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Filed on behalf of: Medtronic, Inc.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.,
Petitioner

v.

NIAZI LICENSING CORPORATION
Patent Owner

U.S. Patent No. 6,638,268

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,638,268

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1021	Renato Ricci et al., *Cardiac Resynchronization: Materials, Technique and Results. The InSync Registry*, 2 Eur. Heart J. (SUPPLEMENT J) J6, J6-J15 (2000) ("*Ricci*")
1022	Helmut Pürerfellner et al., *Transvenous Left Ventricular Lead Implantation with the EASYTRAK Lead System: The European Experience*, 86 The Am. J. of Cardiology 157K, 157K-64K (2000) ("*Pürerfellner*")

I. INTRODUCTION

Medtronic, Inc. ("Petitioner") requests *inter partes* review of claims 1-3, 6, 7, 10-14, 18, 19, and 23-26 ("the challenged claims") of U.S. Patent No. 6,638,268 ("the '268 patent") (Ex. 1001), which, according to PTO records, is assigned to Niazi Licensing Corporation ("Patent Owner") (Ex. 1004). The '268 patent relates to catheters used to introduce devices, such as pacing leads, into the vasculature of the heart. (*See, e.g.*, Ex. 1001, 1:8-9, 2:17-55.) The challenged claims recite a "double catheter" and methods for placing an electrical lead in a lateral branch of a coronary sinus vein using a "double catheter." (*See, e.g., id.*, 6:62-7:15, 7:63-8:9.) The claimed subject matter, however, was not new at the time of the '268 patent. Indeed, the claimed subject matter was known in and obvious in view of the prior art.

As the '268 patent acknowledges and the prior art cited herein demonstrates, the medical procedure of placing a lead in a lateral branch of a coronary sinus vein to pace the left ventricle of the heart was known by those skilled in the art. (*Id.*, 1:56-59; Ex. 1019, Abstract.) Shaped catheters designed for use in the coronary sinus were also known in the art before the earliest filing date of the '268 patent. (Ex. 1001, 1:41-43; *see also* Exs. 1017, 1018.) In fact, the technique of telescoping a smaller inner catheter through an outer catheter for accessing portions of the cardiac vasculature, was disclosed in the prior art and used for lead

placement in a coronary sinus vein. (*See* Ex. 1019, 2:41-44, 3:22-38.) For these reasons and those below, this petition shows that there is a reasonable likelihood that Petitioner will prevail with respect to and establish the unpatentability of the challenged claims by a preponderance of evidence. Trial should be instituted and the challenged claims should be cancelled.

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

Real Party-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner identifies Medtronic, Inc. as the real party-in-interest. Medtronic plc is the ultimate parent of Medtronic, Inc.

Related Matters: Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following related matters. The '268 patent is being asserted in the following pending litigations in the District of Minnesota: *Niazi Licensing Corp. v. Medtronic, Inc.*, No. 0-17-cv-05095; *Niazi Licensing Corp. v. Boston Scientific Corp.*, No. 0-17-cv-05094; and *Niazi Licensing Corp. v. St. Jude Medical S.C., Inc.*, No. 0-17-05096. The '268 patent was previously asserted in two cases that were dismissed: *Niazi, Imran v. Merit Medical Systems, Inc.*, No. 3-16-cv-00668 (W.D. Wis.); *Niazi, Imran v. Pressure Products Medical Supplies, Inc.*, No. 3-16-cv-00670 (W.D. Wis.). The '268 patent was also asserted in the following cases in the Western District of Wisconsin, which were dismissed without prejudice on November 7, 2017: *Niazi, Imran v. Medtronic, Inc.*, No. No. 3-17-cv-00283; *Niazi,*

Imran v. St. Jude Medical S.C., Inc., No. 3-16-cv-00183; *Niazi, Imran v. Boston Scientific Corp.*, No. 3-16-cv-00184; and *Niazi, Imran v. Biotronik, Inc.*, No. 3-17-cv-00185.

Petitioner is also concurrently filing another petition for IPR of the '268 patent that includes a challenge to the priority date of the '268 patent.

Counsel and Service Information: Lead counsel is Naveen Modi (Reg. No. 46,224). Paromita Chatterjee (Reg. No. 63,721) is back-up counsel. The mailing address for all correspondence is Paul Hastings LLP, 875 15th St. N.W., Washington, D.C., 20005 (Telephone: 202.551.1700/Fax: 202.551.1705). Petitioner consents to electronic service of documents at PH-Medtronic-Niazi-IPR@paulhastings.com.

III. PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15 AND 42.103

Petitioner submits the required fees with this petition. Please charge any additional fees required for this proceeding to Deposit Account No. 50-2613.

IV. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '268 patent is available for *inter partes* review, and that Petitioner is not barred or estopped from requesting such review of the '268 patent on the grounds identified.

V. PRECISE RELIEF REQUESTED AND GROUNDS RAISED

Petitioner respectfully requests review of claims 1, 10-14, 18, 19, and 23-26 of the '268 patent and cancellation of these claims as unpatentable in view of the following grounds[1]:

- **Ground 1**: Claim 11 is unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,935,160 to Auricchio et al. ("*Auricchio*") (Ex. 1019);
- **Ground 2**: Claims 12 and 24 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Auricchio* and U.S. Patent No. 5,775,327 to Randolph et al. ("*Randolph*") (Ex. 1017);
- **Ground 3**: Claims 13, 14, 18, 19, 23, 25, and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Auricchio*, *Randolph*, and International Publication No. WO 99/49773 to Payne et al. ("*Payne*") (Ex. 1009);

[1] Petitioner does not rely on any prior art reference other than those listed here for purposes of the listed grounds. Other prior art references discussed herein are provided to show the state of the art at the time of the alleged invention. *See*, *e.g.*, *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015).

- **Ground 4**: Claims 1 and 10 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,277,107 to Lurie et al. ("*Lurie*") (Ex. 1018) and U.S. Patent No. 5,833,673 to Ockuly to ("*Ockuly*") (Ex. 1020); and
- **Ground 5**: Claims 1 and 10 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Lurie*, *Ockuly*, and Blanc et al, titled "A Method for Permanent Transvenous Left Ventricular Pacing," PACE, vol. 21, part I (1998) ("*Blanc*") (Ex. 1015).

VI. BACKGROUND

The '268 patent was filed as U.S. Application No. 09/828,502 ("the non-provisional application") on April 6, 2001. (Ex. 1001.) It issued on October 28, 2003, and purportedly claims priority to U.S. Provisional Application No. 60/195,701 ("the provisional application") (Ex. 1002), filed on April 7, 2000. (Ex. 1001, 1:4-5.)

A. Overview of the Technology

A typical human heart includes four chambers: a right ventricle, a right atrium, a left ventricle, and a left atrium. (Ex. 1005, ¶16.) Blood from the body enters the right atrium though the vena cava and flows into the right ventricle where it is pumped to the lungs through the pulmonary artery. (*Id*.) Oxygenated blood returns from the lungs to the left atrium of the heart via the pulmonary veins

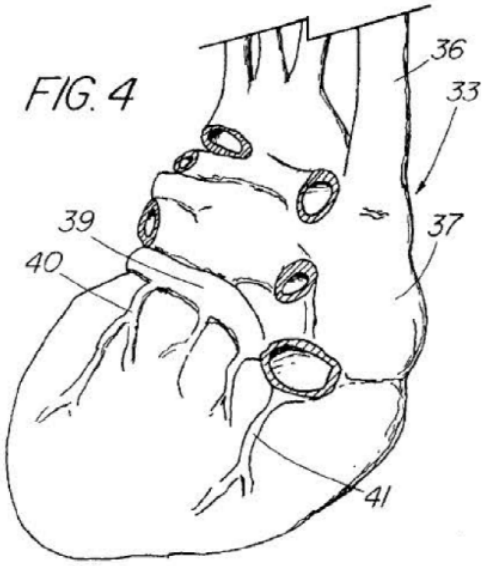
and then flows into the left ventricle where it is pumped to the organs and tissues of the body. (*Id*.) In a normal heart, the atria and ventricles work together in synchrony, alternately contracting and relaxing, to circulate blood throughout the heart, with the atria contracting in synchrony and the ventricles contracting in synchrony. (*Id*., ¶17)

Heart failure occurs due to a structural or functional cardiac disorder that impairs the ability of a ventricle to fill with or eject blood commensurate with the needs of the body. (Ex. 1005, ¶18.) When the heart does not circulate blood normally, it can lead to the build-up of fluid in the lungs and the body tissue which is commonly referred to as "congestive heart failure." (*Id*.) Congestive heart failure can occur, for example, when the ventricles do not contract effectively. (*Id*.)

At the time of the alleged invention, left ventricular and biventricular pacing were being used to treat patients with congestive heart failure that exhibited asynchronous contraction of the left ventricle. (*See* Ex. 1001, 1:50-55; Ex. 1005, ¶19.) This treatment is now referred to as cardiac resynchronization therapy (CRT). (Ex. 1005, ¶19.) Biventricular pacing is typically administered via an implantable device, such as a pacemaker, having leads for pacing the walls of the left ventricle from the right and left ventricles. (*Id*.) These leads deliver pacing stimuli to restore synchrony of left ventricular contraction. (*Id.*)

The historical approach to pacing the left ventricle was to attach a pacing electrode directly to the outer surface of the heart over the left ventricle in a major surgical procedure. (Ex. 1013, 138D-139D.) By the late 1990s, transvenous left ventricular (LV) pacing leads were developed to be placed in contact with the left ventricle without requiring major thoracic surgery. (*See id.*, 139D.) These leads were designed to be inserted into the vasculature on the surface of the left ventricle. (*Id.*) To accomplish this, the leads were introduced through the vasculature (the subclavian vein, for example) into the right atrium, from there into the coronary sinus, and finally positioned within a branch vein in a position where they could stimulate the free wall of the left ventricle. (*Id.*; Ex. 1005, ¶20, fn.3.)

A schematic representation of the anatomy of the coronary sinus and its venous branches from U.S. Patent No. 6,502,049 to Norlander et al. ("*Norlander*") is included below:



(Ex. 1007, FIG. 4.) The coronary sinus ostium (or orifice) is accessible from the right atrium of the heart. (Ex. 1005, ¶21.) The coronary sinus (39) travels over the posterior surface of the heart and has branches (40, 41) extending along the free wall of the left ventricle. (*Id*.) The illustration above shows two branches of the coronary sinus (39): the middle cardiac vein (41) and the posterior vein (40). (Ex. 1007, 7:33-35.) A distal portion[2] of the coronary sinus merges into the great cardiac vein. (Ex. 1005, ¶21.) Antero-lateral, lateral, and postero-lateral veins are also frequently found; however, the size, number, and location of these veins vary between patients. (*Id*.) At the time of the alleged invention, it was known that the appropriate branch veins for LV lead placement included branches that extended along and drain the lateral portion of the free wall ("lateral wall of the left ventricle"), as well as branches of the middle cardiac vein and the great cardiac vein that extended to the lateral wall of the left ventricle. (Ex. 1005, ¶22; Ex. 1014, 406.)

Physicians initially implanted leads without the use of any catheter delivery system. (Ex. 1005, ¶23; Ex. 1013, 139D.) By the late 1990s, however, it was

[2] The orientation of the coronary sinus is defined in the '268 patent with a proximal end of the coronary sinus located in the right atrium. (Ex. 1001, 4:46-49.)

common for physicians to use a catheter[3] to access the coronary sinus, including for lead implantation. (Ex. 1005, ¶24; Ex. 1014, 406.) Shaped catheters or "steerable" catheters (*i.e.*, catheters incorporating steering components) were often used to locate the coronary sinus. (Ex. 1005, ¶24 Exs. 1012, 1016-1018.) A common catheter design incorporated a hook or J-shaped primary curve to direct a distal end of the catheter toward the coronary sinus ostium. (Ex. 1005, ¶24; Exs. 1012, 1016-1018.) Shaped catheters were already widely used in other procedures in the heart, and some physicians used these well-known, shaped catheters to access the coronary sinus. (Ex. 1005, ¶24; Ex. 1021, J7.)

