, 2069), the Examiner erred in failing to reject the claims over a combination of any of those references and art

teaching tissue valve leaflets having a thickness of at least about 0.011 inches that were loaded in such catheters, including, for example, **Nguyen** and **Sands**.

The Board should not exercise its §325(d) discretion to deny institution.

B. §314(a)

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, Inc*. 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. IPR20210-00243; IPR2021-00242; IPR2021-00239; and IPR20210-00240, IPR2021-00241 and IPR2021-00310. **2:** Trial is scheduled for October 2022, more than three months after a final written decision will issue in this IPR. Ex. 1036. **3:** To date, the court has not issued any substantive orders related to the '708, and Petitioners have moved to dismiss pending claims. Infringement contentions have been served but invalidity contentions have not, 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. **5**: The litigation and PTAB parties are the same. **6**: The merits of this Petition are particularly strong as shown herein.

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 '708 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 in addressing other issues, e.g., infringement. All claim terms should be construed according to their plain and ordinary meaning as would have been understood by a POSITA in view of the specification. Drasler ¶¶50-51.

A. Preambles

Regardless of whether the preambles are limiting, the prior art discloses the preambles. *See* §X; Drasler ¶52.

B. "at least about 0.011 inches"

Regardless of the exact metes and bounds of this term, the prior art discloses this limitation. *See* §§X.A.3.[21.3], X.B.3.[21.3], X.C.3.[21.3], X.D.3.[21.3]; Drasler ¶¶53-54.

C. "natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure"

Claim 21 recites a "natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure." While the limitation is ambiguous as to whether it requires "a leaflet" or multiple "leaflets" that meet the thickness requirement, the prior art relied on herein satisfies either possible construction, and the Board therefore need not reach this issue. *See* §X (each ground shows multiple "leaflets" satisfying the thickness requirement); Drasler ¶63.

PO contends that this phrase extends to a prosthetic valve with leaflets formed of biological tissue such as the pericardium. Ex. 1032, 42-43 (alleging porcine pericardium meets this limitation). (Pericardium is a type of mammalian tissue not found in mammalian valves. Drasler ¶62.) Petitioner contends this phrase should be construed as requiring leaflets formed from leaflet tissue harvested from a natural

mammalian donor valve, *i.e.*, donor leaflets, whether in the form of a complete donor valve or donor leaflets removed from a donor valve and attached to additional structures (e.g., other tissues) to form a valve. While the Board need not reach this issue as the claims are unpatentable both under this construction (Grounds 1-2) as well as the broader construction where the leaflets may be made of other biological materials (Grounds 3-4) (*see* §X), Petitioners' construction should be adopted if the Board does construe the term.

The specification refers to two types of tissue valve leaflets: "donor valve leaflets" and those formed of "other biological materials." '708, 2:15-22, 15:26-28; Drasler ¶61.

During prosecution, PO argued that prior art prosthetic valves derived from tissues other than natural leaflets (*e.g.*, pericardium tissue) did not qualify as "tissue valves" as recited in then-pending claims. *Compare* '708FH, 353-54, *with* Osborne (Ex. 1033) ¶¶[0059]-[0060] ("any suitable biocompatible material" including "natural materials"), [0064] ("pericardium"); Sarac (Ex. 1034), Abstract ("peritoneal tissue, pleural tissue or pericardial tissue"); Allen (Ex. 1035), 4:23-27 ("fixed collagenous membrane of animal origin, such as pericardium…."); *see also* Cai (Ex. 1007) ¶[0004] ("natural materials such as tissue"); '708 FH, 629 (PO admitting Osborne teaches using "extracellular matrix material" (*e.g.*, pericardium) and admitting Sarac teaches leaflets made from biological material). To narrow the

claimed invention to PO's interpretation of "tissue leaflets," PO subsequently amended claim 21 to require "a natural tissue valve comprising a leaflets having a thickness of at least 0.011 inches." '708FH, 2123 (cl. 21), 2124-25; *compare also* '708FH, 354, 629-631, 2087-88, 2124-25 (applicant arguing art does not disclose tissue valve), *with* '708FH, 608 and 2101 (Examiner disagreeing); Drasler ¶¶55-58.

The Examiner allowed the claims based on this amendment—expressly stating in notices of allowance that the claims were allowed because, among other things, they require "*a natural valve leaflet*." *Id.* at 2746, 2769 (emphasis added). Drasler ¶59-61. Even if it could be argued that the claims would otherwise encompass leaflets formed of "other biological materials" beyond natural valve leaflets, PO disclaimed this coverage during prosecution. *See Arendi S.A.R.L. v. Google LLC*, 882 F.3d 1132, 1133-1136 (Fed. Cir. 2018) (applying prosecution disclaimer where record showed what was amended and why and examiner confirmed those reasons).

X. GROUNDS OF UNPATENTABILITY

Although the '708 purports to have invented a delivery catheter sized 18 French or smaller for delivering a cardiovascular prosthetic implant with natural tissue valve leaflets of at least about 0.011 inches, such methods were well known in the art. As explained below, the Claims are unpatentable as obvious. Drasler ¶¶1-196.

Grounds 1 and 4: **Salahieh** discloses an elongate delivery catheter sized 18 French or smaller that transluminally delivers a cardiovascular prosthetic implant made of biologic tissues (e.g., natural valve leaflets or pericardium tissue) to the implantation site in the heart and deploys it, upon which the delivery catheter is removed from the patient. **Sands** teaches the donor porcine valve leaflets in tissue implants similar to the one described in Salahieh that have a thickness of at least 0.011 inches (Ground 1) and **Nguyen** teaches pericardium-based implants similar to the one in Salahieh that have leaflets with a thickness of at least 0.011 inches (Ground 4). Drasler ¶¶68-100, 167-175.

Ground 2: **Leonhardt** discloses an elongate delivery catheter sized 18 French or smaller that transluminally delivers a native porcine valve in a stent to the implantation site in the heart and deploys it, after which the delivery catheter is removed from the patient. **Sands** teaches that native porcine valves naturally have leaflets with a thickness of at least 0.011 inches. Drasler ¶¶101-131.

Ground 3: Grube discloses an elongate delivery catheter sized 18 French or smaller that transluminally delivers a porcine pericardium-based bioprosthesis to the implantation site in the heart and deploys the bioprosthesis, upon which the delivery catheter is removed from the patient. **Nguyen** teaches that the bioprosthesis in Grube has leaflets with a thickness of at least 0.011 inches. Drasler ¶¶132-166.

The prior art renders the Claims unpatentable. This Petition is supported by the Declaration of William J. Drasler, Ph.D., which describes the scope and content of the prior art at the time of the alleged '708 invention. Declaration of William J. Drasler (Ex. 1002) ¶¶1-196.

A. Ground 1: Claims 21-22 Are Rendered Obvious by Salahieh in view of Sands

1. Overview of Salahieh

Salahieh teaches a system for "…endovascularly replacing a patient's heart valve,…" "and a replacement valve disposed within the delivery catheter." Salahieh, 3:21-26. A POSITA would have understood **Salahieh**'s endovascular catheter-delivery technique to be an example of a minimally invasive technique. Drasler ¶¶68-69; *see also, e.g.*, Ex. 1055, Abstract, Ex. 1056, 1:49-58. The system includes a replacement heart valve "apparatus 10," comprising a "replacement valve 20" coupled to self-expanding, "cylindrical" "anchor 30." Salahieh, 6:23-41. The replacement valve is formed from "biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues," and is attached at its "commissures 24" (where the leaflets abut each other) to "posts 38" of the anchor, as exemplified in Figures 1A and 2A below.

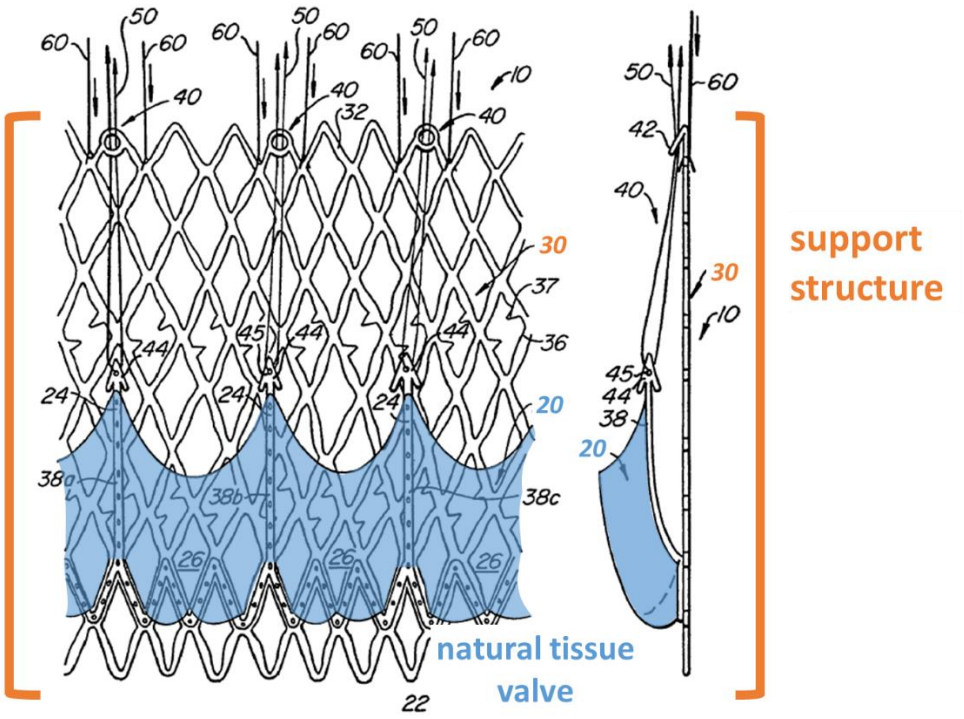
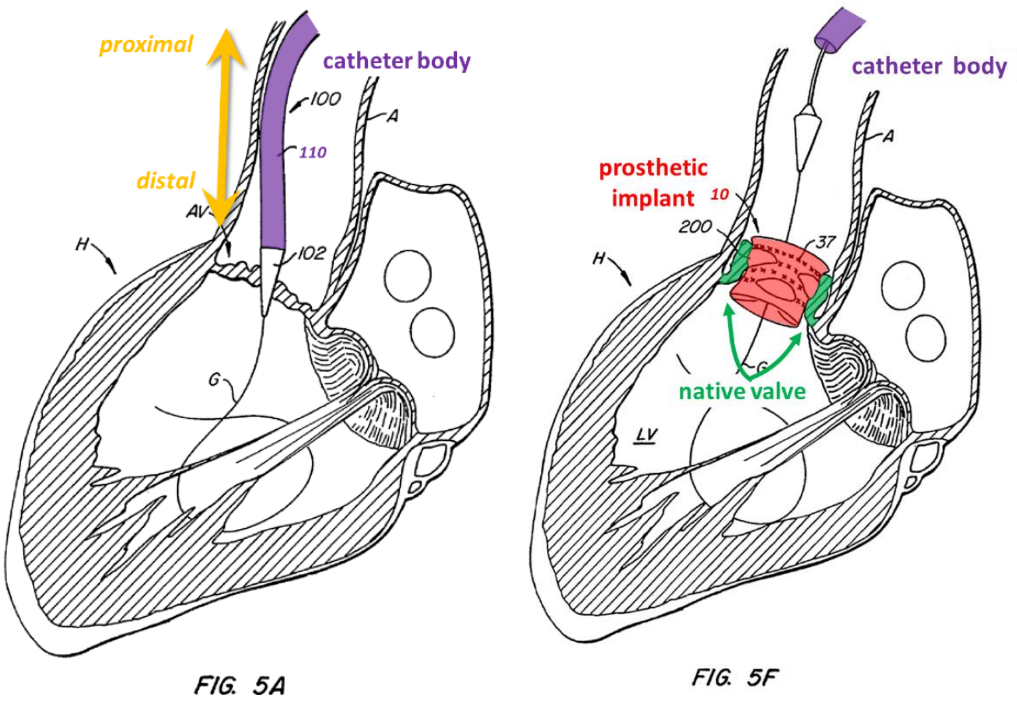


FIG. 1A FIG. 2A

Salahieh, 6:29-41, 6:12-16 ("FIG. 1 schematically illustrate individual cells of anchor 30 of apparatus 10, and should be viewed as if the cylindrical anchor has been cut open and laid flat. FIG. 2 schematically illustrate a detail portion of apparatus 10 in side-section."), Figs. 1A-2A (showing constrained delivery configuration); Drasler ¶69. The valve apparatus is disposed in a "collapsible…delivery configuration" within the lumen of a "delivery sheath or catheter" and the delivery assembly is advanced endovascularly over a guide wire through the aorta to "the patient's diseased aortic valve." Salahieh, 9:10-17, 8:11-14. **Salahieh** teaches the delivery catheter has a "reduce[d]…delivery profile" of "no more than 17 french" to facilitate the delivery in a retrograde fashion. Salahieh,

6:49-55, 11:7-9. At the placement site, the valve is deployed by "retracting" an outer sheath relative to the delivery catheter, causing the valve device to "dynamically self-expand to a…deployed configuration." Salahieh, 8:14-33. After deployment and positioning is complete, the delivery catheter is separated from the replacement heart valve apparatus and removed from the patient. Drasler ¶70.

