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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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1019	U.S. Patent No. 5,935,160 to Auricchio et al. ("*Auricchio*")
1020	U.S. Patent No. 5,833,673 to Ockuly ("*Ockuly*")
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, 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 vein of a coronary sinus 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.

As the '268 patent acknowledges, the medical procedure of placing a lead in a lateral branch vein of the coronary sinus to pace the left ventricle of the heart was known by those skilled in the art. (*Id.*, 1:56-59.) Shaped catheters designed for use in the coronary sinus were also known in the art before the earliest filing date of the '268 patent. (*Id.*, 1:41-43.) In fact, the use of a double catheter to implant a lead in a lateral branch vein of the coronary sinus was already described in U.S. Patent No. 6,562,049 to Norlander et al. ("*Norlander*") and its related provisional application, which predate the earliest effective filing date of the '268 patent. 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 challenging the '268 patent based on prior art references having earlier prior art dates.

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**: Claims 1, 10, 11, 12, and 24 are unpatentable under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 6,562,049 to Norlander et al. ("*Norlander*") (Ex. 1007);
- **Ground 2**: Claims 10 and 24 are unpatentable under 35 U.S.C. § 103 as obvious over *Norlander*; and
- **Ground 3**: Claims 13, 14, 18, 19, 23, 25, and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over *Norlander* and International Publication No. WO 99/49773 to Payne et al. ("*Payne*") (Ex. 1009).

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,

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[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).

2003, and purportedly claims priority to U.S. Provisional Application No. 60/195,701 (Ex. 1002), filed on April 7, 2000. (Ex. 1001, 1:4-5.)

A. Overview of the Technology

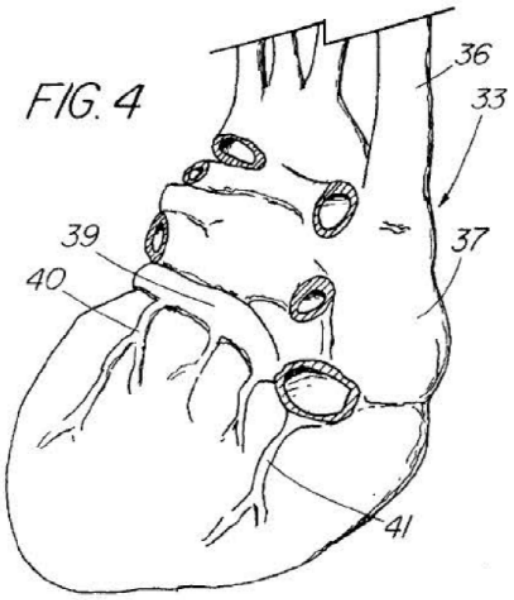
A typical human heart includes four chambers: a right ventricle, a right atrium, a left ventricle, and a left atrium. (Ex. 1005, ¶16.) Blood from the body enters the right atrium though the vena cava and flows into the right ventricle where it is pumped to the lungs through the pulmonary artery. (*Id*.)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

[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.)

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 common for physicians to use a catheter[3] to access the coronary sinus, including for lead implantation. (Ex. 1005, ¶24; Ex. 1014, 406; Ex. 1015, 2222.) 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-

[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.)

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, ¶23; Ex. 1013, 139D-142D.) Physicians used various techniques to implant the available leads.[4] (Ex. 1005, ¶25.) In one known 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, "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

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

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 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, 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 out 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.)