By the time of the alleged invention, pacing leads specifically designed for the coronary sinus had been developed, including open lumen leads that tracked over a guide wire. (Ex. 1005, ¶24; Ex. 1013, 139D-42D.) Physicians used various techniques to implant the available leads.[4] (Ex. 1005, ¶25.) In one known

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[3] A PHOSITA would have known that terms "catheter," "introducer," and "sheath," as used in the prior art are synonymous and generally refer to a flexible tube inserted through a body cavity to a location that is otherwise inaccessible without more invasive procedures. (Ex. 1005, fn.5.)

[4] The following discussion of techniques used by physicians in the prior art and known to a PHOSITA is intended to be exemplary and is not an exhaustive list of

technique, a guide wire was used to locate the coronary sinus ostium and then a shaped guiding catheter designed for the coronary sinus was introduced over the guide wire into the coronary sinus. (Ex. 1005, ¶26; Ex. 1013, 140D-141D.) If a physician had trouble accessing the coronary sinus, it was known that they might then insert an inner member (*e.g.*, a stiff guide wire, dilator, obturator, balloon catheter, or a "steerable" catheter, etc.) into the catheter in order to assist with locating and entering the coronary sinus. (Ex. 1005, ¶26; Ex. 1021, J7; Ex. 1022, 158K.) Once the outer catheter was positioned within the coronary sinus, the inner member might be removed and the anatomy of the coronary sinus would then be visualized by injecting contrast media through the lumen of the catheter under fluoroscopy, with the assistance of a blocking balloon catheter, to obtain a venogram and thereby visualize the surrounding vasculature. (Ex. 1005, ¶26; Ex. 1013, 139D.) After the venogram was used to select a target vein for lead placement, the same or a smaller diameter guide wire was used to position the lead in the target vein. (Ex. 1005, ¶26; Ex. 1022, 158K.) If an over-the-wire lead was used, the lead was either preloaded with the guide wire or advanced over the guide

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the techniques practiced which varied among physicians and reflected the tools available and the techniques known for accessing different parts of the heart. (Ex. 1005, ¶25.)

wire into the target vein. (Ex. 1005, ¶26; Ex. 1022, 158K.) If the tortuous anatomy of the vein made it difficult to advance the lead into the vein using only a guide wire for support, a small diameter catheter might then have been used to direct delivery of the guide wire and/or the lead. (Ex. 1005, ¶26; Ex. 1019, 3:22-32.)

By the time of the alleged invention, telescoping catheter systems consisting of outer and inner catheters were being used to "provide quicker and easier placement of a pacing lead or other device through a complex tortuous path to a remote anatomical location." (Ex. 1007, 2:8-11; *see also* Ex. 1019, 2:41-44, 8:49-52.) These delivery systems were advantageous as they allowed the outer catheter to enter the coronary sinus and then allowed an inner, telescoping catheter to advance through the distal end of the outer catheter "to access a second target site which usually comprises a duct or vessel with a smaller diameter than the first target site and which could not be safely accessed by the larger outer introducer sheath." (*Id.*, 5:32-38.) Indeed, this approach was well-known at the time of the alleged invention and used for accessing and delivering devices to other parts of the heart. (*See, e.g.*, Exs. 1009, 1020; Ex. 1005, ¶27.)

B. Overview of the '268 Patent

The '268 patent specification is directed to catheters used to introduce devices, such as pacing leads, into the vasculature of the heart. (*See, e.g.*, Ex. 1001, 1:8-9, 2:12-14, 2:17-55; Ex. 1005, ¶28.)

A first embodiment, shown in FIGS. 1 and 2 below, is directed to a double catheter 10 that includes an outer catheter 11 and an inner catheter 12. (Ex. 1001, 2:62-63, 3:9-10.) Outer catheter 11 is "made from a braided silastic or similar material" and has "sufficient shape memory to return to its original shape when undistorted." (*Id.*, 3:10-12, 4:21-23.) Inner catheter 12, which is "constructed of a more pliable, soft material," is slidably disposed within outer catheter 11 and can be advanced outer of outer catheter 11 to increase the length of double catheter 10. (*Id.*, 3:12-14, 3:22-26, 3:14-17; Ex. 1005, ¶29.)

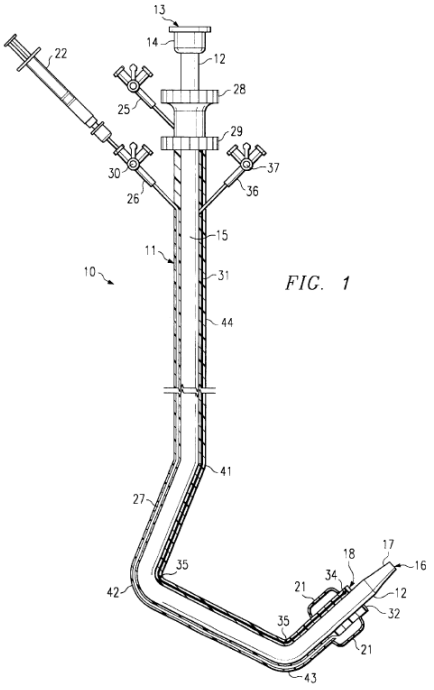

FIG. 1

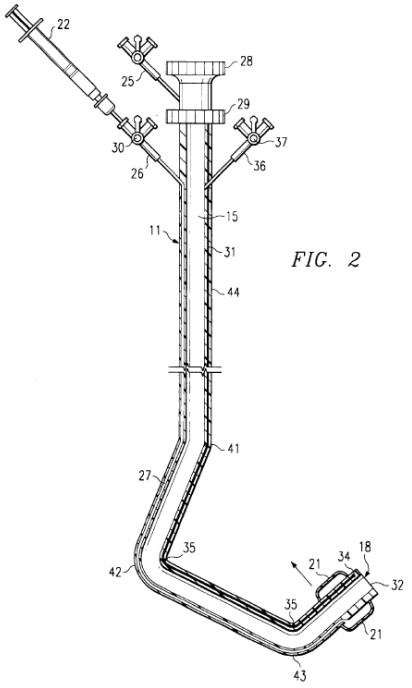

FIG. 2

The specification describes outer catheter 11 as having a hook-shaped distal end. (*Id.*, 4:8-10.)[5] The hook-shaped distal end includes substantially straight segments spanning three bends 41, 42, and 43 in the ranges of about 130º to 180º, 75º to 100º, and 130º to 175º respectively. (*Id.*, 4:10-17, FIGS. 1, 2.) The specification explains that "[t]hese ranges refer to the angle formed by the straight segments adjacent each bend when the catheter is in an undistorted state." (*Id.*, 4:17-19.) The specification also teaches that the outer catheter, in its undistorted state, can have a first bend with an angle that equals 180° which is "no first bend." (*Id.*, 4:27-28.) The shape of outer catheter 11 may be adjusted with the use of a well-known cable mechanism. (*Id.*, 4:19-21; Ex. 1005, ¶¶ 30, 31.)

A method of using double catheter 10 to place a pacing lead in a lateral branch of the coronary sinus is also disclosed. (Ex. 1001, 2:41-44; Ex. 1005, ¶32.) A double catheter 10 is inserted through a venous sheath into the left subclavian vein and guided into the right atrium. (Ex. 1001, 4:35-36.) The guide wire and sheath are then removed. (*Id.*, 4:36-38.) Double catheter 10 is subsequently manipulated until its distal end is within the coronary sinus. (*Id.*, 4:38-52.) Once

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[5] The '268 patent admits that hook-shaped catheters designed for used in the coronary sinus were known. (Ex. 1001, 1:41-43 (citing U.S. Patent No. 5,423,772 (Ex. 1012); *see also* Ex. 1012, 1:6-8, 4:57-61, 5:46-49.)

the coronary sinus is cannulated, "inner catheter 12 is advanced out of outer catheter 11 to make the entire system longer" and "[a] coronary sinus lead is . . . positioned using a guide wire in an appropriate branch of the coronary sinus." (*Id.*, 4:52-55, 4:59-62.)

The '268 patent specification also discloses a second embodiment directed to a catheter 50, shown in Figure 3 (reproduced to the left). (*Id.*, 4:63-67, FIG. 3; Ex. 1005, ¶33.) Catheter 50 includes "an outer guide catheter 51, an inner guide catheter 52 nested therein, [and] an obturator 53 nested inside the inner guide 52." (*Id.*, 4:67-5:3.) In this embodiment, the insertion of inner guide 52 straightens outer guide 51, "i.e., makes the angle of the outer guide 51 shallower" and insertion of "both obturator 53 and inner guide 52 makes the outer guide angle even shallower" which "eliminates the need for a cable system to change the curvature of the catheter." (*Id.*, 6:6-18, 6:35-36.)

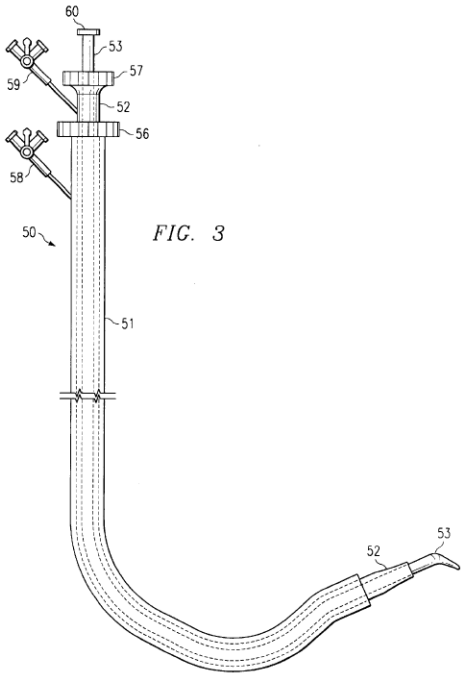


FIG. 3

C. Overview of the '268 Patent Claims

The '268 patent has 27 claims, but this petition requests review of claims 1, 10-14, 18, 19, and 23-26. Claims 1, 11, 13, 18, and 24 are independent. Claim 1

recites a "double catheter" having "an outer, resilient catheter," "an inner, pliable catheter slidably disposed in the outer catheter," and "a mechanism . . . for changing the curvature of the distal end of the outer catheter." (Ex. 1001, 6:62-7:9.) Claims 11 and 24 recite "a method for placing a [*sic*] electrical lead in a lateral branch of a coronary sinus vein using a double catheter." (*Id.*, 7:63-66, 9:16-17.) Claims 13 and 18 similarly recite "an outer catheter" and "an inner . . . catheter," and require the outer catheter to have bends with particular ranges of angles. (*Id.*, 8:13-28, 8:42-64; *see also* Ex. 1005, ¶34.) For purposes of this petition, Petitioner has assumed that the claims have an effective filing date of April 7, 2000.[6]

D. Prosecution History of the '268 Patent

The PTO issued a single Office Action where the examiner indicated that certain dependent claims contained allowable subject matter. (*See* Ex. 1003, 58.) Applicant incorporated that subject matter into the independent apparatus claims, which eventually led to the allowance of these claims. Applicant also argued, and the Examiner agreed, that the prior art cited by the examiner did not disclose the

[6] As noted above, Petitioner has filed a second IPR petition that includes a challenge to this claimed priority date.

claimed angles or describe the claimed methods for leaving a lead wire in a branch vein. (*Id.*, 72, 82.)[7]

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the art (PHOSITA) at the time of the alleged invention of the '268 patent would have been a cardiologist, cardiac electrophysiologist, or interventional cardiologist having experience using catheters (or introducers or sheaths) in the heart, including catheters used for placement of, for example, leads.[8] (Ex. 1005, ¶¶14-15.) Alternatively, a PHOSITA would have been an engineer with a bachelor's degree in the relevant field (e.g., electrical, mechanical, or biomedical engineering) having at least three to five years of experience designing catheters of the type used in the heart, including catheters used for placement of, for example, leads, and an understanding of the heart and associated procedures. (*Id.*)

VIII. CLAIM CONSTRUCTION

A claim in an unexpired patent in an IPR receives the "broadest reasonable construction in light of the specification of the patent in which it appears."