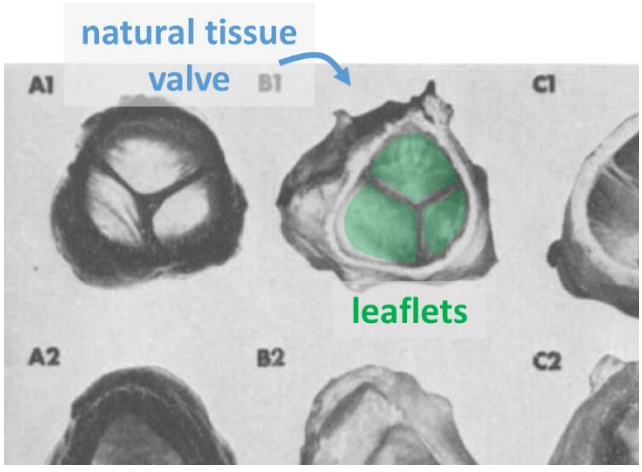


Salahieh, 8:30-33, 9:50-54, Figs. 5A, 5F. Drasler ¶70.

2. Overview of Sands and Motivation to Apply Its Teachings to Salahieh

Sands discloses the characteristics of native human, porcine, and bovine aortic valves that inform "selection of the most favorable heterograft donor species." Sands, Abstract, 407. A heterograft is a tissue graft taken from a species different from that of the recipient—*e.g.*, a porcine valve being implanted into a human. *Id.*;

Drasler ¶71. In the study, the valve "leaflet thickness of the different species was measured microscopically." Sands, 408. Sands noted that "[v]ariation in leaflet thickness…may be important" because "heterografts…must retain functional durability for prolonged periods of time in the absence of normal systems by which supporting structures…are maintained or regenerated." Sands, 412 (rejecting extremely thin sheep leaflets). The porcine valve (e.g., as shown below in Fig. 2), with respective mean leaflet thicknesses near the leaflet base and the free edge of "0.80 mm and 0.70 mm" (i.e., between 0.0276 and 0.0315 inches), was identified as the "more optimal aortic valve heterograft[]." Thus, Sands's teachings meet the "thickness of at least about 0.011 inches" limitation across the entire leaflet expanse.



Sands, 408, 412-413, Fig. 2; Drasler ¶71.

Salahieh and **Sands** are in the same field as the '708—prosthetic cardiovascular implants—and reasonably pertinent to the alleged problem(s) identified in the '708 of a need for a natural tissue heart valve prosthesis. '708,

Abstract, 1:16-20, 3:39-46, 15:21-22 ("Some tissue valves are native valves such as pig…valves"); Salahieh, Abstract, 1:11-19 (discussing the need to replace diseased heart valves when "there is a narrowing of the native heart valve…or when the native valve leaks or regurgitates"), 1:20-28 (stating prior art mechanical valves "require lifelong anticoagulant medication to prevent blood clot formation"); Sands, Abstract, 412-413 (analyzing optimal aortic valve heterograft for transplantation into humans).

While **Salahieh** teaches endovascular delivery and implantation of a "biologic tissue[]" valve formed from native "porcine valve leaflets," **Sands** specifies that such leaflets have a thickness between 0.0276 and 0.0315 inches. Salahieh, 6:29-31; Drasler ¶72-73. A POSITA thus would have been motivated to apply **Sands'** teachings of porcine valve leaflets of a certain thickness to **Salahieh's** porcine valve leaflets to achieve the beneficial and predictable result of incorporating the characteristics of a heterograft valve known to work in humans into a natural tissue valve for at least the following independent reasons. Drasler ¶¶72-73.

First, **Sands** teaches an optimization for replacement aortic valves (sourcing valve grafts from porcine aortic valves due to their particular characteristics including leaflet thickness), and **Salahieh** teaches a replacement aortic valve that uses porcine aortic valve leaflets. Drasler ¶74. As discussed in §IX.C, a bioprosthetic heart valve formed with heterograft natural valve leaflets is a natural

tissue valve. **Salahieh** teaches coupling natural porcine valve leaflets to an anchor support structure to form replacement valve 20 to replace native aortic valve function. Salahieh, 6:29-41, 9:10-13, 9:45-48, Figs. 5A-D. **Sands** measured the thickness of heterograft porcine aortic valve leaflets at the leaflet base and distal free edge, and proposed using donor porcine aortic valves in part because of their leaflet thickness. Sands, 407, 411-413. A POSITA would have further been motivated to apply Sands' teachings of using porcine aortic valve leaflets of the indicated thickness—a thickness known to function in human patients—in implementing **Salahieh's** natural tissue valve. Drasler ¶74.

Second, **Salahieh** teaches using donor porcine aortic valves to construct a prosthetic replacement valve, but leaves to a POSITA the detail as to the thickness of the selected leaflet. Drasler ¶75. Therefore, a POSITA would have been expected to look at other references or to rely on the state of the art. *Id.* **Sands** teaches that "[v]ariations in leaflet thickness" are important considerations for maintaining the "functional durability" of the valve prosthesis "for prolonged periods of time." Sands, 412. For example, **Sands** states that the "extremely thin and fragile leaflets" of heterograft sheep valves, which have a mean thickness between 0.0091 inches and 0.0128 inches, "may not be structurally strong enough to support heavy pressure loads for long periods of time." *Id*. Sands teaches the thickness of usable porcine aortic valve leaflets. A POSITA would have further been motivated to apply

Sands's teachings to select porcine aortic valve leaflets, which have the taught thicknesses, in implementing **Salahieh**'s valve constructed from porcine aortic leaflets. Drasler ¶75.

Third, given that there is a need to use a cardiovascular prosthetic implant with heterograft leaflets to replace native valves in the heart as recognized in **Salahieh**, and given that there are a finite number of solutions for such leaflets, it would have been obvious to try a porcine aortic valve leaflets having a thickness of at least 0.011″ given that these were known to work in the art for catheters smaller than 18 French. MPEP 2144.05; *KSR*, 550 U.S. at 421; Drasler ¶76.

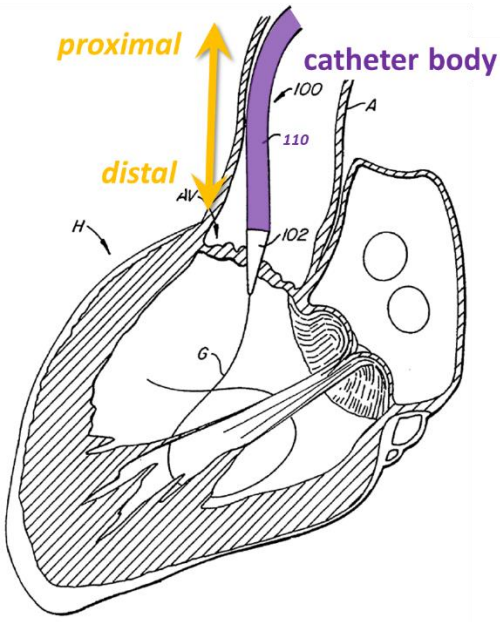
In light of the above teachings, a POSITA also would have had a reasonable expectation of success in applying **Sands'** teachings of known thicknesses of native porcine valve leaflets to **Salahieh's** natural tissue valve. Sands, 412. Indeed, **Salahieh** teaches using "biologic tissues, e.g., porcine valve leaflets" in a replacement heart valve apparatus for endovascular delivery in a catheter having a diameter "no more than 17 french." Salahieh, 6:6-12, 6:29-31, 6:51-55. Indeed, the thickness of a suitable porcine aortic valve leaflet was well-known and a POSITA would have therefore found it obvious and straightforward to apply the teachings of a porcine valve comprising leaflets having a thickness of at least 0.011 inches to **Salahieh**. Drasler ¶¶77-78. For example, **Sauren**, **Talman**, and **Weind** teach that the thickness of porcine aortic valve leaflet specimens is greater than 0.011 inches.

Sauren, A. "The Mechanical Properties of Porcine Aortic Valve Tissues," *J. Biomechanics* Vol. 16 No. 5 (Ex. 1017, published 1983), 330 ("The experiments were conducted on porcine aortic valve tissue….The average thickness of the leaflet, sinus and aortic strips was, respectively, 0.5 [0.02 inches], 2.1 and 3.1 mm"); Talman, E. "Internal Shear Properties of Porcine Aortic Heart Valve Cusps," *The University of Western Ontario* (Ex. 1018, published 1999), 26 ("…[Porcine aortic heart valve cusps] are thickest (about 1 mm [0.04 inches]) at the line of attachment to the aorta and taper down to a thickness of less than 500 μm [0.02 inches] in the central region of the cusp and at the free edge….")); Weind, K. "Aortic Valve Cusp Vessel Density: Relationship with Tissue Thickness," *The Journal of Thoracic and Cardiovascular Surgery* Vol. 123 No. 2 (Ex. 1019, published 2002), Table 3A (showing mean porcine aortic valve thickness between 0.36 to 0.48 mm (0.014 to 0.019 inches)). Drasler ¶¶77-78, 184-190.

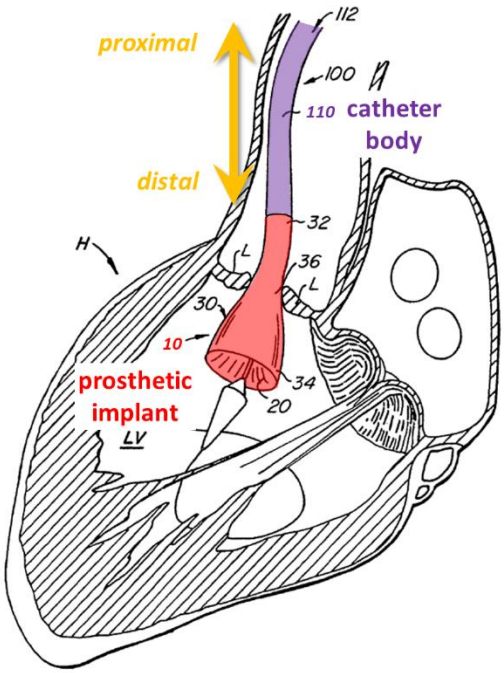
3. Claim Chart

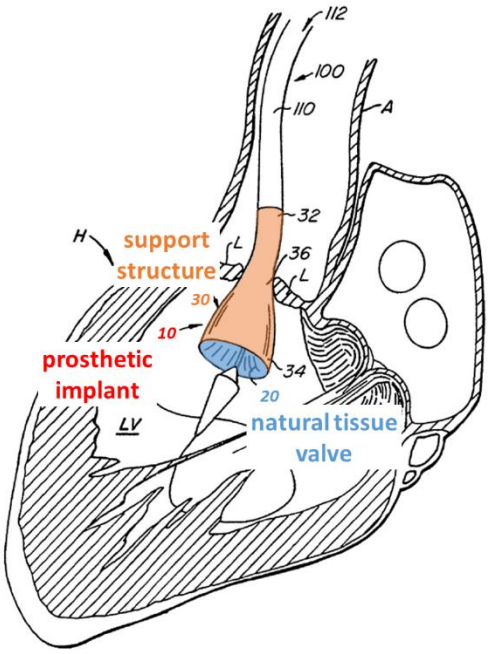
Claim Element	Salahieh in view of Sands
[21.pre] A delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure, wherein the delivery catheter comprises:	**Salahieh discloses a delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure** (*e.g.*, "endovascularly replacing a patient's heart valve including…a replacement valve disposed within the delivery catheter")**.** ***E.g.*, Salahieh:** **Salahieh** discloses a "delivery catheter" assembly for "endovascularly replacing a patient's heart valve," using replacement heart valve "[a]pparatus 10" comprising a