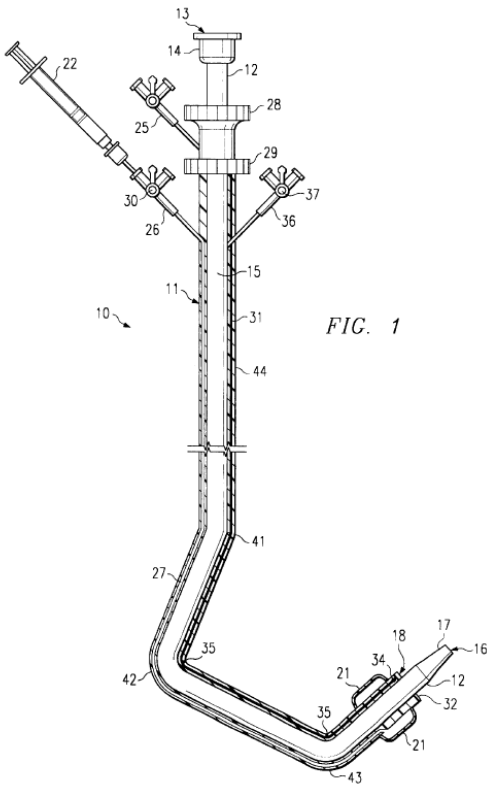


FIG. 1

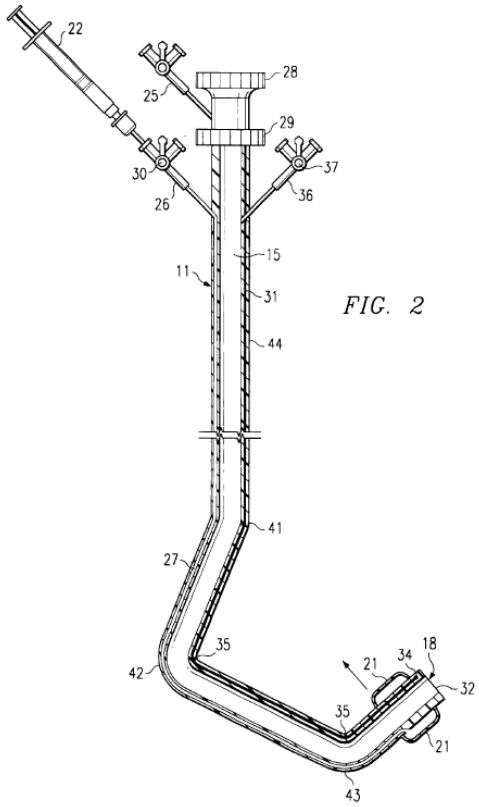


FIG. 2

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.*,

[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.)

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 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.)

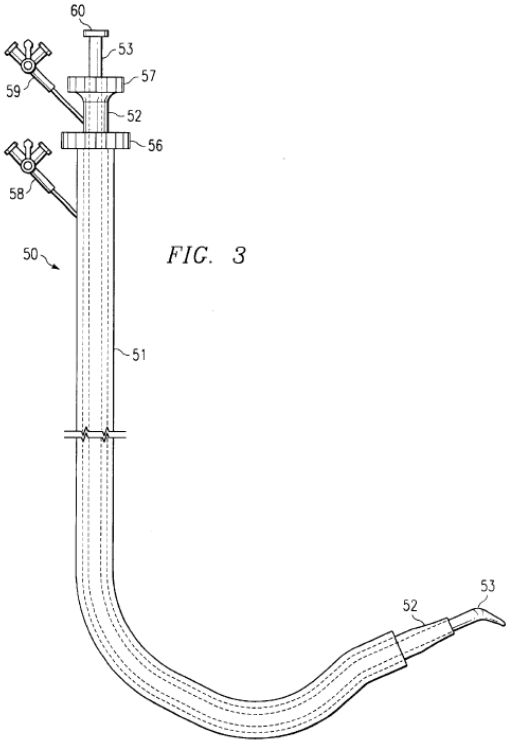


FIG. 3

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.)

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.) As demonstrated in Section IX, the challenged claims of the '268 patent have an effective filing date of April 6, 2001, because they are not entitled to claim a right of priority to U.S. Provisional Application No. 60/195,701.

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 claimed angles or describe the claimed methods for leaving a lead wire in a branch vein. (*Id.*, 72, 82.)[6]

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

[6] 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.

electrophysiologist, or interventional cardiologist having experience using catheters (or introducers or sheaths) in the heart, including catheters used for placement of, for example, leads.[7] (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." 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

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

remaining terms should be interpreted in accordance with their plain and ordinary meaning under the BRI standard.[8]

A. <u>"mechanism . . . for"</u>

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. 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,

[8] 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.

"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 (1) an inner guide or (2) 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 EFFECTIVE PRIORITY DATE OF THE '268 PATENT CLAIMS IS APRIL 6, 2001

The Board may consider priority in IPR proceedings. *SAP Am., Inc. v. Pi-Net Int'l, Inc.*, IPR2014-00414, Paper 11 at 11-16 (P.T.A.B. Aug. 18, 2014). Under 35 U.S.C. § 119(e)(1), a claim in a U.S. application is entitled to the benefit of the filing date of an earlier filed U.S. provisional application if the subject

matter of the claim is disclosed in the earlier filed application in accordance with the written description requirement. *See New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co. and Earth Tool Company, L.L.C.*, 298 F.3d 1290 (Fed. Cir. 2002) (citing 35 U.S.C. § 119(e)(1)). The written description requirement is satisfied with "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). When a limitation in a claim "is not present in the written description whose benefit is sought[,] it must be shown that a POSITA would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998). "It is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure . . . . Rather, it is a question whether the application necessarily discloses that particular device." *Id.* at 1353-54. In other words, it must be shown that "any absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent application was filed." *Id.* at 1354-55. That is not the case here. The challenged claims are not entitled to the priority date of U.S. Provisional Application No. 60/195,701 ("the provisional application").