[7] The examiner did not evaluate the priority claim or consider whether new matter was included in the non-provisional application that matured into the '268 patent.

[8] Petitioner submits the declaration of Dr. Ronald David Berger, M.D., Ph.D. (Ex. 1005), an expert in the field of the '268 patent.

37 C.F.R. § 42.100(b). For purposes of this proceeding, the claims of the '268 patent should be given their broadest reasonable interpretation ("BRI"). Under this standard, Petitioner provides constructions for the terms identified below. The remaining terms should be interpreted in accordance with their plain and ordinary meaning under the BRI standard.[9]

A. "mechanism . . . for"

Claims 1 and 23 recite "a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter." (Ex. 1001, 7:7-9, 9:12-15.) For purposes of this proceeding the "mechanism . . . for" terms of claims 1 and 23 should be interpreted as means-plus-function terms. "When a claim term lacks the word 'means,' the presumption [that § 112, para. 6 does not apply] can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Williamson v. Citrix Online, LLC*, 792 F.3d. 1339, 1348 (Fed. Cir.

[9] Because of the different claim interpretation standards used in this proceeding and in district courts, any claim interpretations herein are not binding upon Petitioner in any litigation involving the '268 patent. Moreover, Petitioner does not concede that the challenged claims are not invalid under other sections of the Patent Act.

2015) (citing *Watts v. XL Sys.*, 232 F.3d 877, 880 (Fed. Cir. 2000)); *see also* pre-AIA 35 U.S.C. § 112, para. 6. The claims here do not define any structure associated with the "mechanism . . . for" terms or their functions. Moreover, "mechanism" is a generic term that does not in itself suggest any particular structure. *See Williamson*, 796 F.3d at 1350 (finding "mechanism" to be a generic term). Therefore, the "mechanism . . . for" terms, as recited in claims 1 and 23, should be interpreted under § 112, para. 6.

Construing a means-plus-function claim term requires that the function recited in the claim be first identified, and then the written description of the specification must be consulted to identify the corresponding structure that performs the identified function and equivalents thereof. *See Williamson*, 796 F.3d at 1351. Claims 1 and 23 recite "a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter." (Ex. 1001, 7:7-9, 9:12-15.) Based on the claim language, the claimed function is "changing the curvature of the distal end of the outer catheter." (*Id.*, 7:8-9.)

The '268 patent specification includes a first embodiment directed to a double catheter 10 having a torque screw 29 "attached to a cable or wire 31 that runs in the wall of outer catheter 11" and is "anchored, as by embedding a [*sic*] enlarged end thereof, at a point 34 close to a tip 32 of outer catheter 11." (Ex. 1001, 3:55-59.) The specification states that "[r]otation of torque screw 29 causes

cable 31 to be retracted, which changes the shape of the outer catheter 11 . . . and counter-rotation does the opposite." (*Id.*, 3:61-65.) In this embodiment, a PHOSITA would have understood that the structure corresponding to the claimed function of "changing the curvature of the distal end of the outer catheter" includes a torque screw on the outer catheter that is attached to a pull wire or cable, which is anchored close to the tip of the outer catheter. (Ex. 1005, ¶¶37-38.)

The specification also includes a second embodiment directed to a catheter 50 that is "not deflectable using an [*sic*] screw adjustment mechanism" but can "nevertheless be used to cannulate the coronary sinus whether the latter is placed normally, higher than normal, or lower than normal." (Ex. 1001, 6:2-6.) In this embodiment, "[t]he angle of outer guide 51 can be changed by inserting or withdrawing the inner guide 52." (*Id.*, 6:6-8.) The specification further states that the insertion of "both [an] obturator 53 and inner guide 52 makes the angle of the outer guide even shallower." (*Id.*, 6:11-12.) Thus, a PHOSITA would have understood that the structure corresponding to the claimed function of "changing the curvature of the distal end of the outer catheter" includes an inner guide or an inner guide in combination with an obturator. (Ex. 1005, ¶¶37, 39.)

In sum, the corresponding structure for the claimed function is (1) a torque screw attached to a pull wire or cable anchored close to the tip of the outer catheter, (2) an inner guide, or (3) an inner guide in combination with an obturator,

and equivalents thereof. This is consistent with claims 2, 4, and 10 which mirror the functional language in claim 1 and also specify structure for performing the claimed function. (Ex. 1001, 7:10-15, 7:31-40, 7:58-62.)

B. "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus"

The preamble of claim 24 recites a number of features including "an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus." (Ex. 1001, 9:16-27.) But at least the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" does not breathe life and meaning into the claim and is not necessary to understand any positive limitations in the body of claim 24 or any claims depending from claim 24. Indeed, the body of claim 24 and the claims dependent from claim 24 do not recite anything related to the distal coronary sinus. Moreover, the phrase "permit advancement of the outer catheter into a distal coronary sinus" constitutes merely an intended use. Therefore, it is not limiting. *See Pitney Bowes, Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (explaining that preamble is limiting if it is "'necessary to give life, meaning, and vitality' to the claim" but that "[i]f, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the

purpose or intended use of the invention, then the preamble . . . cannot be said to constitute or explain a claim limitation"); *Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) (considering whether preamble terms are "necessary to understand positive limitations in the body of claims," to determine limiting status).

Even if Patent Owner were to argue that other portions of the preamble are limiting, the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" is still not limiting. *See, e.g., TomTom, Inc. v. Michael Adolph*, 790 F.3d 1315, 1324 (Fed. Cir. 2015) (holding that a portion of the preamble that does not recite essential structure or steps, or give necessary life, meaning, and vitality to the claim does not become limiting simply because of the presence of another limiting phrase in that preamble.) Moreover, for purposes of the prior art here the Board need only resolve whether the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" is limiting. *See, e.g.*, *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (explaining that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy"). (*See also* Ex. 1005, ¶40.)

IX. THE CHALLENGED CLAIMS OF THE '268 PATENT ARE UNPATENTABLE OVER THE PRIOR ART

The challenged grounds rely on one or more prior art references, none of which were considered during prosecution of the '268 patent. Moreover, as explained in more detail below, a PHOSITA would have combined the teachings of these references with a reasonable expectation of success.

A. Overview of Prior Art

1. Overview of *Auricchio*

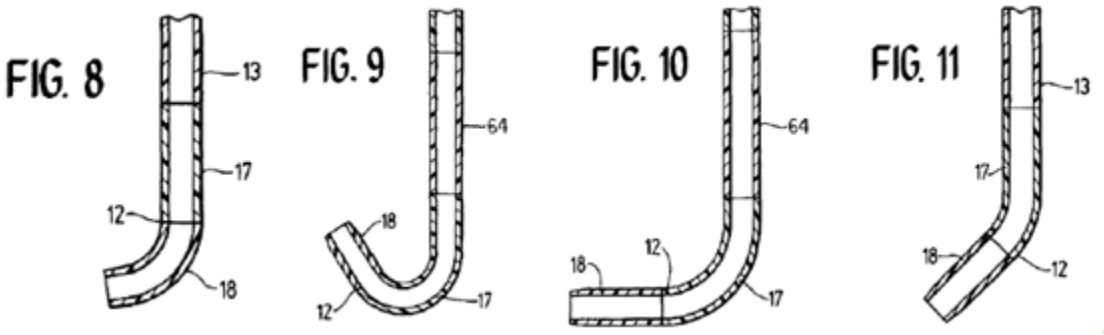
Auricchio issued August 10, 1999, and is thus prior art under at least pre-AIA 35 U.S.C. § 102(a). (Ex. 1019.) It discloses a transvenous coronary vein lead 10 designed for pacing the left ventricle from one of the heart's posterior veins, middle veins, or great vein and describes methods for delivering the lead to a preselected coronary vein. (Ex. 1019, 5:25-29, 2:26-31, 2:41-44, 3:12-38, 8:21-53, FIG. 17.) These methods generally involve inserting at least one guide catheter into the coronary sinus which "increases the ability of the operator to properly position the coronary vein lead 10 within a preselected coronary vein." (*See id.*, 3:12-17, 8:30-38, FIG. 17; Ex. 1005,¶¶41, 42.)

Auricchio discloses that, in one embodiment, "[t]he method of positioning the coronary vein lead at a desired position within a preselected coronary vein may include the use of a guide catheter, guide wire and support catheter." (*Id.*, 2:41-44.) In this embodiment, a guide catheter is first inserted through the superior vena

cava into the ostium of the coronary sinus, and a guide wire is then inserted into the guide catheter and advanced to the desired position within a preselected coronary vein. (*Id.*, 3:22-28.) "Once the guide wire is in position, a thin walled support catheter is advanced over the guide wire to the distal end of the guide wire" and used to position the coronary vein lead 10 within a preselected coronary vein. (*Id.*, 3:26-28, 8:52-53.) *Auricchio* teaches that after the lead is positioned at a desired site within the preselected coronary vein, the support catheter is retracted or peeled away from the lead body leaving the lead in place. (*Id.*, 3:35-38.)

2. Overview of *Randolph*

Randolph issued on July 7, 1998, and is thus prior art under pre-AIA 35 U.S.C. § 102(b). (Ex. 1017.) *Randolph* is one example of a guiding catheter shaped for use in the coronary sinus. (*See, e.g.*, Ex. 1017, title, abstract, 1:66-2:10, 4:49-53, FIGS. 8-11.) *Randolph* teaches that the guiding catheter has a relatively flexible distal shaft section which is formed of a material that is in part shaped or is shapeable via a control line to a shape suitable for advancement within the patient's coronary sinus. (*Id.*, 2:6-14, 2:20-31, 4:49-55.) FIGS. 8-11 illustrate various conventional shapes for the distal end of the guiding catheter, including hook-shaped curves. (*Id.*, 3:57-59, 4:49-55, FIGS. 8-11; Ex. 1005, ¶43.)



3. Overview of *Payne*

Payne published October 7, 1999. (Ex. 1009.) *Payne* is prior art under at least pre-AIA 35 U.S.C. § 102(a). *Payne* discloses a "delivery catheter system for delivering a substance delivery member into a patient's left ventricle." (Ex. 1009, Abstract; Ex. 1005, ¶44.) Delivery catheter system 10 includes a first delivery catheter 11 and a second delivery catheter 12 "which is longer than the first delivery catheter and slidably and rotatably disposed within the first delivery catheter." (Ex. 1009, 12:12-15.)

Payne teaches that "[t]he distal sections of the first and second delivery catheters are preferably preformed into a desired shape so that they will provide a desired orientation for the delivery system when they extend into the patient's heart chamber." (*Id.*, 9:22-25; *see also id.*, 12:17-21.) *Payne* discloses an embodiment of first delivery catheter 11, shown in Figure 5 below, which "has a shaped distal shaft section 13 with a first segment 53 and a second segment 57." (*Id.*, 17:1-3; Ex. 1005, ¶45.)