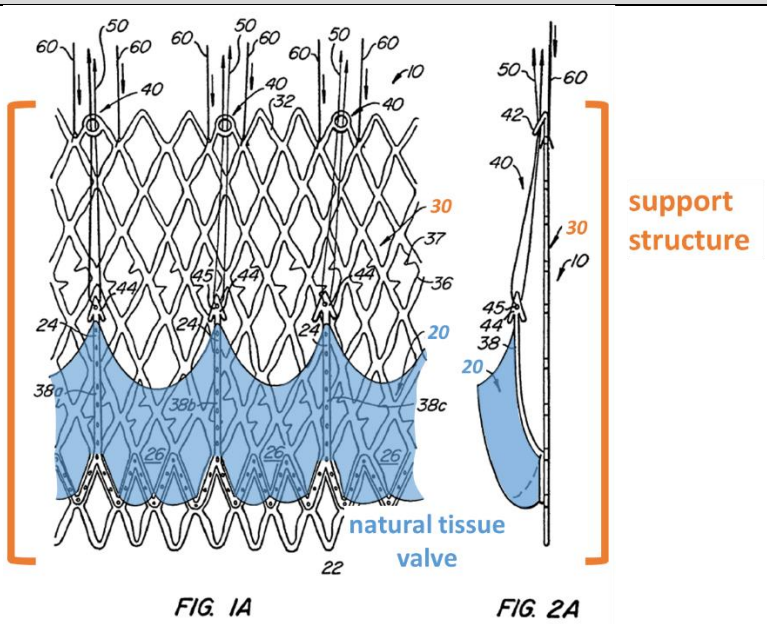
Claim Element	Salahieh in view of Sands
	"replacement valve…coupled to the anchor" (a prosthetic). • 3:21-26 ("One aspect of the invention provides an apparatus for ***endovascularly replacing a patient's heart valve, including: a delivery catheter*** having a diameter of 21 french or less; an expandable anchor disposed within the delivery catheter; and ***a replacement valve disposed within the delivery catheter***.…") • 6:11-12 ("***Apparatus 10 comprises replacement valve 20*** disposed within and ***coupled to anchor 30.***") • *See also* 6:23-29 Drasler ¶¶79-81.
[21.1] an elongate, flexible catheter body having a proximal end and a distal end, wherein the distal end has an outer diameter of 18 French or less; and	**Salahieh discloses the delivery catheter** (*see* [21.pre]) **comprises an elongate, flexible catheter body** (*e.g.*, "catheter" configured for "endovascularly replacing a[n]…aortic valve") **having a proximal end and a distal end** (*e.g.*, proximal region and "distal region" of catheter)**, wherein the distal end has an outer diameter of 18 French or less** (*e.g.*, "having a diameter no more than…17 french")**.** ***E.g.*, Salahieh:** ***See* [21.pre].** In addition, **Salahieh** discloses the long and flexible catheter is configured for endovascularly delivering a replacement heart valve apparatus, such that during delivery the catheter extends from outside the patient (the proximal end) through a patient's aorta to the heart's left ventricle (the distal end). Salahieh, 6:49-55, 7:2-10, Fig. 5A. The catheter has a diameter of "no more than 17 french" to limit the catheter delivery profile and provide

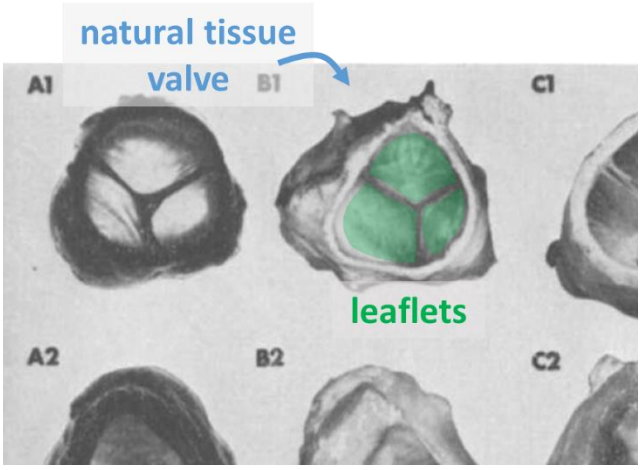
Claim Element	Salahieh in view of Sands
	sufficient flexibility to facilitate a retrograde delivery. Salahieh, 6:49-55, 9:10-17. • 9:10-17 ("Referring to FIG. 5, a method of ***endovascularly replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described***. As seen in FIG.5A, sheath 110 of delivery system 100, having apparatus 10 disposed therein…") • Fig. 5A  FIG. 5A • 6:49-55 ("The anchor and valve may thereafter be repositioned and even retrieved into ***the delivery sheath or catheter***. The apparatus may be delivered to the vicinity of the patient's aortic valve in a retrograde approach in a ***catheter having a diameter*** no more than 23 french,…or more preferably ***no more than 17 french***.") • 9:18-20 ("In FIG. 5B, ***sheath 110 is positioned such that its distal region is disposed within left ventricle LV*** of the patient's heart H.")

Claim Element	Salahieh in view of Sands
	• *See also* 7:2-10, 11:7-9. Drasler ¶¶82-85.
[21.2] a cardiovascular prosthetic implant loaded within the distal end of the catheter body,	**Salahieh discloses the delivery catheter** (*see* [21.pre]) **comprises a cardiovascular prosthetic implant loaded within the distal end of the catheter body** (*e.g.*, replacement heart valve "[a]pparatus 10" loaded within a "distal region" of the catheter)**.** ***E.g.*, Salahieh:** **Salahieh** discloses an "[a]pparatus 10" comprising "replacement valve 20" "coupled to anchor 30" (and therefore prosthetic) disposed within and deployed from a "distal region" of the catheter. • 3:21-26, 6:11-12, 6:23-29 (see [21.pre]) • 9:10-17 ("Referring to FIG. 5, a method of endovascularly replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described. As seen in FIG.5A, ***sheath 110 of delivery system 100, having apparatus 10 disposed therein***, is endovascularly advanced over guide wire G….") • Fig. 5B

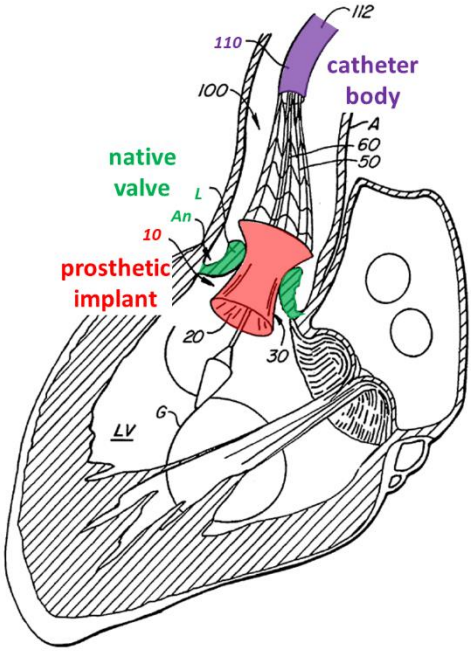
Claim Element	Salahieh in view of Sands
	 FIG. 5B • 6:49-51 ("The anchor and valve may thereafter be repositioned and even retrieved into ***the delivery sheath or catheter***.") • 9:18-24 ("In FIG. 5B, sheath 110 is positioned such that ***its distal region is disposed within left ventricle LV of the patient's heart H. [¶] Apparatus 10 is deployed from lumen 112 of sheath 110***,...as in FIG. 5C.") • 6:11-16, Figs. 4A, 5A-5C, 8:8-14. Drasler ¶¶86-88.
[21.3] wherein the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve comprising a leaflets having a	**Salahieh discloses the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve comprising leaflets coupled to the support structure** (*e.g.*, "replacement heart valve apparatus…comprises replacement valve 20…coupled to anchor 30," valve 20 is made "from biologic tissues, e.g. porcine valve leaflets")**.**

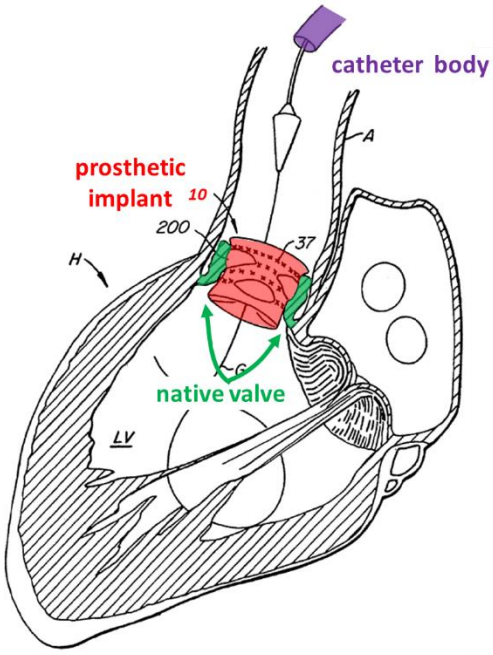
Claim Element	Salahieh in view of Sands
thickness of at least about 0.011 inches coupled to the support structure.	***E.g.*, Salahieh:** **Salahieh** discloses replacement heart valve "[a]pparatus 10," comprising "replacement valve 20…coupled to anchor 30." Salahieh, 6:6-12. Replacement valve 20 is a "biologic tissue[]" valve formed from "porcine valve leaflets." Salahieh, 6:29-41. • Fig. 5B  FIG. 5B • 6:6-12 ("With reference now to FIGS. 1-4, a first embodiment of ***replacement heart valve apparatus*** in accordance with the present invention is described….Apparatus 10 ***comprises replacement valve 20 disposed within and coupled to anchor 30.***") • Figs. 1A-2A

Claim Element	Salahieh in view of Sands
	 FIG. 1A FIG. 2A • 6:23-41 ("…***Replacement valve 20 is preferably from biologic tissues***, ***e.g. porcine valve leaflets*** or bovine or equine pericardium tissues….Annular base 22 of ***replacement valve 20 preferably is coupled to*** skirt region 34 of ***anchor 30***, while commissures 24 of replacement valve leaflets 26 are coupled to posts 38.") • Figs. 1A-2A, 6:12-16. **Sands discloses a natural tissue valve comprising leaflets having a thickness of at least about 0.011 inches** (*e.g.*, "aortic valve[]…heterografts," "[m]ean leaflet thickness measurements" of pig valves were "0.80 mm and 0.70 mm"—0.0315 inches and 0.0276 inches)**.** ***E.g.*, Sands:** As discussed in §X.A.2, while **Salahieh** leaves to a POSITA the detail as to the thickness of the porcine valve leaflets of its prosthetic implant, **Sands** discloses the "[m]ean leaflet thickness" at the leaflet base and distal free edge of donor porcine aortic valves is between "0.80 mm

Claim Element	Salahieh in view of Sands
	and 0.70 mm," i.e., between 0.0315 inches and 0.0276 inches. • 412 ("SERIES II ¶ ***Mean leaflet thickness measurements***, near the leaflet base and distal free edge, respectively, ***were***…***pig, 0.80 mm. and 0.70 mm.***....") • 410 ("FIG. 2. A comparison of three views of human (A), ***pig*** (B), calf (C), and sheep (D) ***aortic valves*** that were inflated with air to a pressure of 100 mm. Hg and fixed by freezing in liquid nitrogen. The ***upper row of photographs shows the superior or aortic side of the valve leaflets***…") • Fig. 2  • 408 ("SERIES II ¶ In the second series, ***leaflet thickness of the different species was measured*** microscopically.") Drasler ¶¶73-78, 89-93.
[22.pre] A method of deploying a cardiovascular prosthetic implant, the method	**Salahieh discloses a method of deploying a cardiovascular prosthetic implant** (*e.g.*, "a method for endovascularly replacing a heart valve…delivering a replacement heart valve")**.** ***E.g.*, Salahieh:**

Claim Element	Salahieh in view of Sands
comprising the steps of:	***See* [21.pre].** • Abstract ("The invention also includes a ***method for endovascularly replacing a heart valve of a patient... endovascularly delivering a replacement valve*** and an expandable anchor ***to a vicinity of the heart valve*** through the catheter….") Drasler ¶¶94-96.
[22.1] translumenally advancing a catheter of claim 21 to a position proximate a native valve of a patient; deploying the cardiovascular prosthetic implant within the patient; and removing the catheter from the patient.	**Salahieh discloses translumenally advancing a catheter of claim 21** (*see* [21]) **to a position proximate a native valve of a patient** (*e.g.*, "catheter" is delivered "endovascularly…to a vicinity of the heart valve")**; deploying the cardiovascular prosthetic implant within the patient** (*e.g.*, "deploying the…replacement valve")**; and removing the catheter from the patient** (*e.g.*, "delivery system 100 is removed from the patient")**.** ***E.g.*, Salahieh:** ***See* [22.pre].** **Salahieh** discloses endovascularly advancing catheter 110, "having apparatus 10 disposed therein," to "the patient's diseased…valve," then deploying the valve so that it "dynamically self-expand[s]" within the diseased valve, and subsequently removing the catheter from the patient to complete the procedure. • Abstract ("…[T]he method includes the steps of: ***inserting a catheter*** having a diameter no more than 21 french ***into the patient; endovascularly delivering a replacement valve*** and an expandable anchor ***to a vicinity of the heart valve through the catheter***; and ***deploying* the anchor and *the replacement valve***.") • 9:12-24 ("As seen in FIG.5A, ***sheath 110 of delivery system 100, having apparatus 10 disposed therein, is endovascularly advanced over guide wire*** G,…through a patient's aorta A ***to the***

Claim Element	Salahieh in view of Sands
	patient's diseased aortic valve AV….Apparatus 10 is deployed from lumen 112 of sheath 110…such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration, as in FIG. 5C.") • 9:38-41 ("***Once properly aligned***, wires 50 are retracted relative to tubes 60 to impose foreshortening upon anchor 30 and ***expand apparatus 10 to the fully deployed configuration***, as in FIG. 5D.") • Fig. 5D  FIG. 5D • 9:50-54 ("As seen in FIG. 5F,...tubes 60 are decoupled from anchor 30, e.g. via wires 62, and ***delivery system 100 is removed from the patient***, thereby completing deployment of apparatus 10.") • Fig. 5F

Claim Element	Salahieh in view of Sands
	 FIG. 5F • 3:35-45, 6:51-56, 8:30-33, 8:50-9:9. Drasler ¶¶97-100.