A. Claims 11, 12, and 24

The provisional application does not provide adequate written support for the method of claims 11, 12, and 24, including the step of "advancing [an] inner catheter out of a front end opening of [an] outer catheter along [a] guide wire into [a] branch vein" of the coronary sinus as recited in independent claims 11 and 24. The provisional application does not describe this step. The provisional application discloses advancing the double catheter to the right atrium over a guide wire, and then states that "[t]he guide wire and sheath are then removed" ***before*** the catheter is advanced into the coronary sinus, and ***before*** any catheter or lead is advanced into a branch vein of the coronary sinus. (Ex. 1002, 3-4.) It never discloses reinserting a guide wire into the coronary sinus branch vein. Nor does it disclose that the inner catheter is to be advanced into the branch vein let alone over a guide wire. Even if this were one of several possible techniques available to a PHOSITA at the time of the provisional filing date (*see supra* Section VI.A), this would not satisfy the written description requirement as a PHOSITA would not have understood the provisional application to disclose the claimed method. (Ex. 1005, ¶¶42-43.)

Moreover, the non-provisional application added a new embodiment including "an outer guide catheter 51, an inner guide catheter 52 nested therein, [and] an obturator 53 nested inside the inner guide 52." (*Compare* Ex. 1003, 7:14-

15 *with* Ex. 1002; Ex. 1005, ¶44.) The non-provisional application explicitly states that, in this embodiment, "[i]nner catheter 52 is designed to advance over a guide wire into a side branch of the coronary sinus," a disclosure lacking from the provisional application. (Ex. 1003, 7:26-27.) Given that the disclosure of advancing an inner catheter along a guide wire into a branch vein was first introduced in the non-provisional application, claims 11 and 24 are not entitled to a priority date earlier than April 6, 2001, the filing date of the '268 patent.

Claim 12 depends from claim 11 and incorporates all of the features of claim 11. For at least the reasons discussed above, the provisional application does not provide adequate support for claim 12. (Ex. 1005, ¶45.) Therefore, claim 12 is also not entitled to a priority date earlier than April 6, 2001.

B. Claims 13, 14, 18, 19, 23, 25, and 26

The provisional application does not provide adequate written support for an outer catheter including three bends with "a first bend adjoining a straight, proximal portion of the outer catheter [that] is in the range of 130° ***to 180°***, a second, intermediate . . . in a direction opposite the first bend, and a third bend . . . in the same direction as the second bend" as recited in claims 13, 18, and 25, or that "the first bend ***equals 180°***, rendering the outer catheter substantially J-shaped" as recited in claims 14, 19, and 26. An outer catheter with three bends including a first bend that equals 180° (*i.e.*, no first bend) is not expressly

described in the provisional application. This disclosure was first added in the non-provisional application, where the specification explains that an angle of 180° is actually "no bend." (*Compare* Ex. 1002 *with* Ex.1003, 11.)

As filed, the provisional application included a six-page description, an abstract, 8 claims, and 9 figures. (Ex. 1002.) The only description of the shape of the outer catheter in the provisional application is in claim 8 and in the figures. Clam 8 depends from claim 7, which further depends from claim 1. Together these claims disclose an outer catheter having a hook-shaped distal end with ***three*** bends including "a first bend adjoining a straight, proximal portion of the outer catheter" in "the range of 130° ***to 175***°." (Ex. 1002, 5-6.) While the provisional application also includes a figure that depicts a curved, generally J-shaped double catheter (*See, id.*, FIG. 8), it does not depict a catheter with straight sections joined by bends or disclose the angles of any such bends. A PHOSITA would not have understood the provisional application to disclose a catheter with three bends having a first of three bends over 175°, including 180°, *i.e.*, "no bend." (Ex. 1005, ¶¶46-47.) Therefore, claims 13, 14, 18, 19, 25, and 26 are not entitled to a priority date earlier than April 6, 2001, the filing date of the '268 patent.

Claim 23 depends from claim 18 and incorporates all of the features of claim 18. For at least the reasons discussed above, the provisional application does not

provide adequate support for claim 23. (Ex. 1005, ¶48.) Therefore, claim 23 is also not entitled to a priority date earlier than April 6, 2001.