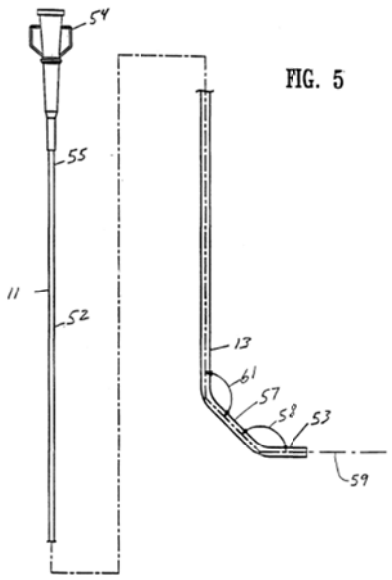


FIG. 5

"[F]irst segment 53 is shaped to be at an angle 58 with respect to the proximally adjacent second segment 57" and "second segment 57 is shaped to be at an angle 61 with respect to the proximally adjacent main shaft section 52." (Ex. 1009, 17:3-6.) *Payne* teaches that angle 58 "can be from about 90 to about 160º" and angle 61 "can be from about 95 to about 165º." (*Id.*, 17:6-12.)

4. Overview of *Lurie*

Lurie was filed on May 9, 1997 and issued on August 21, 2001, and is thus prior art under pre-AIA 35 U.S.C. § 102(e). (Ex. 1018.) *Lurie* discloses a coronary sinus guiding introducer for introducing medical devices, such as electrode leads, into the coronary sinus of a human heart. (*See, e.g.*, *id.*, title Abstract, 2:54-57, 3:12-15, 4:49-52, 5:25-31.) The disclosed coronary sinus introducer includes a precurved distal section, the advantage of which is that "[t]he particular structure and curvature of the guiding introducer's distal section permits

ease in locating the ostium of the coronary sinus in either the inferior or superior approach." (*Id.*, 10:5-8; *see also id.*, 5:43-7:22, FIGS. 2A-2C, 3, 4, 5, 6, 7A-7C.) *Lurie* discloses that "[t]he stiffness of the coronary sinus guiding introducer can also be enhanced by insertion of a dilator or shaped catheter within the lumen of the guiding introducer" to assist with positioning the coronary sinus guiding introducer within the coronary sinus. (*Id.*, 8:31-33; Ex. 1005, ¶46.)

5. Overview of *Ockuly*

Ockuly issued on November 10, 1998, and is prior art under pre-AIA 35 U.S.C. § 102(b). (Ex. 1020.) *Ockuly* discloses a guiding introducer system for use in the treatment of left ventricular tachychardia comprising inner and outer guiding introducers. (*Id.*, 3:33-52; Ex. 1005, ¶47.) *Ockuly* teaches that "the inner guiding introducer is inserted into the outer guiding introducer until the distal end of the inner guiding introducer extends out from the distal end of the outer guiding introducer." (Ex. 1020, 6:39-43.) *Ockuly* explains that "[b]eing able extend the inner guiding introducer within the outer guiding introducer and to rotate the inner guiding introducer within the outer guiding introducer permits a wide variety of overall shapes, which is particularly useful to medical practitioners." (*Id.* 8:60-64.)

6. Overview of *Blanc*

Blanc was published in November 1998, and is thus prior art under pre-AIA 35 U.S.C. § 102(b). (Ex. 1015.) *Blanc* describes a "long guiding sheath

technique" for accessing the coronary sinus. (*Id.*, 2022.) The technique involves first inserting an electrophysiological catheter into the coronary sinus and then guiding a sheath over the electrophysiological catheter. (*Id.*) *Blanc* teaches that a contrast medium can be injected through the electrophysiological catheter to visualize the anatomy of the coronary sinus during the procedure. (*Id.*, 2022-23; Ex. 1005, ¶48.)

B. Ground 1: Claim 11 Is Obvious Based on *Auricchio*

1. Claim 11

i. [11.a] "A method for placing an electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter and an inner catheter slidably disposed inside the outer catheter, comprising:"

To the extent the preamble is limiting, *Auricchio* discloses a method for placing a coronary vein lead 10 ("electrical lead") in a lateral branch of a coronary sinus vein using a guide catheter ("outer catheter") and a support catheter ("inner catheter"), which collectively form a double catheter, with the support catheter slidably disposed inside the guide catheter. (*See* Ex. 1019, 1:14-17, 2:41-44, 3:22-38, 5:25-29, 8:49-53, FIGS. 15, 17; Ex. 1005, ¶¶49-50; *see also infra* Sections IX.B.1.ii-vi.)

Auricchio discloses that coronary vein lead 10 is "specifically adapted for use in connection with a cardiac pacemaker, and designed for pacing the left ventricle from one of the heart's posterior veins, middle veins, or great vein." (Ex.

1019, 5:25-29.) *Auricchio* states that "[t]he method of positioning the coronary vein lead at a desired position within a preselected coronary vein may include the use of a guide catheter, guide wire and support catheter." (*Id.*, 2:41-44.) The support catheter is inserted through the guide catheter as it states that "[the] guide catheter may be used to direct a guide wire which is used to guide [the] support catheter to a desired position." (*Id.*, 8:50-53.) It also states that the "thin walled support catheter is advanced ***over the guide wire*** to the distal end of the guide wire." (*Id.*, 3:26-28 (emphasis added).) Indeed, a PHOSITA would have understood that "support catheter" refers to a small diameter catheter that is inserted into a guide catheter. (Ex. 1005, ¶50.) The support catheter is used to place the coronary vein lead 10 within a preselected coronary vein, such as, for example, the posterior vein. (*See* Ex. 1019, 3:30-32, 5:12-14, 5:25-29, 8:52-53, FIG. 15.) A PHOSITA would have understood the posterior vein to include branches that extend along and drain the lateral wall of the left ventricle. (Ex. 1005, ¶¶22, 50.) *Auricchio* also teaches that the lead can be placed in lateral branches that extend from the middle cardiac vein and great vein. (Ex. 1019, 5:25-29; Ex. 1005, ¶¶22, 50.)

ii. [11.b] "inserting the catheter[10] into the coronary sinus;"

Auricchio discloses inserting the guide catheter and the support catheter of *Auricchio*'s double catheter into the coronary sinus. (*See* Ex. 1019, 3:12-14 ("[t]he method for pacing in accordance with the present invention begins with the physician inserting a guide catheter through the coronary sinus"), *id.*, 8:49-52 ("a guide catheter may be used to direct a guide wire which is used to guide a support catheter to a desired position within a preselected coronary vein"); Ex. 1005, ¶ 51.)

iii. [11.c] "advancing a guide wire through the catheter into a coronary sinus lateral branch vein;"

Auricchio discloses advancing a guide wire through the guide catheter of *Auricchio*'s double catheter into the lateral branch vein. (Ex. 1019, 3:22-30; Ex. 1005, ¶52.) Specifically, *Auricchio* teaches that "[a] guide wire is . . . inserted into the guide catheter and advanced to the desired position within . . . a preselected coronary vein." (Ex. 1019, 3:24-26.) Like the '268 patent, *Auricchio* teaches that "a guide catheter may be used to direct a guide wire which is used to guide a

[10] Claim 11 lacks antecedent basis for "the catheter." For purposes of this petition, however, Petitioner assumes that this term refers to the "double catheter." As detailed in this section, *Auricchio* teaches that the guide catheter and the support catheter are both inserted into the coronary sinus.

support catheter to a desired position within a preselected coronary vein." (*Compare* Ex. 1001, 5:46-58 *with* Ex. 1019, 8:49-52.)

To the extent it is found that the claim requires advancing the guide wire relative to both the "outer catheter" *and* the "inner catheter" of "the catheter," this step was well-known to a PHOSITA, and a PHOSITA would have found it obvious to perform this step in combination with the steps explicitly disclosed in *Auricchio*. (Ex. 1005, ¶52.) A PHOSITA would have understood the benefits of advancing a guide wire through both the guide catheter and support catheter, advancing a support catheter over it, and then using the support catheter to provide axial support as the guide wire is delivered to a desired position in the target vein. (*Id*.) To the extent the guide wire was displaced during the procedure, a PHOSITA would have also been motivated to advance the guide wire relative to both the support catheter and the guide catheter in order to reposition the guide wire at the desired location within the preselected coronary vein. (*Id.*) Moreover, if a PHOSITA encountered difficulties inserting the support catheter within the preselected coronary vein because of the tortuosity of the vein, a PHOSITA would have performed this step in order to position the guide wire in a second branch vein. (*Id.*) For similar reasons, it would have been obvious to a PHOSITA to advance the guide wire relative to both the guide catheter and the support catheter, particularly in view of *Auricchio*'s disclosure that the guide wire is used to "guide

a support catheter to a desired position within a preselected coronary vein." (Ex. 1019, 8:49-52; Ex. 1005 at ¶52.)

iv. [11.d] "advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;"

Auricchio discloses advancing the support catheter ("inner catheter") out of the distal or front end of the guide catheter ("outer catheter") "to the distal end of the guide wire" which is positioned within a branch vein, and thus teaches advancing the support catheter along the guide wire into the branch vein. (*See* Ex. 1019, 3:26-28, 8:49-52; Ex. 1005, ¶53.)

v. [11.e] "inserting the lead through the outer and inner catheters to a target location in the branch vein; and"

Auricchio discloses a method in which "the coronary vein lead . . . is advanced through the support catheter to the desired site in the coronary vein." (Ex. 1019, 3:30-32.)

While Auricchio teaches that "[t]he guide catheter and guide wire are . . . removed, leaving the support catheter in place" before inserting lead 10 through the support catheter (*id.*, 3:28-32), it would have been obvious to a PHOSITA to have kept the guide catheter in the coronary sinus while placing the lead, rather than removing it first. (Ex. 1005, ¶54.) A PHOSITA would have been motivated to leave the guide catheter in the coronary sinus because, as the guide catheter is withdrawn, there is a risk that the support catheter may be displaced from the

preselected coronary vein. (*Id*.) In addition, this would avoid the need to recannulate the coronary sinus to exchange support catheters, if such exchange is needed. (*Id*.) By leaving the guide catheter in position within the coronary sinus, the support catheter could also be manipulated or withdrawn without repeatedly drawing the support catheter back and forth over the vessel wall. (*Id*.)

With the outer, guide catheter in the coronary sinus and the support catheter in the branch vein, the lead would be inserted though both the support catheter and the guide catheter to a target location in the branch vein. (*Id*.) A PHOSITA would have recognized that this arrangement would have been advantageous, as the guide catheter can provide axial support to the pliable support catheter and to the coronary vein lead 10 as the lead is advanced through the support catheter and into the preselected coronary vein. (*Id*.) A PHOSITA would have recognized that this would have been particularly useful when, for example, the vein is at an acute angle and an axial force on the lead could cause the support catheter or lead to slip out of the vein. (*Id*.)

vi. [11.f] "withdrawing the catheter leaving the lead in the branch vein."