B. Ground 2: Claims 21-22 Are Rendered Obvious by Leonhardt in view of Sands

1. Overview of Leonhardt

Leonhardt, a Medtronic-owned patent, teaches an artificial heart valve delivered percutaneously and transluminally using a deployment catheter. Leonhardt, Abstract, 6:34-39. A POSITA would have understood **Leonhardt**'s percutaneous, transluminal catheter-delivery technique to be an example of a minimally invasive technique. Drasler ¶102. The artificial heart valve is a "valve stent 20" comprising a "biological valve 22" including leaflets—preferably a treated

porcine valve—and "attached to stent 26," as shown in Figure 4, with sutures or a biocompatible adhesive.

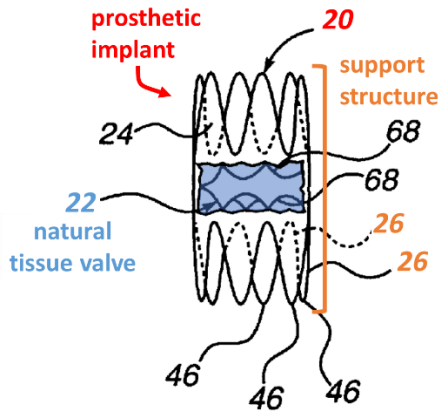


FIG. 4

Leonhardt, 4:14-16, 6:23-31, 10:64-67, Fig. 4; Drasler ¶¶101-102. Prior to delivery, the valve stent is "pre-loaded within the distal end of [an] outer sheath 106" of the flexible, long, tubular "deployment catheter 100" by "sliding outer sheath 106 over the [valve/stent's] tip and on until valve stent 20 resides within outer sheath 106...." Leonhardt, 6:13-17, 6:35-45, 6:55-61, 9:51-55, Fig. 5. The "[o]uter sheath 106 is made of a low friction and flexible material" and has a diameter "size rang[ing] from 12 FR to 20 FR."

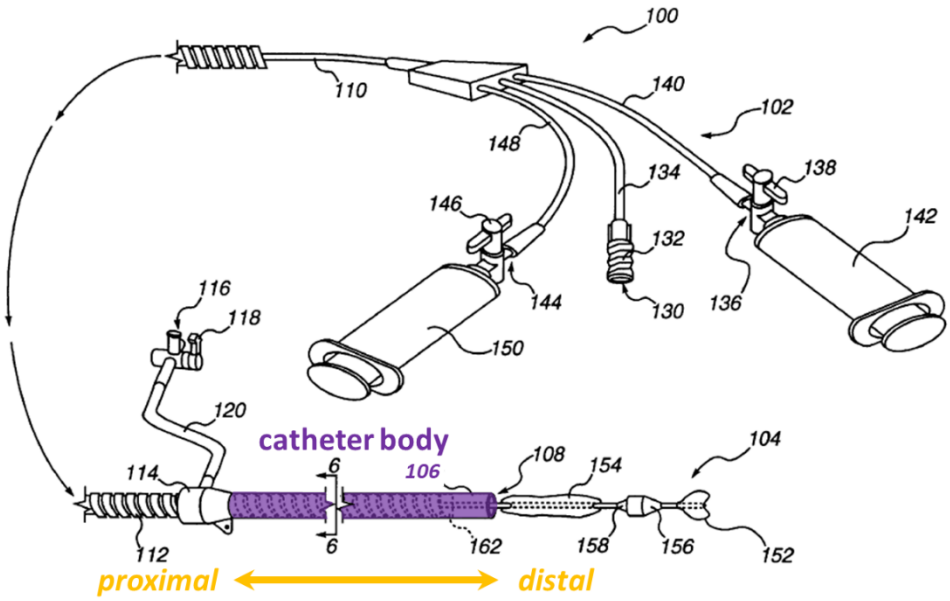
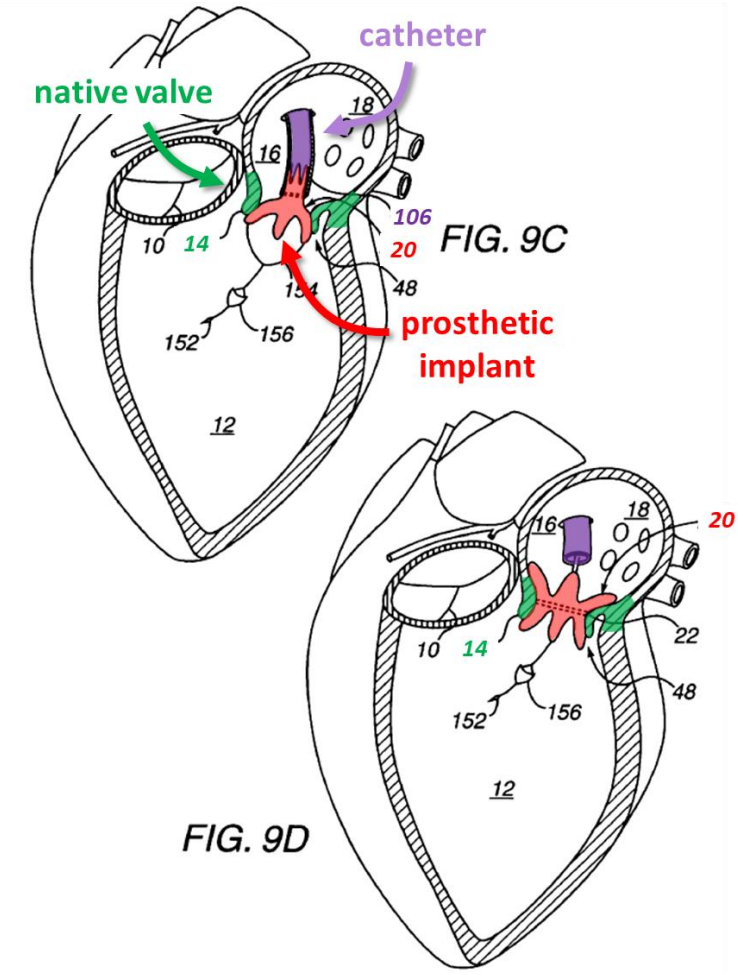


FIG. 5

Leonhardt, 6:42-51, 6:51-59, Fig. 5; Drasler ¶103. The deployment catheter 100 with the valve stent loaded into outer sheath 106 is then introduced into the patient "through the largest femoral artery" and "advance[ed]…to the placement site" at the aortic valve. Leonhardt, 9:63-67, 10:3-11. Valve stent 20 is deployed by "withdrawing outer sheath 106…while holding push rod 112 stationary" so that valve stent 20 "protrude[s] from outer sheath 106." Leonhardt 10:53-64. After deployment, "catheter 100 [including outer sheath 106] is removed" from the patient.



Leonhardt 11:63-64, Figs. 9C-9D; Drasler ¶104.

2. Motivation to Apply Sands' Teachings to Leonhardt

As discussed in §§X.A.2-3, **Sands** teaches that native porcine aortic valves, with a mean leaflet thickness between "0.80 mm and 0.70 mm," have "the most favorable" characteristics of heterograft valves among native bovine, porcine, and ovine valves. Sands, Abstract, 407-408, 412-413.

Leonhardt and **Sands** are in the same field as the '708—prosthetic cardiovascular implants—and reasonably pertinent to the alleged problem(s)

identified in the '708 of a need for a heart valve prosthesis. '708, Abstract, 1:16-20, 3:39-46, 15:21-22 ("Some [replacement] tissue valves are native valves such as pig…valves"); Leonhardt, Abstract, 6:61-65 (describing valve/stent's conical tip contributing to two-French reduction in outer sheath 106, resulting in "a smaller entry incision and less trauma to the patient's access passageway"), 11:29-40 (describing repositioning and recovery of valve stent after full or partial deployment); Sands, Abstract, 412-413 (analyzing optimal aortic valve heterograft for transplantation into humans). Drasler ¶105.

While **Leonhardt** teaches implantation of a porcine valve using a catheter having a diameter size below 18 French, it leaves to a POSITA the detail of the thickness of the porcine valve's leaflets. **Sands** specifies that such valves have a leaflet thickness of between 0.0276 and 0.0315 inches. Drasler ¶106. A POSITA would have been motivated to apply **Sands'** teachings of porcine valve leaflets of a certain thickness to **Leonhardt**'s porcine biological valve to achieve the beneficial and predictable result of a porcine valve bioprosthesis known to work as a heterograft for at least the following independent reasons. Drasler ¶106**.**

First, **Sands** specifies the thickness of the porcine valves that are used in **Leonhardt**. Drasler ¶107**. Leonhardt** teaches the use of a natural porcine (pig) valve pre-sized to fit within a stent, which is delivered via a catheter between 12 French and 20 French in diameter. Leonhardt, 6:23-31, 6:55-57. Sands describes

the characteristics of such porcine aortic valves that are suitable for implantation in human patients. Moreover, a POSITA would have had a reasonable expectation of success in using Sands' porcine valves—which are described as suitable for humans—in Leonhardt's narrow gauge delivery catheter. For example, **Feinstein** teaches mounting a porcine aortic valve onto a stent and advancing the combined valve/stent through a 16 French sheath. Feinstein, J. "Percutaneous Pulmonary Valve Placement in a 10-Month-Old Patient Using a Hand Crafted Stent-Mounted Porcine Valve," *Catheterization and Cardiovascular Interventions* Vol. 67 No. 4 (Ex. 1031, published April 2006), 645 ("A porcine valve…[was] sutured into the stent….The sheath in the right internal jugular vein was replaced with a 16-Fr sheath…" and "stent…[was] advanced" through sheath), 647; Drasler ¶¶107, 184-185, 187, 190. **Sands** measured the leaflet thickness of such valves. Sands, 412-413. Drasler ¶107.

Second, **Sands** teaches that natural porcine valves, e.g., with a mean leaflet thicknesses near the leaflet base and the free edge of "0.80 mm and 0.70 mm" (i.e., between 0.0276 and 0.0315 inches) respectively, are the "more optimal aortic valve heterograft[]"—further motivating a POSITA to apply Sands's teachings. Sands, 412-413; Drasler ¶108 In comparing various heterograft valves that can be implanted in the heart to determine the most optimal, **Sands** teaches that "thickness…may be important" because "heterografts…must retain functional

durability for prolonged periods of time in the absence of normal systems by which supporting structures…are maintained or regenerated." Sands, 412 (rejecting extremely thin sheep leaflets). In contrast to other options, porcine valve heterografts, like the one taught in **Leonhardt**, were found to be optimal, in part because its leaflets were between 0.0276 and 0.0315 inches—providing enough support to retain functional durability for prolonged periods of time. *Id.*; Drasler ¶108.

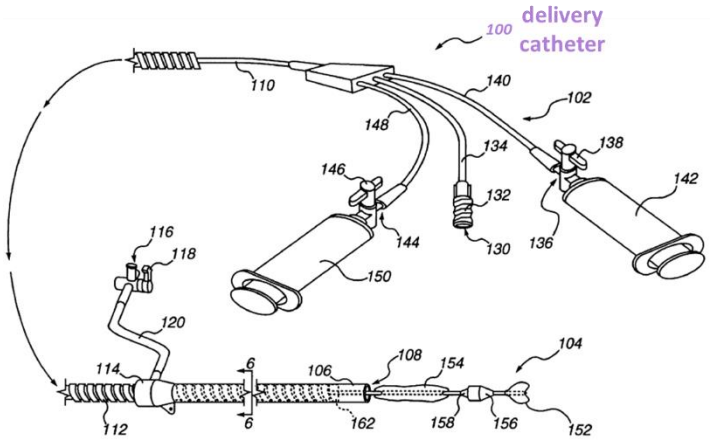
Third, given that there is a design need to use a natural tissue valve with leaflets to replace natural valves in the heart as recognized in **Leonhardt** and **Sands**, and given that there are a finite number of solutions for such leaflets, it would have been obvious to try a natural tissue valve with leaflets greater than 0.011" given that these were known to work in the art for catheters smaller than 20 French. MPEP 2144.05; *KSR*, 550 U.S. at 421; Ex. 1041, at 1; Drasler ¶109.