C. Claims 1 and 10

Claim 1 recites "a mechanism operable from the proximal end of the outer catheter for changing the curvature of the distal end of the outer catheter." As discussed *supra* at Section VIII.A, the "mechanism" term should be construed as a means-plus-function term under § 112, para. 6. As the Federal Circuit has explained, the proper analysis for determining priority of means-plus functions claims includes determining priority by ***first*** construing the means-plus-function claims under § 112, para. 6, and ***then*** determining if the earlier application described the invention with all of its claim limitations to show possession of the claimed subject matter as of the date of the filing. *See Uniloc USA, Inc. v. Sega of Am., Inc.*, 2017 WL 47772565 *3 (Fed. Cir. Oct. 23, 2017). Courts have held that each of the structures corresponding to a means-plus-function claim must be recited in an earlier application for the claim to gain the benefit of the earlier priority date. *See Uniloc USA, Inc. v. Sega of Am., Inc.*, 2017 WL 47772565 *3; *Lucent Tech., Inc. v. Gateway, Inc.*, 543 F.3d 710, 719 (Fed. Cir. 2008) (finding that a claim with means-plus-function claim term corresponding to several structures was not entitled to filing date of the earliest priority application because the structures were not disclosed in that application); *Automotive Tech. Int'l, Inc. v.*

Delphi Corp., 776 F. Supp. 2d 469, 492 (E.D. Mich., March 9, 2011) (holding that "each and every structure corresponding to a means-plus-function claim found in a continuation-in-part application, as construed in a Markman order, must be recited in a parent application for the claim to gain the benefit of the parent's priority date").

As discussed above, the structure corresponding to the claimed function for the recited "mechanism" term in claim 1 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. (*Supra* Section VIII.A.) Contrary to what is required, the provisional application does not disclose at least that an inner guide alone or in combination with an obturator is configured to reduce the curvature of an outer catheter. (Ex. 1005, ¶¶49-50.) These disclosures were first introduced in the non-provisional application. (*Compare* Ex. 1003, 9:4-14 *with* Ex. 1002.) For at least this reason, claim 1 is not entitled to a priority date earlier than April 6, 2001, the filing date of the '268 patent.

Claim 10 depends from claim 1 and incorporates all of the features of claim 1. For at least the reasons discussed above, the provisional application does not provide adequate support for claim 10. (Ex. 1005, ¶51.) Therefore, claim 10 is also not entitled to a priority date earlier than April 6, 2001.

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

The challenged grounds rely on *Norlander* alone or in combination with *Payne*, neither of which were considered during prosecution of the '268 patent. Moreover, as explained in detail below, a PHOSITA would have combined the teachings of the references with a reasonable expectation of success.

A. Overview of Prior Art

1. *Norlander*

Norlander was filed on November 9, 2000 and issued on May 13, 2003. (Ex. 1007.) Because the challenged claims are not entitled to any priority date earlier than the filing date of the '268 patent, i.e., April 6, 2001 (*see supra* Section IX), *Norlander* is prior art under pre-AIA 35 U.S.C. § 102(e) as of its November 9, 2000 filing date.

Even if the challenged claims of the '268 patent were entitled to the date of its provisional application, *Norlander* would still be prior art under Section 102(e). *Norlander* claims priority to U.S. Provisional Application No. 60/185,996 ("the '966 provisional") (Ex. 1008), filed March 1, 2000. (Ex. 1007.) *Norlander* was filed within one year of its '966 provisional filing, names at least one inventor in common, and includes a specific reference to the '966 provisional. (*Id.*) Petitioner submits that at least claim 1 of *Norlander* is fully supported and enabled by the '966 provisional, and provides the following exemplary mapping:

Claim Language	**Support in '966 provisional (Ex. 1008)**
A medical introducer apparatus, comprising:	*See, e.g.*, Ex. 1008, Title, 7:11-14, FIG. 1
a first introducer sheath having a distal end, a proximal end and at least a first passageway extending therethrough;	*See, e.g.,* Ex. 1008, 7:11-14, 11:26-12:1, 16:8-10, 17:2-5, FIGS. 1, 7, 8
a second introducer sheath having a distal end, a distal portion, a proximal end, and at least a first passageway extending therethrough;	*See, e.g.*, Ex. 1008, 7:11-14, 10:17-18, 11:11-20, 16:5-8, FIGS. 1, 5, 6
the first and second introducer sheaths configured to be longitudinally splittable;	*See, e.g.*, Ex. 1008, 7:14-19, 9:16-20, 9:22-10:8
the first and second introducer sheaths further configured to co-extend into a bodily passage, whereby the distal portion of the second introducer sheath is at least partly extendable beyond the distal end of the first introducer sheath;	*See, e.g.*, Ex. 1008, 3:11-18, 3:20-4:2, 7:11-14, 7:20-25, FIGS., 1, 3, 3a, 4a
wherein the first introducer sheath	*See, e.g.*, Ex. 1008, 3:20-24, 8:9-9:3,

includes a preformed bend in a portion of said sheath that extends in said bodily passage.	FIG. 1