Auricchio describes removing both the guide catheter and the support catheter from the coronary sinus to leave the lead in the branch vein. (Ex. 1019, 3:28-30, 3:34-37, 8:28-29, 8:46-49; Ex. 1005, ¶55.) For example, *Auricchio* describes that the guide catheter as "the tear away type known to those skilled in

the art" that is split as it is removed from the body. (Ex. 1019, 8:28-29, 8:46-49; Ex. 1005, ¶55.) *Auricchio* teaches that "the support catheter is retracted or peeled away from the lead body." (*Id.*, 3:35-38.) As discussed above at Section IX.B.1.v, it would have been obvious to a PHOSITA to position the guide catheter within the coronary sinus so that the lead would be inserted though both the support catheter and the guide catheter to the desired location in the branch vein. In this method, both the guide catheter and the support catheter would be retracted or peeled away from the lead body to leave the lead in the branch vein. (Ex. 1005, ¶55.)

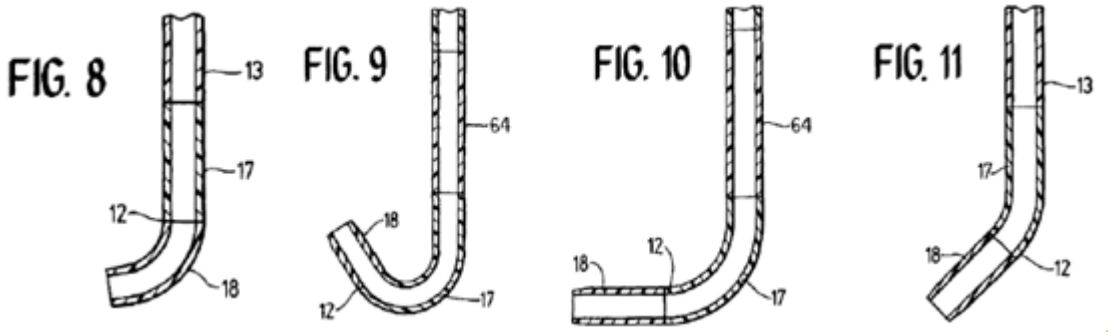
C. Ground 2: Claim 12 and 24 Are Obvious Based on *Auricchio* and *Randolph*

1. Claim 12

i. The method of claim 11, further comprising: adjusting the curvature of the double catheter in order to enter the coronary sinus.

The combination of *Auricchio* and *Randolph* discloses this limitation. (Ex. 1005, ¶56.) As discussed above at Section IX.B.1.i, *Auricchio* discloses a double catheter comprising a guide catheter ("outer catheter") and a support catheter ("inner catheter"). While *Auricchio* does not disclose adjusting the curvature of the double catheter in order to enter the coronary sinus, this technique would have been obvious in view of *Randolph*. (Ex. 1005, ¶56.) As discussed in detail below, a PHOSITA would have combined the teachings of *Auricchio* and *Randolph*, and would have had a reasonable expectation of success in doing do. (*Id.*)

Randolph teaches a guiding catheter for accessing the coronary sinus. (*See, e.g.*, Ex. 1017, title, abstract, 1:66-2:10, 3:57-59, 4:49-55, FIGS. 8-11.) This catheter includes a relatively flexible distal shaft section 12 "which is at least in part shaped or is shapeable to a shape suitable for advancement within the patient's coronary sinus and particularly a branch thereof." (*Id.*, 2:6-10.) *Randolph* discloses that the distal shaft section 12 can be shaped into various conventional shapes, including those having hook-shaped curves. (*See id.*, 4:49-55, FIGS. 8-11; Ex. 1005, ¶56.)



Randolph also teaches that "[i]f desired, control lines (not shown) may be incorporated into the wall of the catheter and extend out of the proximal end of the catheter shaft, whereby when tension is applied thereto after the catheter is inserted into the patient, the distal extremity of the catheter shaft is deflected or shaped in a desired manner." (Ex. 1017, 4:60-65.)

Based on the teachings of *Randolph*, a PHOSITA would have found it obvious to use a deflecting catheter for *Auricchio*'s guide catheter to adjust the curvature of the guide catheter after it has been inserted into the patient's body to

assist with locating the coronary sinus. (Ex. 1005, ¶56.) A PHOSITA would have been motivated to shape the guide catheter after it has been inserted into the patient's body to assist with navigating the anatomy around the coronary sinus ostium that can otherwise complicate coronary sinus cannulation and to locate and enter the coronary sinus. (*Id.*) A PHOSITA would have recognized that both *Auricchio* and *Randolph* describe catheters for delivering a device into a branch vein of the coronary sinus, and would have considered *Randolph*'s complementary teachings when designing an improved delivery system for LV lead placement. (*Id.*) Moreover, the use of steerable or deflectable catheters to locate the coronary sinus was well-known in the art. (*Id*; Ex. 1013, 139D; Ex. 1022, 158K.) A PHOSITA would have recognized that adjusting the curvature of a guide catheter with the use of a deflecting mechanism to cannulate the coronary sinus would be the application of a known technique that would allow for efficient lead placement. (Ex. 1005, ¶56.) *See KSR Int.'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

2. Claim 24

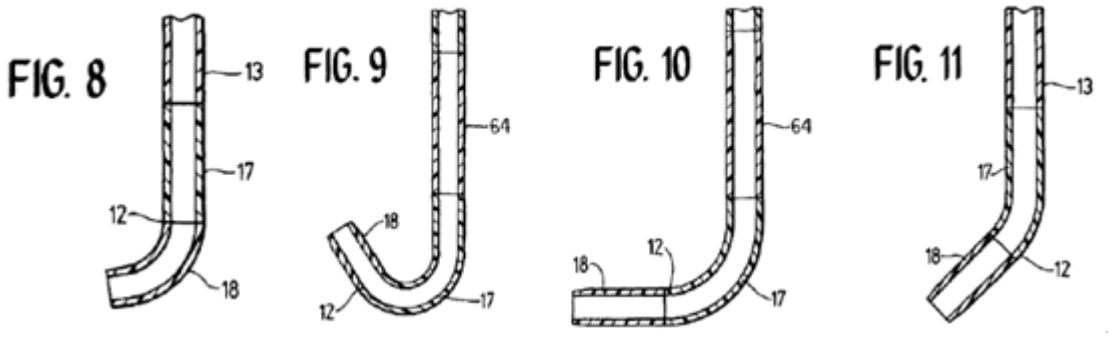
i. [24.a] "A method for placing a [sic] electrical lead in a lateral branch of a coronary sinus vein using a double catheter including an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and having a hook-shaped distal end, and an inner, pliable catheter slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter to vary the overall length of the double catheter, the method comprising:"

The combination of *Auricchio* and *Randolph* discloses this limitation. (Ex. 1005, ¶58; *see also infra* Sections IX.C.2.ii-vi; Ex. 1005, ¶57.) As discussed above in Section IX.B.1.i, *Auricchio* discloses a double catheter comprising a guide catheter ("outer catheter") and a support catheter ("inner catheter") and teaches that the support catheter is slidably disposed inside the guide catheter. Given that *Auricchio* describes the support catheter as a "thin walled support catheter," a PHOSITA would have understood the support catheter to be pliable. (Ex. 1019, 3:27; Ex. 1005, ¶58.) *Auricchio* teaches that the support catheter is advanced to a "distal end of the guide wire" positioned within a preselected coronary vein, and thus teaches that the support catheter is of greater length than the guide catheter so that a distal end portion of the support catheter can be extended or retracted from a

distal end opening of the guide catheter for placement in the preselected coronary vein. (Ex. 1019, 3:24-28; Ex. 1005, ¶58.)

As noted above, the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" is not a limiting requirement of the preamble. (*See supra* Section VIII.B.) Even if it were limiting, a PHOSITA would have understood that the guide catheter described in *Auricchio* meets this limitation as it can be used to deliver a lead to a distal coronary vein. (Ex. 1019, 3:11-37, 5:25-29, 8:28-53, FIG. 17; Ex. 1005, Ex. 1005, ¶58.) *Auricchio* does not expressly disclose that its guide catheter is a "resilient tube having shape memory" and has "a hook-shaped distal end"; *Randolph*, however, teaches these features. As discussed in detail below, a PHOSITA would have combined the teachings of *Auricchio* and *Randolph* and would have had a reasonable expectation of success in doing do. (*Id.*)

Randolph discloses a guiding catheter designed for accessing a branch vein of the coronary sinus. (Ex. 1017, 1:66-2:5, FIG. 7.) *Randolph* teaches that its guiding catheter is formed of thermoplastic polymer materials that are resilient and have shape memory. (*See* Ex. 1017, 2:20-31, 4:55-65.) FIGS. 8-11 illustrate various conventional shapes of the guiding catheter, including shapes having hook-shaped curves. (*See id.* at 3:57-59, 4:49-55, FIGS. 8-11; Ex. 1005, ¶57.)



It would have been obvious to a PHOSITA to combine the teachings of *Auricchio* and *Randolph* by using a catheter like *Randolph*'s guiding catheter in the method disclosed in *Auricchio*. (Ex. 1005, ¶58.) A PHOSITA would have been motivated to look to *Randolph*'s disclosure to facilitate "rapid advancement of an intravascular device into a patient's coronary sinus and particularly into a cardiac vein draining into the coronary sinus." (Ex. 1005, ¶58; Ex. 1017, 1:61-63.) Given that *Auricchio* and *Randolph* describe coronary sinus catheters for introduction of a device into the coronary sinus, a PHOSITA would have combined the disclosures to result in an improved outer guide catheter for use with a support catheter for delivering a pacing lead into a branch vein of the coronary sinus. (Ex. 1005, ¶58.)

A PHOSITA would have had reason to use a preformed guide catheter shaped like the guiding catheter disclosed in *Randolph* as it generally matches the anatomical pathway to the coronary sinus ostium 38 and would facilitate access to the coronary sinus. (*Id*.) Indeed, a PHOSITA would have recognized that the selection of features such as catheter shape would have been an obvious design choice based on the knowledge known to such a skilled person and common sense.

(*Id*.) *See KSR*, 550 U.S. at 421. Moreover, there were only a limited number of materials from which a guide catheter can be made, and selecting a guide catheter with physical properties that render the sheath resilient and having shape memory, like the guide catheter of *Randolph*, would have been a routine design choice. (Ex. 1005, ¶58.) The substitution of the guide catheters of *Auricchio* and *Randolph* would also be the predictable use of prior art elements according to their established functions. *See KSR*, 550 U.S. at 417.

ii. [24.b] "inserting the catheter into the coronary sinus;"

As discussed in connection with claim 11, *Auricchio* discloses inserting both the guide catheter and the support catheter of *Auricchio*'s double catheter into the coronary sinus. (*See supra* Section X.B.1.ii; Ex. 1005, ¶59.)

iii. [24.c] "advancing a guide wire through the catheter into a coronary sinus lateral branch vein;"

As discussed in connection with claim 11, *Auricchio* discloses advancing a guide wire through the guide catheter, and also renders obvious the step of advancing the guide wire through both the guide catheter and the support catheter of *Auricchio*'s double catheter into a coronary sinus lateral branch vein. (*See supra* Section X.B.1.iii; Ex. 1005, ¶60.)

iv. [24.d] "advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;"

As discussed in connection with claim 11, *Auricchio* discloses advancing the support catheter ("inner catheter") out of a front or distal end of the guide catheter ("outer catheter") to the distal end of the guide wire located within the branch vein. (*See supra* Section X.B.1.iv; Ex. 1005, ¶61.)

v. [24.e] "inserting the lead through the outer and inner catheters to a target location in the branch vein; and"

As discussed in connection with claim 11, it would have been obvious to a PHOSITA to insert coronary vein lead 10 through the support catheter ("inner catheter"), while it is positioned within the guide catheter ("outer catheter"), to a target location in the branch vein. (*See supra* Section X.B.1.v; Ex. 1005, ¶62.)

vi. [24.f] "withdrawing the catheter leaving the lead in the branch vein."