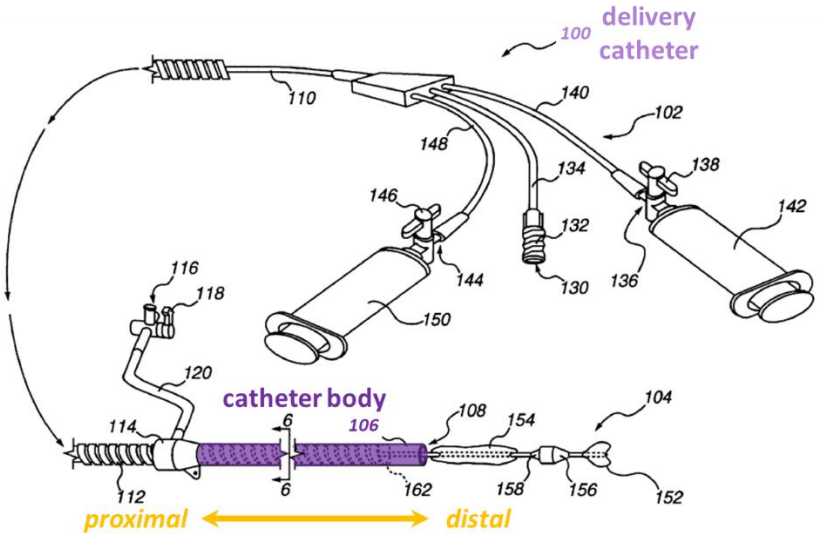
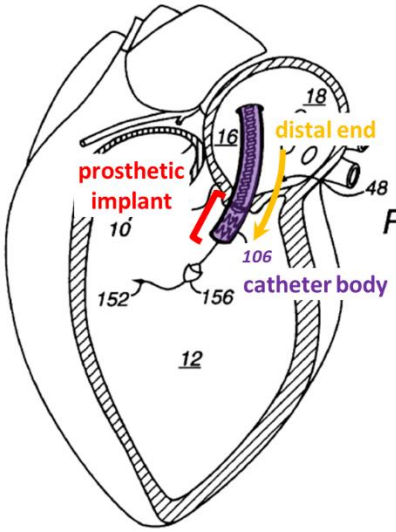
In light of the above teachings, a POSITA also would have had a reasonable expectation of success in applying **Sands'**s teachings of known thicknesses of native porcine valve leaflets to **Leonhardt's** natural porcine valves. Sands, 412. Indeed, **Leonhardt** already teaches using such porcine valves in a valve stent for delivery via a catheter with a diameter "size rang[ing] from 12 FR to 20 FR." Leonhardt, 6:23-34, 6:42-51, 6:55-57. As also discussed in §X.A.2 with respect to Salahieh, the thickness of a porcine aortic valve leaflet was well-known and a POSITA would

have found it obvious and straightforward to apply the teachings of a porcine valve comprising leaflets having a thickness of at least 0.011 inches to Leonhardt. Drasler ¶110.

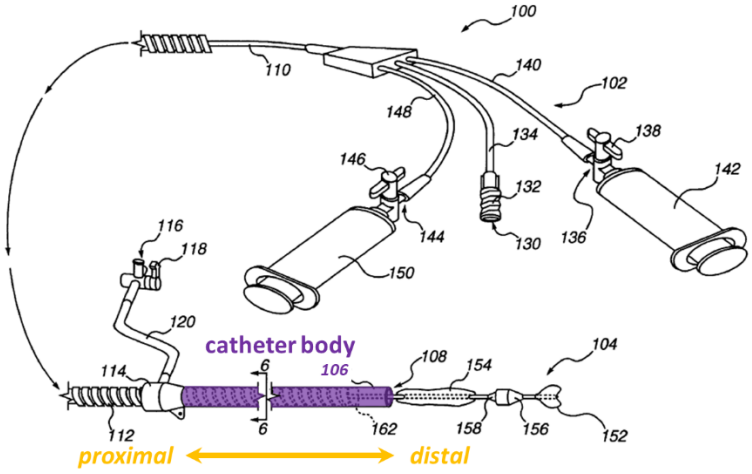
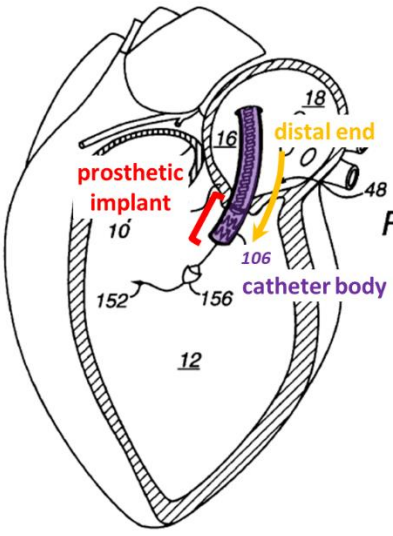
3. Claim Chart

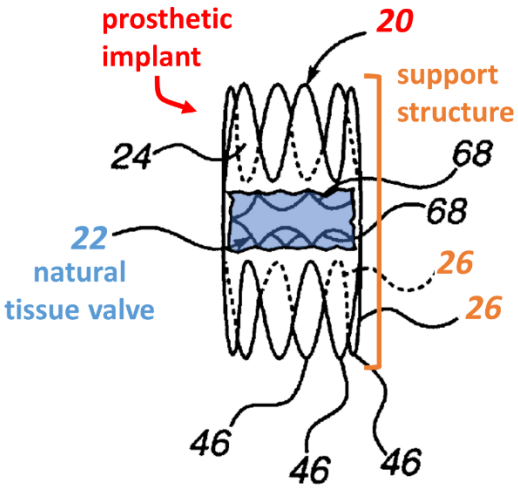
Claim Element	Leonhardt in view of Sands
[21.pre] A delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure, wherein the delivery catheter comprises:	**Leonhardt discloses a delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure** (*e.g.*, "Deployment catheter 100" which includes "outer sheath 106" "permit[s] percutaneous delivery of valve stent 20")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses "a valve stent 20" (a prosthetic implant) delivered percutaneously (through the skin) and transluminally (along the vasculature) within "outer sheath 106" of deployment catheter 100—a minimally invasive procedure. • 6:34-37 ("A preferred deployment catheter 100 is illustrated in FIGS. 5 and 6. ***Deployment catheter 100 is*** generally long and tubular ***permitting percutaneous delivery of valve stent*** 20 to the placement site.") • 9:50-54 ("FIGS. 9a-9d illustrate a method of surgically implanting ***valve stent 20***. that an appropriately sized ***valve stent 20 has been selected and pre-loaded within the distal end of outer sheath 106*** passage of appropriately sized deployment catheter 100.") • Fig. 5

Claim Element	Leonhardt in view of Sands
	 FIG. 5 • 3:15-29, 3:32-37, 5:41-42. Drasler ¶¶111-113.
[21.1] an elongate, flexible catheter body having a proximal end and a distal end, wherein the distal end has an outer diameter of 18 French or less; and	**Leonhardt discloses the delivery catheter** (*see* [21.pre]) **comprises an elongate, flexible catheter body** (*e.g.*, "Outer sheath 106" of deployment catheter 100 "has an axially extending sheath passage" and "is made of a…flexible material") **having a proximal end and a distal end** (*e.g.*, has a "proximal end" and a "distal end")**, wherein the distal end has an outer diameter of 18 French or less** (*e.g.*, "sizes range from 12 FR to 20 FR")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses "[d]eployment catheter 100" comprises an "[o]uter sheath 106 which "axially extend[s]" of sufficient length to extend from "side port means" outside the patient to the deployment site and includes "proximal" and "distal" ends. Leonhardt, 6:36-43, 6:66-67, 8:14-17. The "[o]uter sheath 106 is made of a…flexible material" and has a diameter within the "range from 12 FR to 20 FR." Leonhardt, 6:42-52, 6:55-57. • Fig. 5

Claim Element	Leonhardt in view of Sands
	 FIG. 5 • Figs. 9A  FIG. 9A • 6:42-51 ("***Outer sheath 106 has an axially extending sheath passage 108*** and receives an elongated compression spring push rod 112 within sheath passage 108….***Outer sheath 106 is made of a low friction and flexible material***, preferably PTFE.")

Claim Element	Leonhardt in view of Sands
	• 6:66-67 ("***Outer sheath 106 has a*** side port means 116 near its ***proximal end.***") • 8:14-17 ("Tapered head 156 preferably defines a first annular abutment lip 158 arranged to ***engage the distal end of outer sheath 106*** which prevents tapered head 156 from entering outer sheath 106 passage.") • 6:55-57 ("***The size of outer sheath 106*** depends on the size of valve stent 20 to be implanted. ***Common sizes range from 12 FR to 20 FR***.") • *See* also, 6:35-42, 6:36-38. Drasler ¶¶114-116.
[21.2] a cardiovascular prosthetic implant loaded within the distal end of the catheter body,	**Leonhardt discloses the delivery catheter** (*see* [21.pre]) **comprises a cardiovascular prosthetic implant loaded within the distal end of the catheter body** (*e.g.*, "valve stent 20…[]loaded within the distal end of outer sheath 106")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses "valve stent 20…pre-loaded within the distal end of outer sheath 106" by "sliding outer sheath 106 over the tip [of valve stent 20] and on until valve stent 20 resides within outer sheath 106." • 9:50-55 ("FIGS. 9a-9d illustrate a method of surgically implanting valve stent 20. It is assumed…that an appropriately sized ***valve stent 20 has been selected and pre-loaded within the distal end of outer sheath 106 passage of*** appropriately sized ***deployment catheter 100***.") • Fig. 5

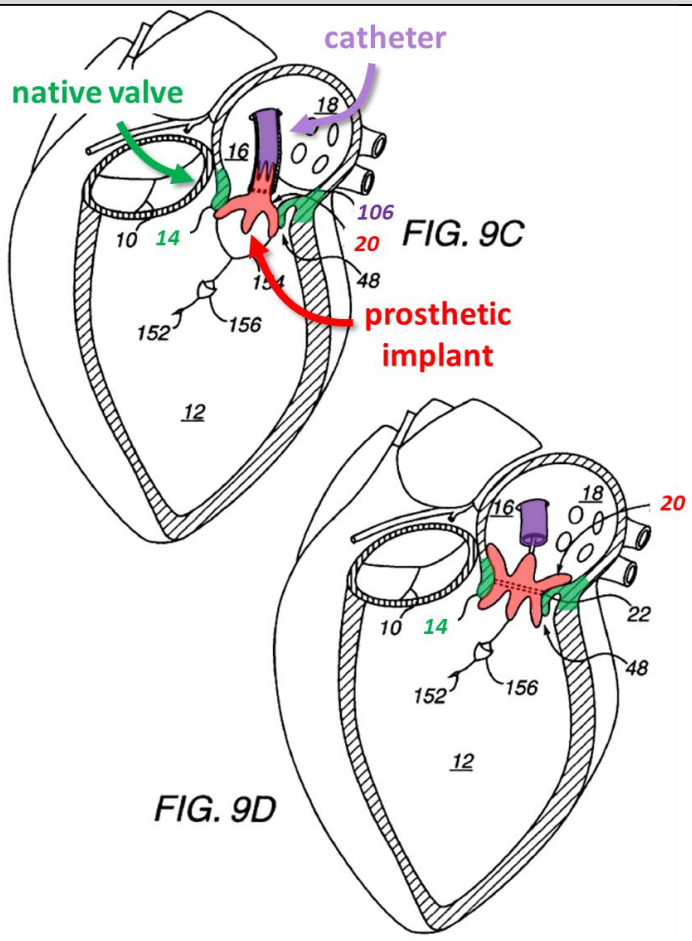
Claim Element	Leonhardt in view of Sands
	 FIG. 5 • 6:55-61 ("…Collapsing distensible fingers 46 of ***valve stent 20*** together forms a conical tip which ***allows for easy loading by sliding outer sheath 106 over the tip and on until valve stent 20 resides within outer sheath 106*** and beyond by approximately five millimeters.") • Fig. 9a  FIG. 9A • 6:13-17, 6:55-57, 7:11-20. Drasler ¶¶117-119.

Claim Element	Leonhardt in view of Sands
[21.3] wherein the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure.	**Leonhardt discloses wherein the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve** (*e.g.*, "valve stent 20, comprised of…stent 26, biological valve 22") **comprising leaflets** (*e.g.*, "leaflets of biological valve 22") **coupled to the support structure** (*e.g.*, "attached to stent 26")**.** ***E.g.*, Leonhardt:** **Leonhardt** discloses "valve stent 20" comprised of "[b]iological valve 22…attached to stent 26" at the "commissural points 68" where the valve's "leaflets" about each other, where "[b]iological valve 22 is preferably a porcine valve." • 4:14-16 ("FIG. 4 shows the preferred embodiment of ***valve stent 20, comprised of three elements***. The three elements are ***stent 26, biological valve 22, and graft material 24***.") • Fig. 4  FIG. 4 • 6:23-31 ("***Biological valve 22 is preferably a porcine valve*** treated and prepared for use in a human…. ***Biological valve 22 is attached to stent 26***, to graft material 24, or both ***with sutures 60 or***

Claim Element	Leonhardt in view of Sands
	biocompatible adhesive or a combination of the two. Biological valve 22 is pre-sized to fit within the internal diameter of cylinder 48 formed by stent 26 attached to graft material 24. ***Attachment is along biological valve's 22 commissural points 68*** and around its base.") • 10:64-67 ("The ***leaflets of biological valve 22*** may be slightly overlapped by expansion balloon 154, but the base of biological valve must be free from contact with expansion balloon 154.") **Sands discloses a natural tissue valve comprising leaflets having a thickness of at least about 0.011 inches** (*e.g.*, "aortic valve[]…heterografts," "[m]ean leaflet thickness measurements" of pig valve heterografts were "0.80 mm and 0.70 mm"—0.0315 inches and 0.0276 inches)**.** ***E.g.*, Sands:** *See* §X.A.3.[21.3] (discussing Sands's teachings). As discussed in §X.B.2, while **Leonhardt** does not disclose the thickness of its porcine heterograft biological valve 22, **Sands** discloses the "[m]ean leaflet thickness" of porcine "aortic valves," including those eligible for "transplantation" into humans, is between "0.80 mm. and 0.70 mm," i.e., between 0.0315 inches and 0.0276 inches. Sands, 407, 408, 410, 412, Fig. 2. *See* X.A.3[21.3]. Drasler ¶¶106-110, 120-124.
[22.pre] A method of deploying a cardiovascular prosthetic implant, the method comprising the steps of:	**Leonhardt discloses a method of deploying a cardiovascular prosthetic implant** (*e.g.*, "replace existing valve[]…in the heart," "method of implanting the artificial valve")**.** ***E.g.*, Leonhardt:** ***See* [21.pre].**

Claim Element	Leonhardt in view of Sands
	• 1:4-8 ("This invention relates to artificial valves, specifically those placed percutaneously by a catheter. ***The artificial valve disclosed may replace existing valves such as are in the heart*** or esophagus, or may be placed where fluid flow needs to be maintained in one direction only.") • Abstract ("A ***method of implanting the artificial valve*** is also disclosed.") • 4:8-10 ("Figs. 9a-9d are a series of elevational views depicting a ***method of deploying the valve stent in the mitral valve position***.") • 3:15-29, 10:53-55. Drasler ¶¶125-127.
[22.1] translumenally advancing a catheter of claim 21 to a position proximate a native valve of a patient; deploying the cardiovascular prosthetic implant within the patient; and removing the catheter from the patient.	**Leonhardt discloses translumenally advancing a catheter of claim 21** (*see* [21]) **to a position proximate a native valve of a patient** (*e.g.*, "advancing the deployment catheter 100", including "outer sheath 106" through the entry site at "femoral artery" to "placement site…in…aortic valve")**; deploying the cardiovascular prosthetic implant within the patient** (*e.g.*, "Deployment of…valve stent 20 is initiated")**; and removing the catheter from the patient** (*e.g.*, "deployment catheter 100 is removed")**.** ***E.g.*, Leonhardt:** ***See* [22.pre], [21].** In addition, **Leonhardt** discloses pushing "deployment catheter 100," including "outer sheath 106," loaded with the valve stent, through "the entry point" at the femoral artery to the "placement site" within the patient, "[d]eploy[ing]……valve stent 20," then removing the catheter from the patient. • 9:64-67 ("If the ***placement site is in the aorta or aortic valve 10, entry may be made through the***

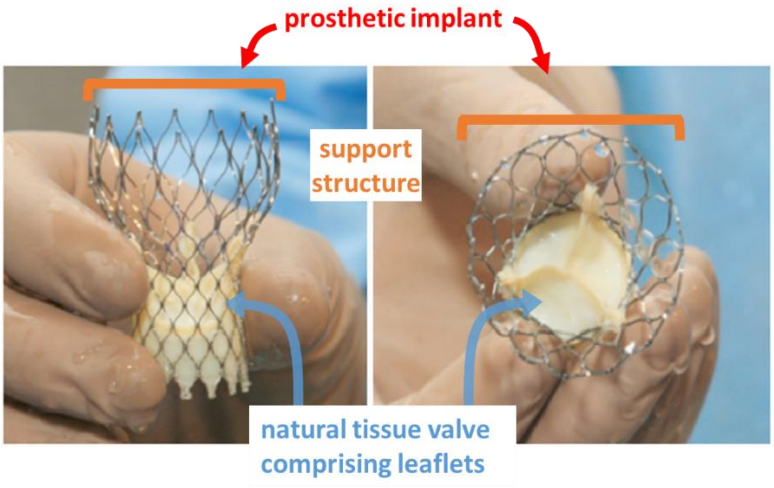
Claim Element	Leonhardt in view of Sands
	largest femoral artery in the groin area and into the aorta.") • 10:3-11 ("A flexible guide wire with a tip balloon 152 is inserted through the same entry point and advanced to immediately above aortic valve 10 or into left ventricle 12. ***Deployment catheter 100***, prefilled with heparinized solution through side port means 116, ***is then inserted through the entry point and into the patient*** by inserting first inner track 124 of inner catheter 110 over the flexible guide wire and ***slowly advancing the deployment catheter 100 to the placement site***.") • 10:48-50 ("Deployment catheter 100 is positioned so ***outer sheath 106 is extending through mitral valve 14*** approximately one (1) centimeter as is seen in FIG. 9a.") • 10:53-11:32 ("***Deployment of the distal end of valve stent 20 is initiated by withdrawing outer sheath 106 approximately 11 to 13 mm while holding push rod 112 stationary***….[¶] Inner catheter 110 is now withdrawn such that it is clear of valve stent 20…. Valve stent 20 is now monitored for proper function and patency.") • 4:8-10 ("Figs. 9a-9d are a series of elevational views depicting a ***method of deploying the valve stent in the mitral valve position***.") • Figs. 9C-9D

Claim Element	Leonhardt in view of Sands
	 • 11:63-12:5 ("Then ***deployment catheter 100 is removed*** leaving the guide wire in place…. Finally, any remaining catheters and the guide wire are removed and the entry site attended by standard procedure.") • 10:44-45, 11:3-24. Drasler ¶¶128-131.

C. Ground 3: Claims 21-22 Are Rendered Obvious by Grube in view of Nguyen

1. Overview of Grube

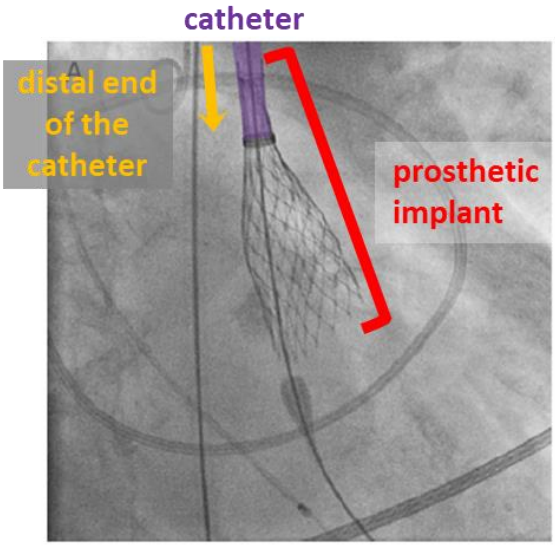
Grube discloses clinical outcomes of percutaneous (through the skin) delivery and implantation of the third generation prosthetic CoreValve device—an earlier version of what PO accuses of infringement in the corresponding litigation. Grube, Abstract, 69-70; Ex. 1032; Drasler ¶¶133, 177-183. In light of PO's allegations, PO cannot dispute that the CoreValve system disclosed in Grube and further described in Nguyen meets the claim limitations. 35 U.S.C. §301; *10x Genomics, Inc. v. Bio-Rad Labs., Inc.*, No. IPR2020-00086, 2020 WL 2026683, at *8 (P.T.A.B. Apr. 27, 2020) (finding statute permits petitioners to "rely[] on a claim construction that it believes is incorrect, namely the claim construction [p]etitioner understands [p]atent [o]wner to rely upon to assert infringement in the related district court action"). The CoreValve system is an "aortic valve prosthesis" delivered endovascularly to the diseased valve in a retrograde approach using a "flexible delivery catheter." Grube, 70. A POSITA would have understood Grube's percutaneous, endovascular catheter-delivery technique to be an example of a minimally invasive technique. Drasler ¶¶132-133. The aortic valve prosthesis is comprised of a "trileaflet bioprosthetic porcine pericardial tissue valve, which is mounted and sutured in a self-expanding nitinol stent," as illustrated in Figure 1.



Grube, 71, Fig. 1. **Grube** is silent as to the thickness of the porcine pericardial tissue used, leaving it to a POSITA to identify other references teaching the thickness. Drasler ¶133. The prosthetic valve is loaded into the distal tip of a delivery catheter with a "profile reduc[ed]" from the second generation 21-F catheter to "the 18-F catheter" to improve procedural outcomes, where "F" refers to French. Grube, 70, 73-74, 76. Drasler ¶134.

Grube further teaches the CoreValve prosthesis and delivery catheter assembly is introduced percutaneously into the patient through the "common iliac artery, the common femoral artery, or the subclavian artery," and endovascularly advanced to the stenosed valve. Grube, 71. The valve is implanted by performing a balloon valvuloplasty (widening the opening of the valve and separating the valve flaps) before device placement "across the native valve position," then deploying the

valve from the delivery catheter (retracting an outer sheath) across the valve under fluoroscopic guidance. Grube, 72.



Grube, 74, Fig. 2A. After implantation, the delivery catheter is then withdrawn from the patient. *Id.* Drasler ¶¶135-136.

2. Overview of Nguyen and Motivation to Apply Its Teachings to Grube

Nguyen, which is assigned to CoreValve, teaches methods of manufacture and use of the CoreValve prosthesis that is also described in **Grube**. *Compare, e.g.*, Grube, Fig. 1, with Nguyen Figs. 6 and 1C; Drasler ¶137. The CoreValve prosthesis comprises an "expandable frame 12 [annotated orange below] having valve body 14 [annotated blue] affixed to its interior surface."

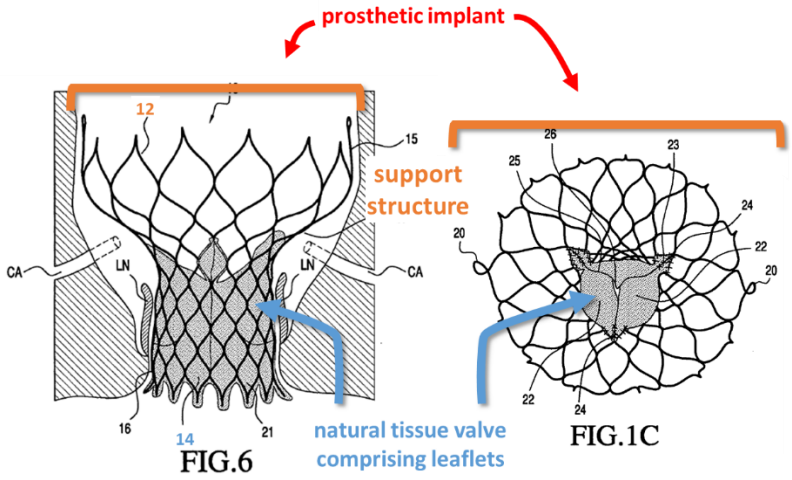


FIG.6 FIG.1C

Nguyen ¶[0039], Figs. 6, 1C; Drasler ¶137. **Nguyen** further discloses the valve body 14 "comprises individual leaflets assembled to a skirt" and is formed from a natural tissue, such as "porcine…pericardium." Nguyen ¶[0039]. The tissue leaflets have a thickness "preferably between 0.012" and 0.014"." Nguyen ¶[0049]. Drasler ¶138.

Grube and **Nguyen** are in the same field as the '708—prosthetic cardiovascular implants—and reasonably pertinent to the alleged problem(s) identified in the '708 of a need for a workable, minimally invasive heart valve deployment system that addresses difficulties relating to partial deployment. '708, Abstract, 1:16-20, 3:39-46; Grube, 70-71, 73-74 (describing 18-F catheter as reducing need for general anesthesia, reducing need for surgical cut-down of entry vessel, and reducing need for hemodynamic support and describing procedure for partial deployment and repositioning after partial deployment), 76; Nguyen

¶¶[0011], [0012] (implanted via minimally invasive techniques), [0015] (compacted to a greater degree than previously known designs); Drasler ¶139.