As discussed in connection with claim 11, *Auricchio* describes removing both the guide catheter and the support catheter from the coronary sinus to leave the lead in the branch vein. (*See supra* Section X.B.1.vi; Ex. 1005, ¶63.)

D. Ground 3: Claims 13, 14, 18, 19, 23, 25, and 26 Are Obvious Based on *Auricchio*, *Randolph*, and *Payne*

1. Claim 13

i. [13.a] "An outer catheter configured for use with an inner, pliable catheter which can be slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter,"

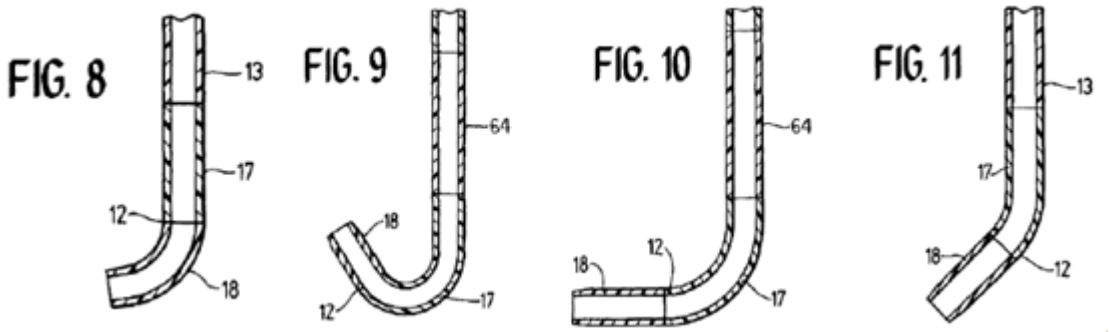
As discussed above for claim 24, *Auricchio* discloses a guide catheter ("outer catheter") configured for use with a "thin walled" and thus pliable support catheter ("inner catheter") which can be slidably disposed in the outer catheter and of greater length than the outer guide catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter. (*See supra* Section IX.C.2; *see also infra* Sections IX.D.1.ii-iii; Ex. 1005, ¶¶ 64-65.)

ii. [13.b] "the outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and "

As discussed above for claim 24, the combination of *Auricchio* and *Randolph* discloses this limitation. (*See supra* Section IX.C.2.i; Ex. 1005, ¶66.)

iii. [13.c] "[the outer catheter] having a hook-shaped distal end wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°."

The combination of *Auricchio*, *Randolph*, and *Payne* teaches this limitation. (Ex. 1005, ¶67.) For the reasons discussed above at IX.C.2.i, it would have been obvious to use a guide catheter, like *Randolph*'s guiding catheter, in the method disclosed in *Auricchio*. (Ex. 1005, ¶67.) *Randolph* teaches that its guiding catheter for use in the coronary sinus can be formed with straight, proximal or intermediate shaft sections 13, 64 and a distal section 12 with various hook-shaped curves. (*See* Ex. 1017, 4:49-55, FIGS. 8-11; Ex. 1005, ¶67.)



While *Randolph* discloses a guiding catheter with a hook-shaped distal end, it does not explicitly disclose a shape with at least two bends having angles that fall within the claimed ranges. Shaped catheters with bends having angles that fall within the claimed ranges, however, were known at the time of the alleged invention. (Ex.

1005, ¶67.) For the reasons discussed below, a PHOSITA would have found it obvious to combine the teachings of *Auricchio*, *Randolph*, and *Payne*, and would have had a reasonable expectation of success in doing so. (*Id.*)

Payne discloses a delivery catheter system including a first delivery catheter 11 and a second delivery catheter 12 that is longer than first delivery catheter 11 and slidably disposed within first delivery catheter 11. (*Id.*, 12:12-15.) *Payne* discloses that first (outer) delivery catheter 11 has a shaped distal end section 13. (*See id.*, 9:22-25, 16:21-17:27, FIGS. 4-7.) The embodiment of first delivery catheter 11, as shown in FIG. 5 below, has a distal shaft section 13 with a first segment 53, a second segment 57, and a main shaft section 52. (Ex. 1009, 17:1-6, FIG. 5.) The first segment 53 is shaped at an angle 58 with respect to second segment 57, and the second segment is shaped at an angle 61 with respect to main shaft section 52. (*Id.*, 17:3-6, FIG. 5.)

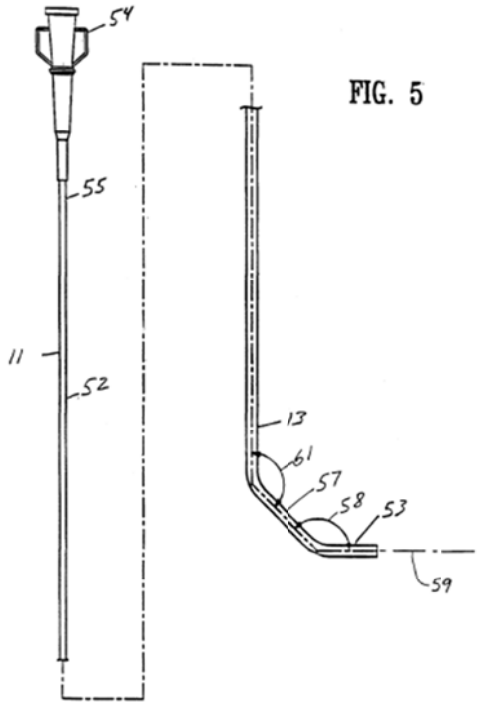


FIG. 5

The embodiment of first delivery catheter 11 shown in FIG. 5 teaches a hook-shaped distal end with bends having angles that fall within the claimed ranges. (Ex. 1005, ¶67.) A PHOSITA would have understood this embodiment of the first delivery catheter 11 to be substantially **J**-shaped and having a hook-shaped distal shaft section 13. (Ex. 1009, FIG. 5; Ex. 1005, ¶67.) As noted above, a bend of 180°, according to the '268 patent, is no bend. (*See supra* Section VI.B.) Therefore, the scope of this limitation includes a catheter with a straight segment adjoining a straight, proximal portion. Like *Randolph*, *Payne* teaches a straight segment with an angle of 180° (*i.e.*, no bend) as it discloses that distal shaft section 13 includes a straight, main shaft section 52. (Ex. 1009, 17:4-6, FIG. 5; Ex. 1005, ¶67.) A PHOSITA would have understood angle 61 to correspond to the claimed

"second, intermediate bend" that is in a different direction than the claimed "first bend" given that the claimed "first bend" may be a straight section with an angle of 180° (i.e., no bend).[11] (Ex. 1005, ¶67.) A PHOSITA would have understood angle 58 to correspond to the claimed "third bend" as it is nearest the distal end of first delivery catheter 11 and is in the same direction as angle 61 ("the second, intermediate bend"). (Ex. 1009, 17:6-8, FIG. 5; Ex. 1005, ¶67.)

Payne discloses ranges of angles for the bends shown in FIG. 5 that overlap with the claimed ranges. (Ex. 1005, ¶67.) *Payne* teaches that angle 61 ("the second, intermediate bend") can be "from about 95° to about 165°. (Ex. 1009, 17:9-12.) *Payne* also teaches that angle 58 ("the third bend") can be "from about 90° to about 160°." (Ex. 1009, 17:6-8; FIG. 5.) "Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." *See Ormco Corp. v. Align Tech. Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006). Only if the prior art teaches away from the claimed range or the claimed range produces new and unexpected results, can this presumption be rebutted. *See Ormco*, 463 F.3d at 131. Here, because, the claimed ranges overlap with the ranges disclosed

[11] Petitioner reserves the right to argue in the concurrent litigation that any claim element requiring a bend in a "different direction" than a straight segment is indefinite.

by the prior art, there is a strong presumption of obviousness. Moreover, the prior art neither teaches away from the claimed range nor does the '268 patent even allege that the claimed range produces new and unexpected results.

In addition, it would have been obvious to a PHOSITA to modify the outer guide catheter of the combination of *Auricchio* and *Randolph* in view of *Payne*. (Ex. 1005, ¶67.) *Randolph* provides motivation for this combination as teaches that catheters used to access the coronary sinus can have a variety of curved shapes. (*See* Ex. 1017, 4:49-55, FIGS. 8-11.) It would have been obvious to a PHOSITA to use the shape described in *Payne* with at least two bend angles that fall within the claimed ranges so that the guide catheter of the combination of *Auricchio* and *Randolph* is preformed into a shape that would orient the guide catheter when it is in the patient's heart. (Ex. 1009, 9:22-25; Ex. 1005, ¶67.)

Indeed, a PHOSITA would have recognized that the selection of features such as outer catheter shape would have been an obvious design choice based on the knowledge known to such a skilled person in the art and common sense. (Ex. 1005, ¶67.) *See KSR*, 550 U.S. at 421. A variety of catheter shapes designed for use within the heart, including in the coronary sinus, were known. (Ex. 1005, ¶67; Exs. 1012, 1016-1018.) As demonstrated by *Payne*, the claimed shape was known and used in other cardiac procedures at the time of the alleged invention. (*See, e.g.*, Ex. 1009, Abstract, 17:1-12, FIG. 5; Ex. 1005, ¶67.) It was common practice

at the time of the alleged invention to adopted catheters or design elements of catheters used in other cardiac procedures for navigating the coronary vessels. (Ex. 1005, ¶67.)

A PHOSITA would have considered the specific teachings of *Payne* because it discloses an outer delivery catheter 11 for use in a cardiac procedure, like *Auricchio* and *Randolph*. (*See, e.g.*, Ex. 1009, 1:13-17, Fig. 5; Ex. 1013 at 139D; Ex. 1017, Abstract; Ex. 1005, ¶67.) In addition, it discloses a catheter having a hook-shaped design which resembles a known shape that matches the anatomical pathway to the coronary sinus ostium. (Ex. 1009, 9:22-25, FIG. 5; Ex. 1005, ¶67.) For this additional reason, a PHOSITA would have found it obvious to shape the outer catheter of the combination of *Auricchio* and *Randolph* in view of *Payne* as it would position the distal end of the guide catheter into a favorable position to cannulate the coronary sinus. (Ex. 1005, ¶67.)

2. Claim 14

i. "The catheter of claim 13, wherein the first bend equals 180°, rendering the outer catheter substantially J-shaped."

As discussed above for claim 13, the outer guide catheter of the combination of *Auricchio* and *Randolph* in view of *Payne* has a shape with a first bend that equals 180°, rendering the outer catheter substantially J-shaped. (*See supra*

Section X.D.1.c (explaining that *Randolph* and *Payne* teach straight segments having an angle of 180°); Ex. 1005, ¶68.)

3. Claim 18

i. [18.a] "A double catheter, comprising:"

Auricchio discloses a double catheter comprising a guide catheter ("outer catheter") and a support catheter ("inner catheter"). (Ex. 1019, 2:31-44, 3:22-38, 8:49-53; *see also infra* Sections IX.D.3.ii-v; Ex. 1005, ¶¶69-70.)

ii. [18.b] "an outer catheter comprising a resilient tube having shape memory and sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus, and"

As discussed above for claim 13, the combination of *Auricchio* and *Randolph* discloses this limitation. (*See supra* Section IX.D.1.ii; Ex. 1005, ¶71.)

iii. [18.c] "[an outer catheter] having a hook-shaped distal end wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°, and"

As discussed above for claim 13, the combination of *Auricchio*, *Randolph*, and *Payne* teaches this limitation. (*See supra* Section IX.D.1.iii; Ex. 1005, ¶72.)

iv. [18.d] "an inner, pliable catheter slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter to vary the overall length of the double catheter,"

As discussed above for claim 13, *Auricchio* teaches a support catheter ("inner catheter") that is pliable and is slidably disposed within the guide catheter and also suggests that the support catheter is of greater length than the guide catheter so that a distal end portion of the support catheter can be extended or retracted from a distal end opening of the guide catheter to vary the overall length of *Auricchio*'s double catheter. (*See* Section IX.D.1.i; Ex. 1005, ¶73.)

v. [18.e] "wherein the inner catheter has an internal lumen suitable for the introduction of a fluid therethrough and a hemostatic valve at a proximal end thereof that prevents leakage of blood when a pacing lead is introduced through the inner catheter into the coronary system."