While **Grube** teaches use of a porcine pericardial tissue valve in a CoreValve device, CoreValve's **Nguyen** reference teaches that such porcine pericardial tissues used to form leaflets in the valve are preferably between 0.012 and 0.014 inches thick, and such a valve can advantageously have a "smaller delivery profile than achievable with previously-known replacement valves." Nguyen ¶¶[0048]-[0049]. A POSITA thus would have been motivated to apply **Nguyen's** teachings of leaflets formed of porcine pericardial tissue preferably between 0.012 and 0.014 inches thick to **Grube**'s porcine pericardial tissue valve to yield the predictable benefit of a functional natural tissue valve deliverable using **Grube**'s reduced profile catheter for at least three independent reasons. Nguyen ¶[0056]; Drasler ¶140.

First, **Nguyen** and **Grube** both describe the CoreValve cardiovascular prosthesis delivery system, as a POSITA would have known by looking at the disclosures in each. Drasler ¶141. Nguyen was filed in 2005, while Grube was published in 2007 and discusses a clinical study conducted after Nguyen was filed. Nguyen, Assignee (CoreValve SA); Grube, 69 ("We sought to determine both the procedural performance and safety of percutaneous implantation of the…third (18-F)-generation CoreValve aortic valve prosthesis…"), 70. Indeed, as shown by the figures in this section and the prior section, the same device is depicted in both

references. *Compare*, *e.g.*, Grube, Fig. 1 (showing a side and top end view photographs of the third generation CoreValve prosthesis), *with* Nguyen, Figs. 6 and 1C (showing side and top views of CoreValve prosthesis, respectively); Drasler ¶142. And the CoreValve system is marked with patents that that issued from Nguyen. *See* Ex. 1009 (CoreValve System instructions) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130021c.pdf), 48 (stating the CoreValve system is "[p]rotected by" U.S. Patent Nos. 7,914,569 (Ex. 1012), which is the patent that issued from the Nguyen publication application, and 8,226,710 (Ex. 1013), which is a continuation of the same application). Accordingly, a POSITA would have understood that the additional description of the thickness of the porcine pericardial tissue used for the prosthetic valve leaflets in **Nguyen** also applies to porcine pericardial tissue used for the prosthetic valve leaflets used in trials in **Grube**. Drasler ¶143.

Second, while **Grube** teaches a delivery catheter with a "profile reduc[ed]" from the second generation 21-French catheter to "the 18-F[rench] catheter" to improve procedural outcomes (Grube, 70, 73-74, 76), **Nguyen** (filed two years earlier) describes the work that underlies the reduction in catheter size to below 20 French. Drasler ¶144. Specifically, **Nguyen's** teachings, which include the use of a porcine pericardium tissue with a thickness of preferably 0.012 to 0.014 inches to form the valve leaflets, advantageously allow for a durable valve that can be "loaded

into a delivery sheath of conventional design, e.g., having a diameter ***of less than 20-24 French***." Nguyen ¶[0065]; Drasler ¶144. **Nguyen** teaches that its valve with leaflets of this size advantageously has a "smaller delivery profile than achievable with previously-known replacement valves." Nguyen ¶¶[0048]-[0049]. A POSITA thus would have been motivated to apply **Nguyen's** advantageous teachings of the use of valve leaflets of this thickness in forming the valve leaflets used in **Grube** with an 18-French catheter.

Third, given that there is a design need to use a natural tissue valve with leaflets (under PO's construction) as recognized in **Grube** and **Nguyen**, and given that there are a "finite number" of solutions for such leaflets, it would have been obvious to try a natural tissue valve with pericardial tissue leaflets having a thickness greater than 0.011" given that these were known to work in the art for catheters smaller than 20 French as taught in **Nguyen**. MPEP 2144.05 §II; *KSR*, 550 U.S. at 421; Drasler ¶¶145. Indeed, it was well-known in the art that a limited number of tissue options were available and used interchangeably, and natural pericardial tissue offers many well-known advantages, including being durable, flexible, and readily available. U.S. Patent Nos. 5,961,549 (Ex. 1014), 1:28-39; 7,025,780 (Ex. 1015, "Gabbay"), 3:38-42, 7:4-7; 5,713,950 (Ex. 1016, "Cox"), 4:35-50; Cribier (Ex. 1041), 1; Drasler ¶145; *see also* Ex. 1054.

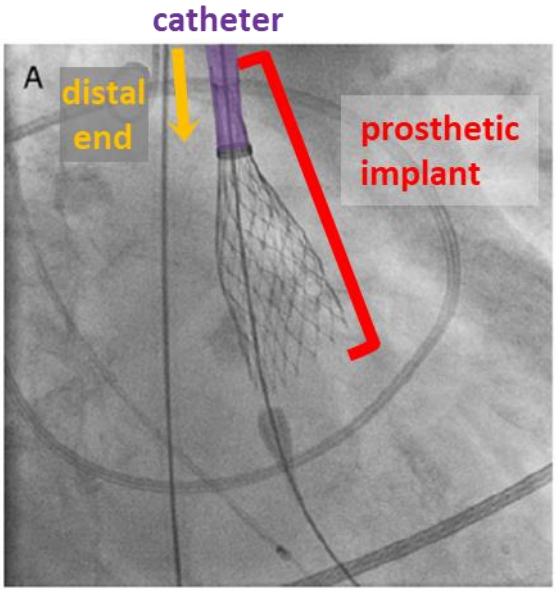
In light of these same disclosures, a POSITA would have had a reasonable expectation of success and would have understood that applying **Nguyen's** detailed teachings of CoreValve porcine pericardial leaflets having a thickness between 0.012″ and 0.014″ to the CoreValve leaflets of **Grube**'s trileaflet prosthetic aortic valve to yield the predictable benefit of a functional natural tissue valve deliverable using **Grube**'s reduced profile catheter. Indeed, the thickness of pericardial tissue was well-known and a POSITA would have found it obvious and straightforward to implement a pericardial tissue valve comprising leaflets having a thickness of at least 0.011 inches. Drasler ¶145; *see also, e.g.,* Simionescu, D. "Mapping of Glutaraldehyde-treated Bovine Pericardium and Tissue Selection for Bioprosthetic Heart Valves," *Journal of Biomedical Materials Research* Vol. 27, 1993 (Ex. 1030), 700 ("All [bovine] pericardia examined exhibited similar patterns with slight variations…. Mean overall thickness was 0.42 mm [0.017 inches] ± 0.12 mm, for n = 1500."), Fig. 5, Table I; Cribier, 1.

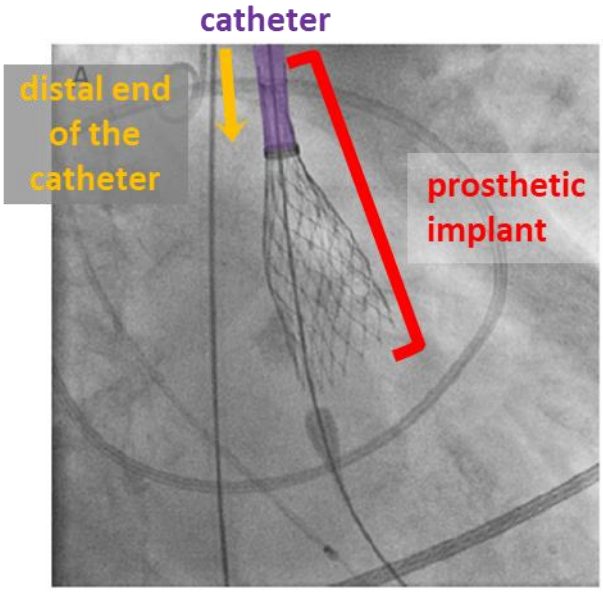
3. Claim Chart

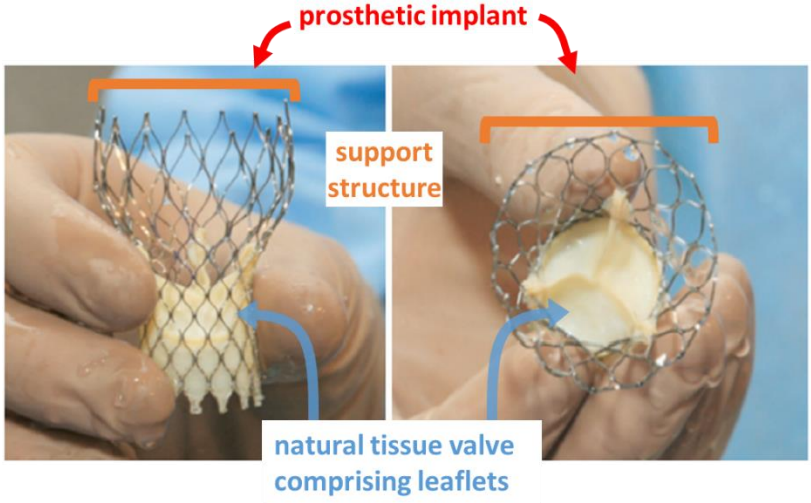
Claim Element	Grube in view of Nguyen
[21.pre] A delivery catheter for deploying a cardiovascular prosthetic implant using a minimally invasive procedure, wherein the	**Grube discloses a delivery catheter** (e.g., "delivery catheter") **for deploying a cardiovascular prosthetic implant using a minimally invasive procedure** (e.g., "percutaneous implantation of the CoreValve prosthesis")**.** ***E.g.*, Grube:** **Grube** discloses a delivery catheter for implanting a "CoreValve aortic valve prosthesis" "using

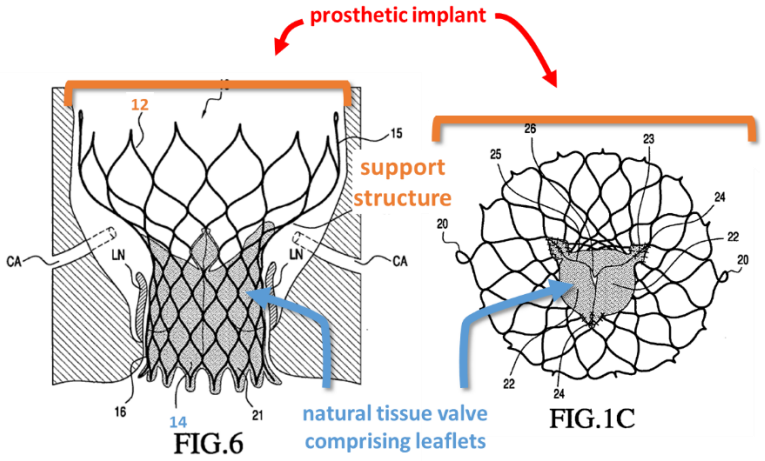
Claim Element	Grube in view of Nguyen
delivery catheter comprises:	a…percutaneous transvascular [i.e., through the lumen of a blood vessel] approach." • **69** ("Treatment of severe aortic valve stenosis in high-risk patients with ***percutaneous implantation of the CoreValve prosthesis*** is feasible and associated with a lower mortality rate than predicted by risk algorithms.") • **70** ("Figure 1 CoreValve Prosthesis [¶] Third generation of ***the CoreValve prosthesis (18-F) before loading into the delivery catheter***.") • **70** ("Our objective was to evaluate the feasibility, safety, and clinical outcome of ***implantation*** of the 21-F and 18-F self-expanding ***CoreValve aortic valve prosthesis*** in high-risk patients with aortic valve disease (stenosis with or without regurgitation) ***using a retrograde percutaneous transvascular approach***.") • **70** ("A less-invasive procedure…[¶]… improved the procedural outcome (12).") • *See also* **72.** Drasler ¶¶146-148.
[21.1] an elongate, flexible catheter body having a proximal end and a distal end, wherein the distal end has an outer diameter of 18 French or less; and	**Grube discloses the delivery catheter** (*see* [21.pre]) **comprises an elongate flexible catheter body having a proximal end and a distal end** (e.g., "delivery catheter" which has a proximal end and a distal end and is configured for "percutaneous transvascular" delivery)**, wherein the distal end has an outer diameter of 18 French or less** (e.g., "device profile reduction to the 18-F catheter")**.** ***E.g.*, Grube**: **Grube** discloses the delivery catheter has a "reduc[ed]" device profile of "18-F," a length and flexibility sufficient to reach from the "common femoral artery" to "the native

Claim Element	Grube in view of Nguyen
	valve position," and is configured for "percutaneous transvascular" delivery of the CoreValve prosthesis. • **70** ("Our objective was to evaluate the feasibility, safety, and clinical outcome of implantation of the 21-F and 18-F self-expanding CoreValve aortic valve prosthesis…using ***a retrograde percutaneous transvascular approach***. …CoreValve prosthesis (18-F) before loading into the ***delivery catheter.***") • **73-74** ("With the use of the ***smaller 18-F sheath*** significant improvements with respect to procedural data were achieved…") • **70** ("F = French") • **76** ("Although the CoreValve technique is still in its infancy, device modifications and procedural advances are proceeding. The ***device profile reduction to the 18-F catheter resulted in remarkable procedural improvements without different safety outcomes***.") • **71** ("***Vascular access was obtained*** either with or without standard surgical cutdown of the common iliac artery, ***the common femoral artery***, or the subclavian artery.") • **72** ("If used, extracorporal circulatory support was activated just before ***device placement across the native valve position***…") • **Fig. 2A**

Claim Element	Grube in view of Nguyen
	 Drasler ¶¶149-151.
[21.2] a cardiovascular prosthetic implant loaded within the distal end of the catheter body,	**Grube discloses the delivery catheter** (*see* [21.pre]) **comprises a cardiovascular prosthetic implant** (e.g., "aortic valve prosthesis") **loaded within the distal end of the catheter body** (e.g., "loading into the delivery catheter" at the distal end of the catheter). ***E.g.*, Grube:** **Grube** discloses the CoreValve is an "aortic valve prosthesis" that is "load[ed] into the delivery catheter['s]" distal end such that when the user "deploy[s] the distal two thirds of the prosthesis," the prosthesis's distal end protrudes from the catheter's distal end. • **70** ("Our objective was to evaluate the feasibility, safety, and clinical outcome of implantation of the 21-F and 18-F self-expanding CoreValve ***aortic valve prosthesis***...") • **70** ("Figure 1 CoreValve Prosthesis [¶] Third generation of the CoreValve prosthesis (18-F) ***before loading into the delivery catheter***.")