Auricchio discloses that "the coronary vein lead of the present invention is advanced through the support catheter," and thus teaches that the support catheter ("inner catheter") has an internal lumen suitable for the introduction of a coronary vein lead 10. (*See* Ex. 1019, 3:30-32; 8:52-53; Ex. 1005, ¶74.) A PHOSITA would have understood that the same lumen would also allow for the introduction of a fluid (e.g., blood) therethrough. (Ex. 1005, ¶74.) While *Auricchio* does not explicitly disclose that the support catheter includes a hemostatic valve at a

proximal end thereof that prevents leakage of blood when coronary vein lead 10 is introduced through the support catheter, it would have been obvious to a PHOSITA to have modified the support catheter to include a hemostatic valve, as exemplified by *Payne*. (*Id*.)

Payne discloses a double catheter system including a first delivery catheter 11 and a second delivery catheter 12 slidably disposed within first delivery catheter 11. (Ex. 1009, 12:12-15.) *Payne* also teaches that a polymer sheath 17 is slidably disposed within second delivery catheter 12 and configured to extend beyond a distal end 21 of second delivery catheter 12 to engage tissue of a heart wall. (*Id.*, 12:22-27.) A proximal hemostasis member 29 engages and seals a proximal end 27 of second delivery catheter 12 and the polymer sheath 17 so that "fluids that are forced into [a] distal end 21 of the second delivery catheter under pressure, such as blood, can not leak out the proximal end 27 of the second delivery catheter where the polymer sheath exits said proximal end of the second delivery catheter." (*Id.*, 13:8-13.)

The use of a hemostatic valve, like hemostatic member 29 of *Payne*, with a catheter in order to minimize blood loss was well-known in the art. (Ex. 1005, ¶74.) It would have been obvious to a PHOSITA to modify *Auricchio*'s support catheter to have a hemostatic valve at a proximal end of the support catheter in order to prevent blood from leaking out of the proximal end of the catheter as

coronary vein lead 10 is introduced through the support catheter. (*Id*.) Both *Auricchio* and *Payne* disclose double catheter systems for use in cardiac procedures having a second catheter for delivering a device into the heart. (*See, e.g.*, Ex. 1019, 1:14-17, 3:22-37; Ex. 1009, 5:13-15, 12:12-15.) Because they are in similar fields and disclose similar devices, a PHOSITA would have been motivated to look to each reference for its additional teachings. (Ex. 1005, ¶74.) For the reasons above, a PHOSITA would have considered the addition of a hemostatic valve, similar to the device disclosed in *Payne*, an obvious design choice and an improvement to *Auricchio*'s double catheter. (*Id*.)

4. Claim 19

i. "The double catheter of claim 18, wherein the first bend equals 180°, rendering the outer catheter substantially J-shaped."

As discussed above for claim 14, the combination of *Auricchio, Randolph*, and *Payne* teaches this limitation. (*See supra* Section IX.D.2; Ex. 1005, ¶75.)

5. Claim 23

i. "The double catheter of claim 18, further comprising a mechanism operable from a proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter."

As noted above, the '268 patent discloses that the corresponding structure for the recited function is (1) a torque screw attached to a pull wire or cable anchored close to the tip of the outer catheter, (2) an inner guide, or (3) an inner

guide in combination with an obturator, or equivalents thereof. (*See supra* Section VIII.) The combination of *Auricchio*, *Randolph*, and *Payne* teach the recited function and at least one structure disclosed in the '268 patent corresponding to the recited function or its equivalents as explained below. To the extent the Board determines that this phrase is not a means-plus-function term, the combination of *Auricchio*, *Randolph*, and *Payne* discloses this limitation under its plain and ordinary meaning for the same reasons discussed below.

As discussed above at Section IX.D.3.1, *Auricchio* discloses a double catheter comprising a guide catheter ("outer catheter") and a support catheter ("inner catheter"). While *Auricchio* does not disclose adjusting the curvature of the double catheter in order to enter the coronary sinus, this technique would have been obvious in view of *Randolph*. (Ex. 1005, ¶76.) *Randolph* teaches the use of a deflecting mechanism, like the cable mechanism disclosed in the '268 patent, with a guiding catheter for changing the curvature of the guiding catheter. (Ex. 1017, 2:6-10; 4:60-65.) *Randolph* teaches that its deflecting mechanism can be manipulated at the proximal end of the guiding catheter for changing the curvature of the distal end of the catheter. (*Id.*, 4:60-65.) *Payne* teaches a similar mechanism to deflect or otherwise shape a distal end section 13 of its first delivery catheter 11. (Ex. 1009, 9:25-29.)

For the reasons discussed above at Section IX.C.1, it obvious to a PHOSITA to use a catheter with a deflecting mechanism, like *Randolph*'s catheter, for *Auricchio*'s guide catheter to adjust the curvature of the guide catheter after it has been inserted into the patient's body to assist with locating the coronary sinus. (Ex. 1005, ¶76.) Adjusting the curvature of the guide catheter using a deflecting mechanism would be nothing more than the predictable use of a technique well-known in the field. (*Id*.)

6. Claim 25

i. "The method of claim 24, wherein a first bend adjoining a straight, proximal portion of the outer catheter is in the range of 130° to 180°, a second, intermediate bend is in the range of 75° to 100° in a direction opposite the first bend, and a third bend nearest the distal end of the outer catheter in the same direction as the second bend is in the range of to 130° to 175°."

As discussed above for claim 13, the combination of *Auricchio*, *Randolph*, and *Payne* teaches this limitation. (*See supra* Section IX.D.1.iii; Ex. 1005, ¶77.)

7. Claim 26

i. "The method of claim 25, wherein the first bend equals 180°, rendering the outer catheter substantially J-shaped."

As discussed above for claim 14, the combination of *Auricchio*, *Randolph*, and *Payne* teaches this limitation. (*See supra* Section IX.D.2; Ex. 1005, ¶78.)

E. Ground 4: Claims 1 and 10 Are Obvious Based on *Lurie* and *Ockuly*

1. Claim 1

i. [1.a] "A double catheter, comprising:"

The combination of *Lurie* and *Ockuly* discloses this limitation. (*See* Ex. 1005, ¶¶ 79-80; *see also infra* Sections IX.E.ii-iv.)

Lurie discloses a coronary sinus guiding introducer "for introducing a medical device, such as a flexible lead for use with a pacemaker, defibrillator or for cardioversion, into the coronary sinus." (Ex. 1018, 2:58-62; *see also id.*, Abstract, 1:14-19, 3:12-15, 4:49-52, 5:25-28.) *Lurie* explains that "[b]ecause of its unique shape, the introducer of the present invention assists in rapid placement of medical devices within the coronary sinus, thereby reducing the amount of time necessary for performance of the medical procedure." (*Id.*, 4:62-66.)

Ockuly discloses a guiding introducer system used in the left ventricle for treatment of ventricular tachycardia comprising an outer guiding introducer and an inner guiding introducer. (Ex. 1020, 3:33-52.) The inner guiding introducer "is inserted into the outer guiding introducer until the distal end of the inner guiding introducer extends out from the distal end of the outer guiding introducer." (*Id.*, 6:39-43.) *Ockuly* explains that the combination of the outer and inner guiding introducers can be used to form various curves and shapes while allowing for precise placement of the distal tip of the system at a specific location within the

body. (*See id.*, 3:54-62, 8:60-64.) *Ockuly* describes the inner guiding introducer as having an internal diameter from 6 to 12 French for the introduction of a medical device. (*Id.*, 8:21-25.)

Both references disclose introducers used to introduce a medical device into the heart. (*See, e.g.*, Ex. 1018, 4:49-52; Ex. 1020, 3:50-52; Ex. 1005 at ¶80.) Both references describe introducers that are designed for use in cardiac procedures performed by a PHOSITA. (*See, e.g.*, Ex. 1018, 1:14-19; Ex. 1020, 1:13-17, 3:44-48; Ex. 1005, ¶80.) Given the similarity in the structure and function of these devices, a PHOSITA would have been motivated to look to each reference for its additional teachings. (Ex. 1005, ¶80.)

Moreover, the disclosure of *Lurie* would have motivated a PHOSITA to look to *Ockuly* and similar disclosures which teach telescoping systems. (Ex. 1005, ¶80.) *Lurie* acknowledges that "[g]aining access to the ostium of the coronary sinus is a very difficult procedure" because of variations in the presence and location of the anatomical structures near the coronary sinus ostium. (Ex. 1018, 2:20-32, 2:37-40.) *Lurie* describes inserting a dilator or shaped catheter in a telescoping manner into the coronary sinus introducer to assist with locating the coronary sinus ostium and positioning the introducer in the coronary sinus. (*See* Ex. 1018, 3:29-36; 8:30-32; Ex. 1005, ¶80.) Accordingly, *Lurie*'s disclosure

would have motivated a PHOSITA to look to other introducer disclosures for details of the telescoping technique; *Ockuly* is one such reference. (Ex. 1005, ¶80.)

Ockuly, like *Lurie*, discloses the use of an inner guiding introducer with the outer guiding introducer. (Ex. 1020, 3:42-43.) *Ockuly*'s inner guiding introducer is "preferably longer than the outer guiding introducer so that its distal end may be extended out from the distal end of the outer guiding introducer to form various curves and shapes." (*Id.*, 6:36-39.) Thus, its telescoping system "permits a wide variety of overall shapes, which is particularly useful to medical practitioners." (*Id.*, 8:60-64.) *Ockuly* teaches that its inner guiding introducer can be used to introduce a medical device into the heart, and teaches that by extending the inner guiding introducer relative to the outer guiding introducer a variety of shapes are formed that are helpful in directing the medical device to a site of interest. (Ex. 1020, 3:33-35, 8:43-49.) In view of these disclosures in *Ockuly*, a PHOSITA would have been motivated to use a telescoping system, like the system described in *Ockuly*, for LV lead placement in order to reach a more distal portion of the coronary sinus vasculature, and would have recognized that the use of such a system would eliminate the need to exchange tools or withdraw tools from within the outer guiding introducer for placement of the lead. (Ex. 1020, 5:50-52; Ex. 1005, ¶80.)

For the reasons discussed above, a PHOSITA would have combined the teachings of *Lurie* and *Ockuly* with a reasonable expectation of success to form a system having an outer, coronary sinus guiding introducer and an inner, telescoping introducer to facilitate insertion of the outer, coronary sinus guiding introducer into the coronary sinus. (Ex. 1005, ¶80.) It would have been obvious to a PHOSITA to use a telescoping system with outer and inner guiding introducers for accessing given that telescoping an inner catheter through an outer catheter was a known technique. (Ex. 1005 at ¶80.) The use of an inner telescoping introducer, like the inner guiding introducer taught in *Ockuly*, for the shaped catheter taught in *Lurie* would have been a simple substitution that would result in a system that forms various curves and shapes for cannulating the coronary sinus. (Ex. 1005, ¶80.) *See KSR*, 550 U.S. at 416.

ii. [1.b] "an outer, resilient catheter having shape memory and a hook shaped distal end configured for cannulation of the coronary sinus with at least one curved bend;"

As discussed above in Section IX.E.1.i, the combination of *Lurie* and *Ockuly* teaches a system that includes an outer coronary sinus guiding introducer ("outer catheter"), like the introducer taught in *Lurie*, and an inner guiding introducer ("inner catheter"), like the inner guiding introducer taught in *Ockuly*. (Ex. 1005, ¶81.) *Lurie*'s coronary sinus guiding introducer receives a "shaped catheter within the lumen of the guiding introducer" and would thus be used as an outer catheter.