Claim Element	Grube in view of Nguyen
	• **74** ("This modified deployment technique…has been introduced during the study course. Having ***deployed the distal two-thirds*** of the prosthesis (Fig. 2), the valve is already sufficiently functioning, whereas the device position can still be adjusted or the device can be pulled back completely.") • **Fig. 2A**  Drasler ¶¶152-154.
[21.3] wherein the cardiovascular prosthetic implant comprises a support structure and a natural tissue valve comprising a leaflets having a thickness of at least about 0.011 inches coupled to the support structure.	Under PO's construction (see §IX.C), **Grube discloses the cardiovascular prosthetic implant comprises a support structure** (e.g., "a self-expanding nitinol stent") **and a natural tissue valve** (e.g., "trileaflet bioprosthetic porcine pericardial tissue valve") **comprising leaflets** (e.g., "trileaflet") **coupled to the support structure** (e.g., "mounted and sutured in a self-expanding nitinol stent")**.** ***E.g.*, Grube:** **Grube** discloses the CoreValve prosthesis comprises a "trileaflet bioprosthetic porcine pericardial tissue valve…mounted and sutured in a self-expanding nitinol stent."

Claim Element	Grube in view of Nguyen
	• **71** ("The CoreValve aortic valve prosthesis consists of a ***trileaflet bioprosthetic porcine pericardial tissue valve***, which is mounted and sutured in ***a self-expanding nitinol stent*** (Fig. 1).") • **Fig. 1**  • *See also* 70. Under PO's construction (see §IX.C), **Nguyen discloses a natural tissue valve comprising leaflets having a thickness of at least about 0.011 inches** (e.g., "[v]alve prosthesis 10 comprises…individual leaflets …formed from a natural…material" "leaflets 22 have a thickness…preferably between 0.012" and 0.014".")**.** ***E.g.*, Nguyen:** **Nguyen** discloses a "valve prosthesis 10…compris[ing] individual leaflets" having "a thickness of…preferably between 0.012" and 0.014"." As discussed in §X.C.2, a POSITA would have been motivated to apply **Nguyen**'s teaching of leaflets preferably between 0.012 and 0.014 inches thick to **Grube**'s pericardial tissue valve leaflets, which both describe the CoreValve design, to yield the predictable benefit of functional leaflets forming a "highly durable

Claim Element	Grube in view of Nguyen
	valve body" that can fit inside an 18 French catheter. *See* Nguyen ¶[0056]. • **[0023]** ("The ***valve body skirt and leaflets preferably are constructed of porcine, bovine, equine*** or other mammalian tissue, such as ***pericardial tissue***, and are sewn, welded, molded or glued together so as to efficiently distribute forces along the leaflets and to the frame.") • **[0039]** ("***Valve prosthesis 10 comprises expandable frame 12 having valve body 14 affixed to its interior surface***, e.g., by sutures….Valve body 14 preferably ***comprises individual leaflets assembled to a skirt***, where all of the ***components are formed from a natural*** or man-made ***material***. Preferred materials for valve body 14 include ***mammalian tissue***, such as porcine, equine or bovine pericardium, or a synthetic or polymeric material.") • **[0049]** ("In a preferred embodiment, skirt 21 and ***leaflets 22 have a thickness of*** between 0.008" and 0.016", and ***more preferably between 0.012" and 0.014"***.") • **Figs. 6 and 1C**  FIG.6 FIG.1C Drasler ¶¶139-145, 155-160.

Claim Element	Grube in view of Nguyen
[22.pre] A method of deploying a cardiovascular prosthetic implant, the method comprising the steps of:	**Grube discloses a method of deploying a cardiovascular prosthetic implant** (e.g., "percutaneous implantation of the CoreValve prosthesis")**.** ***E.g.*, Grube:** ***See* [21.pre].** • **69** ("Treatment of severe aortic valve stenosis in high-risk patients with ***percutaneous implantation of the CoreValve prosthesis*** is feasible and associated with a lower mortality rate than predicted by risk algorithms.") • **74** ("This research comprises the largest population ***treated with a percutaneous valve replacement system*** for treatment of degenerative, severe, symptomatic aortic stenosis.") • 69, 70, 74-76. Drasler ¶¶161-163.
[22.1] translumenally advancing a catheter of claim 21 to a position proximate a native valve of a patient; deploying the cardiovascular prosthetic implant within the patient; and removing the catheter from the patient.	**Grube discloses translumenally advancing a catheter of claim 21** (*see* [21]) **to a position proximate a native valve of a patient** (*e.g.*, "implantation…using a retrograde percutaneous transvascular approach" via "delivery catheter" for "device placement across the native valve position")**; deploying the cardiovascular prosthetic implant within the patient** (e.g., "device was deployed")**; and removing the catheter from the patient** (*e.g.*, "withdrawal of the delivery catheter")**.** ***E.g.*, Grube:** **Grube** discloses implanting the prosthetic valve "transvascular[ly]," by inserting the delivery catheter into a "vascular access" (e.g., "the common femoral artery") pushing it through the vasculature to the placement site, "deploy[ing]" the valve "across the native valve," and subsequently "withdraw[ing]…the delivery catheter" from the patient.

Claim Element	Grube in view of Nguyen
	• **70** ("Our objective was to evaluate the feasibility, safety, and clinical outcome of ***implantation of the*** 21-F and 18-F self-expanding ***CoreValve aortic valve prosthesis*** in high-risk patients with aortic valve disease (stenosis with or without regurgitation) ***using a retrograde percutaneous transvascular approach***.") • **71** ("***Vascular access was obtained*** either with or without standard surgical cutdown of the common iliac artery, ***the common femoral artery***, or the subclavian artery.") • **72** ("Balloon valvuloplasty…was performed before device placement, after which over a stiff guidewire, placed in the left ventricle, the ***device was deployed retrogradely*** under fluoroscopic guidance. If used, extracorporal circulatory support was activated just before ***device placement across the native valve position*** and terminated immediately after ***withdrawal of the delivery catheter*** and confirmation of adequate valve function.") Drasler ¶¶164-166.

D. Ground 4: Claims 21-22 Are Rendered Obvious by Salahieh in view of Nguyen

As discussed in §X.A.1, §X.A.3, and §§X.C.2-3, **Salahieh** discloses a system for "endovascularly replacing a patient's heart valve" with a prosthetic "porcine valve leaflets or bovine or equine…pericardium tissue[]" heart valve disposed within a delivery catheter while **Nguyen** discloses methods of manufacture of a prosthetic pericardial cardiovascular valve that is implantable via minimally invasive

techniques. *E.g.*, Salahieh, 3:21-26, 6:29-36; Nguyen ¶¶[0012], [0023], , [0041], [0045]; Drasler ¶¶167-169.

Salahieh and **Nguyen** are in the same field as the '708—prosthetic cardiovascular implants—and reasonably pertinent to the alleged problem(s) identified in the '708 as discussed in §§X.A.2, X.C.2. Drasler ¶170.

Salahieh in view of Nguyen renders obvious claims 21-22. As discussed in §X.A.3, **Salahieh** discloses every limitation of claims 21-22 with the exception of the requirement in [21.3] of a natural tissue valve comprising leaflets having a thickness of at least about 0.011 inches. *See* §X.A.3. Nguyen discloses this limitation under PO's construction (see §IX.C).

[21.3]: While **Salahieh** teaches use of a porcine, bovine or equine pericardial tissue valve (§X.A.3.[21.3], **Nguyen** teaches the additional detail that such porcine, bovine and equine pericardial tissues used to form leaflets in the valve are preferably between 0.012 and 0.014 inches thick in order to create an advantageously "smaller delivery profile than achievable with previously-known replacement valves." Nguyen ¶¶[0048]-[0049]. A POSITA thus would have been motivated to apply **Nguyen's** teachings of leaflets formed of porcine pericardial tissue preferably between 0.012 and 0.014 inches thick to **Salahieh's** replacement heart valve "from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues" to advantageously use a workable leaflet construction known for yielding a valve

that compacts to a great degree in Salahieh's smaller gauge catheter for at least three independent reasons. Nguyen ¶¶[0015], [0056]; Salahieh, 6:50-55; Drasler ¶171.

First, Nguyen provides additional detail for the thickness of the porcine, bovine or equine pericardial tissue (a biologic tissue) in **Salahieh**'s porcine, bovine or equine natural tissue valve. Salahieh, 6:29-31, 6:51-55. **Nguyen's** teachings, which include the use of a bovine, equine or porcine pericardium tissue with a thickness of preferably 0.012 to 0.014 inches to form the valve leaflets, advantageously allow for a durable valve that can be "loaded into a delivery sheath of conventional design, e.g., having a diameter ***of less than 20-24 French***." Nguyen ¶[0065]; Drasler ¶172.

Second, **Nguyen** teaches that its valve with leaflets of this size advantageously has a "smaller delivery profile than achievable with previously-known replacement valves." Nguyen ¶¶[0048]-[0049]. A POSITA thus would have been motivated to apply **Nguyen's** advantageous teachings of the use of valve leaflets of this thickness in forming the valve leaflets used in **Salahieh** with an 18-French catheter. Drasler ¶173.

Third, given that there is a design need to use a porcine, bovine, or equine natural tissue valve with leaflets as recognized in **Salahieh** and **Nguyen**, and given that there are a "finite number" of solutions for such leaflets, it would have been obvious to try a natural tissue valve with leaflets greater than 0.011" given that these

were known to work in the art for catheters smaller than 20 French (*i.e.*, 18 French or less) as taught in **Nguyen**. MPEP 2144.05 §II; *KSR*, 550 U.S. at 421; Drasler ¶174. Indeed, it was well-known in the art that a limited number of tissue options were available and used interchangeably, and natural pericardial tissue offers many advantages, including being durable, flexible, and readily available. U.S. Patent No. 5,961,549 (Ex. 1014, issued 10/5/1999), 1:28-39; Gabbay 3:38-42, 7:4-7; Cox, 4:35-50; Cribier, 1; Drasler ¶174.

In light of these same disclosures, a POSITA would have had a reasonable expectation of success and would have understood that applying **Nguyen's** detailed teachings of porcine, bovine, or equine pericardial leaflets having a thickness between 0.012″ and 0.014″ to the leaflets of **Salahieh's** porcine, bovine, or equine prosthetic pericardial tissue valve to yield the predictable benefit of a functional natural tissue valve deliverable using **Salahieh's** reduced profile catheter. Simionescu, 700 ("***All [bovine] pericardia examined*** exhibited similar patterns with slight variations…. ***Mean overall thickness was 0.42 mm [0.017 inches]*** ± 0.12 mm, for *n* = 1500."), Fig. 5, Table I; Cribier, 1; Drasler ¶175.

XI. SECONDARY CONSIDERATIONS

There is no evidence in the prosecution history of the '708 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* '708FH; Drasler ¶176. Indeed, as demonstrated by the prior art referenced herein, any purported solutions to problems or unexpected results in the '708 were already well known. Drasler ¶176. 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 '708's Claims, which are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioners will prevail as to claims 21-22. *Inter partes* review of claims 21-22 is accordingly requested.

Dated: January 20, 2021

Respectfully submitted,

/James L. Davis, Jr./
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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 13,973 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.
Reg. No. 57,325

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 '708 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

By: /Crena Pacheco/
Name: Crena Pacheco
ROPES & GRAY LLP