(Ex. 1018, 8:31-33; Ex. 1005, ¶81.) The coronary sinus guiding introducer is a resilient catheter having shape memory as it is "made of any biocompatible material suitable for use in humans which has a memory or permits distortion from and substantial return to the desired three dimensional, such as polyethylene or polyurethane." (Ex. 1018, 7:23-27.) *Lurie* teaches that the introducer contains a precurved distal portion, which curves through an arc of about 50 to 150 degrees, which a PHOSITA would have understood to form a hook-shape, and is configured for cannulating of the coronary sinus. (*See id.*, Abstract, 5:43-7:22, FIGS. 2A-2C, 3, 4, 5, 6, 7A-7C; Ex. 1005, ¶81.) *Lurie* states that "[b]ecause of its unique shape, the introducer . . . assists in rapid placement of medical devices within the coronary sinus, thereby reducing the amount of time necessary for performance of the medical procedure." (Ex. 1018, 4:62-66.)

iii. [1.c] "an inner, pliable catheter slidably disposed in the outer catheter and of greater length than the outer catheter so that a distal end portion of the inner catheter can be extended or retracted from a distal end opening of the outer catheter to vary the overall length of the double catheter, the inner catheter having an internal lumen configured for the introduction of contrast media and a pacing lead into the coronary sinus; and"

The combination of *Lurie* and *Ockuly* discloses this limitation. (Ex. 1005, ¶82.) As discussed above in Section IX.E.1.i, the combination of *Lurie* and *Ockuly* teaches a system that includes an outer coronary sinus guiding introducer ("outer

catheter"), like the introducer taught in *Lurie*, and an inner guiding introducer ("inner catheter"), like the inner guiding introducer taught in *Ockuly*. (Ex. 1005, ¶82.) *Ockuly* teaches that the inner guiding introducer can be made from a pliable material and that "[t]he inner guiding introducer is preferably longer than the outer guiding introducer so that its distal end may be extended out from the distal end of the outer guiding introducer to form various curves and shapes." (Ex. 1020, 6:36-39, 8:18-21; Ex. 1005, ¶82.)

Ockuly also teaches that the inner guiding introducer includes a lumen configured for the introduction of a medical device under fluoroscopy. (Ex. 1020, 3:44-48, 9:51-56.) *Ockuly* teaches that a proximal end of the introducer is secured to valve for attachment to a conventional side port tubing and stop cock for introduction of the medical device and a fluid such as, for example, the contrast media used in fluoroscopic procedures. (Ex. 1020, 6:50-53; 9:51-56; Ex. 1005, ¶82.) It also teaches that the inner guiding introducer has an internal diameter from about 6 to 12 French for insertion of a medical device. (Ex. 1020, 3:44-48, 8:21-25.) *Lurie* confirms that an introducer having an internal diameter of 4 to 16 French and is configured for the introduction of a pacing lead. (Ex. 1018, 7:33-39.) Based on these disclosures, a PHOSITA would have understood *Ockuly*'s inner guiding introducer to be configured for the introduction of contrast media and a pacing lead into the coronary sinus. (Ex. 1005, ¶82.)

As discussed above in Section IX.E.1.i, it would have been obvious to a PHOSITA to use an inner, telescoping introducer with *Lurie*'s outer coronary sinus guiding introducer to assist with cannulating the coronary sinus. (*Id*.) Substituting the inner telescoping introducer taught in *Ockuly* for the shaped catheter taught in *Lurie* to facilitate insertion of the outer coronary sinus guiding introducer into the coronary sinus would yield predictable results. (*Id*.) *See KSR*, 550 U.S. at 416-17. It would also be an improvement of *Lurie*'s device as it would eliminate the need to exchange tools or withdraw tools from within the outer guiding introducer for placement of the lead. (Ex. 1005, ¶82.)

iv. [1.d] "a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter."

As noted above, the '268 patent discloses that the corresponding structure for the recited function is (1) a torque screw attached to a pull wire or cable anchored close to the tip of the outer catheter, (2) an inner guide, or (3) an inner guide in combination with an obturator, and equivalents thereof. (*See supra* Section VIII.) The combination of *Lurie* and *Ockuly* teach the recited function and at least two of the structures disclosed in the '268 patent corresponding to the recited function or its equivalents as explained below. To the extent the Board determines that this phrase is not a means-plus-function term, the combination of

Lurie and *Ockuly* still discloses this limitation under its plain and ordinary meaning for the reasons discussed below.

As discussed above in Section IX.E.1.i, the combination of *Lurie* and *Ockuly* teaches a system that includes an outer coronary sinus guiding introducer ("outer catheter"), like the introducer taught in *Lurie*, and an inner guiding introducer ("inner catheter"), like the inner guiding introducer taught in *Ockuly*. (Ex. 1005, ¶82.) *Lurie* teaches that "[t]he stiffness of the coronary sinus guiding introducer can [] be enhanced by insertion of a . . . shaped catheter." (Ex. 1018, 8:31-32.) *Ockuly* teaches that the inner guiding introducer can be inserted into the outer guiding introducer and manipulated at a proximal end of the outer guiding introducer "[b]y extending and withdrawing the inner introducer in relation to the outer guiding introducer and by rotating the inner guiding introducer within the outer guiding introducer." (Ex. 1020, 9:46-50.) A PHOSITA would have recognized based on the teachings of *Ockuly* and *Lurie* that the insertion of the inner guiding introducer into *Lurie's* outer, coronary sinus introducer would stiffen and thus reduce the curvature of a precurved distal portion of the outer, coronary sinus guiding introducer. (Ex. 1018, 8:31-33; Ex. 1020, 8:25-26; Ex. 1005, ¶83.) Therefore, the combination of *Lurie* and *Ockuly* discloses the "inner guide" structure disclosed in the '268 patent that corresponds to the claimed function. (*See supra* Section VIII; Ex. 1005, ¶83.)

Ockuly also teaches that the inner guiding introducer can accept a dilator. (Ex. 1020, 8:25-26.) As *Lurie* explains, "a 'dilator' is an inner strengthening element intended to be removed to allow placement of the introducer" and, like an obturator, can be used "as a stiffening means for stiffening the structure" of the introducer. (Ex. 1018, 8:33-37; Ex. 1005, ¶83 (citing Ex. 1007, 8:60-64).) A PHOSITA would have recognized based on the teachings of *Ockuly* and *Lurie* that the insertion of the inner guiding introducer in combination with a dilator into the *Lurie*'s outer, coronary sinus introducer would stiffen and thus reduce the curvature of a precurved distal portion of the outer, coronary sinus guiding introducer. (Ex. 1018, 8:31-33; Ex. 1020, 8:25-26; Ex. 1005, ¶83.) Therefore, the combination of *Lurie* and *Ockuly* also discloses a structure like the "inner guide in combination with an obturator" disclosed in the '268 patent that corresponds to the claimed function. (*See supra* Section VIII; Ex. 1005, ¶83.)

2. Claim 10

i. "The double catheter of claim 1, wherein the mechanism for changing the curvature of the hook shaped distal end comprises a portion of the inner catheter configured to reduce the curvature of the hook shaped distal end when inserted in the outer catheter."

The combination of *Lurie* and *Ockuly* disclose this limitation. (Ex. 1005, ¶84.) As discussed above in Section IX.E.1.i, the combined disclosures of *Lurie* and *Ockuly* teach a system including a coronary sinus guiding introducer ("outer

catheter"), as taught in *Lurie*, and an inner guiding introducer ("inner catheter"), as taught in *Ockuly*, for introduction of a pacing lead into the coronary sinus. (Ex. 1005, ¶84.) As discussed above in Section IX.E.1.iv, the insertion of the inner guiding introducer into *Lurie*'s outer, coronary sinus introducer would change the curvature of the overall shape of the distal end of the guiding introducer system. (*Id*.) For example, a PHOSITA would have recognized that the introduction of the inner guiding introducer through *Lurie*'s outer, coronary sinus introducer would reduce the curvature of the curved distal portion of the coronary sinus introducer, particularly if the inner guiding introducer or catheter was straight or had a minimal curve. (*Id*.; Ex. 1018, 8:55-61.)

F. Ground 5: Claims 1 and 10 Are Obvious Based on *Lurie*, *Ockuly*, and *Blanc*

As discussed in Ground 4, the combination of *Lurie* and *Ockuly* render claims 1 and 10 obvious. (*See supra* Section IX.E.) To the extent the Board finds that *Lurie* and *Ockuly* do not explicitly disclose the introduction of contrast media through a lumen of the inner guiding introducer, it would have been obvious to provide such features given it was common practice at the time of the alleged invention to use contrast media to visualize the anatomy during a procedure for placing a pacing lead in the coronary sinus. (Ex. 1005, ¶85.) For example, *Blanc* describes a method of cannulating the coronary sinus using sheaths/catheters manufactured by Diag Corporation (the assignee of *Lurie* and *Ockuly*). (Ex. 1015,

2022.) In the disclosed method, an electrophysiological (EP) catheter is inserted through the sheath and extended beyond the distal end of the sheath to enter the coronary sinus. (*Id*.) The sheath is then tracked over the catheter into the coronary sinus. (*Id.*) *Blanc* teaches that the catheter has a lumen to inject contrast material during the procedure. (*Id.*) As *Blanc* explains, [t]he anatomy of the coronary sinus can . . . be visualized by injecting a small amount of contrast material" and the location of the sheath can be confirmed in a similar manner. (*Id.*) Based on the teachings of *Blanc*, it would have been obvious to a PHOSITA to have introduction of contrast media through a lumen of the inner guiding introducer, similar to that disclosed by *Blanc*, in the combination of *Lurie* and *Ockuly* in order to assist with entering the coronary sinus and placing a lead in the appropriate branch vein. (Ex. 1005, ¶85.)

X. THE BOARD SHOULD ADOPT ALL PROPOSED GROUNDS IN BOTH PETITIONS FOR THE '268 PATENT

As noted above, Petitioner is filing another IPR petition challenging claims 1, 10-14, 18, 19, and 23-26 of the '268 patent which includes a challenge to the priority date of the '268 patent and proposed grounds based on a different prior art reference, *Norlander*. The Board should adopt all proposed grounds in both petitions in the event that Patent Owner tries to swear behind *Norlander* during trial. Petitioner has narrowed the grounds presented in the petitions to achieve the

goal of "just, speedy, and inexpensive resolution" consistent with 37 C.F.R. § 42.1(b).

XI. CONCLUSION

For the reasons given above, Petitioner requests *inter partes* review and cancellation of claims 1, 10-14, 18, 19, and 23-26 of the '268 patent.

Respectfully submitted,

Dated: February 12, 2018

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CERTIFICATION OF WORD COUNT UNDER 37 C.F.R. § 42.24(d)

The undersigned certifies that the foregoing Petition for *Inter Partes* Review contains 13,676 words according to the word count of the word-processing software used to prepare the petition.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition for *Inter Partes* Review and supporting materials were served on February 12, 2018, by express mail at the following address of record as listed on PAIR.

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