(*See also* Ex. 1005, ¶52.) Moreover, as detailed throughout this petition by way of citations to both *Norlander* and the '966 provisional, the teachings that Petitioner relies upon were carried forward from the '966 provisional to *Norlander*. Thus, *Norlander* is entitled to claim a right of priority under 35 U.S.C. § 119(a) to the '966 provisional. *See Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1381-82 (Fed. Cir. 2015); *see also Ex Parte Robert A. Mann and Eric Colaviti,* Appeal 2015-003571, 2016 WL 7487271, at *6 (P.T.A.B Dec. 21, 2016) (holding that under *Dynamic Drinkware*, a non-provisional application can be entitled to the benefit of a provisional application's filing date if the provisional application provides sufficient support for at least one claim of the non-provisional); *Cisco Sys., Inc. v. Capella Photonics, Inc.,* IPR 2014-01276, 2016 WL 783545, at *9 (P.T.A.B Jan. 28, 2016) (citing *Dynamic Drinkware,* 800 F.3d at 1375). Accordingly, subject matter in *Norlander* described in the '966 provisional is prior art under pre-AIA 35 U.S.C. § 102(e), with an effective filing date of March 1, 2000.

Norlander discloses an introducer apparatus 10 used for placement of a pacemaker or defibrillator lead into a vein branching from the coronary sinus to

stimulate the left side of the heart. (Ex. 1007, 2:34-36; *see also* Ex. 1008, 3:3-5, 3:11-14, 3:25-4:2, 8:2-8; Ex. 1005, ¶53.) As shown below in FIG. 1, introducer apparatus 10 includes "a first introducer sheath 11, such as an outer introducer sheath 11, and a second introducer sheath 12, such as a coaxial inner introducer sheath 12." (Ex. 1007 at 4:48-52; Ex. 1008 at 7:11-14.) Inner introducer sheath 12 (identified in green) is longer than outer introducer sheath 11 (identified in orange) to reach a target site in the coronary vasculature that is otherwise difficult to access. (*See* Ex. 1007, 2:22-26, 2:39-43, FIG. 1; *see also* Ex. 1008, 3:14-18, FIG. 1; Ex. 1005, ¶¶54-55.) The sheaths 11, 12 are splittable to facilitate its removal from the patient without disturbing the lead placed within the patient. (*See* Ex. 1007, 4:52-58, 6:50-61; Ex. 1008, 7:14-19, 9:16-20.)

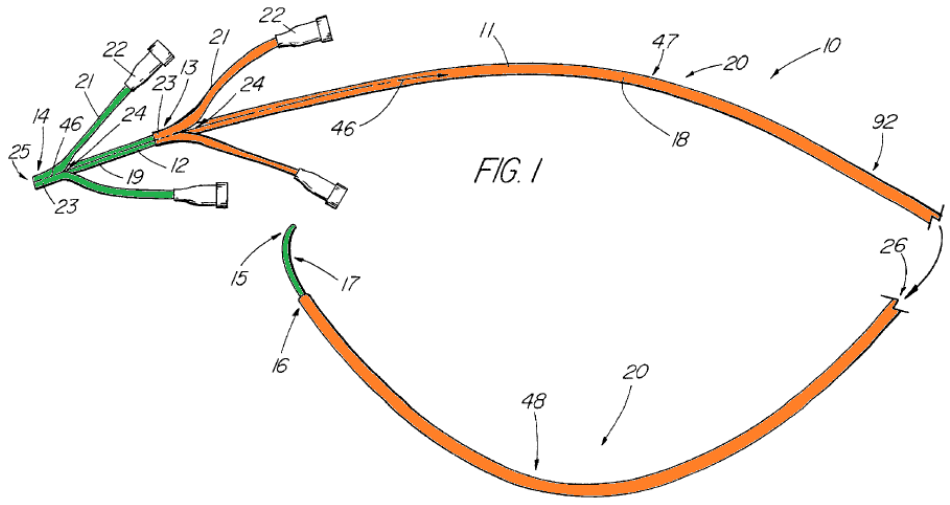


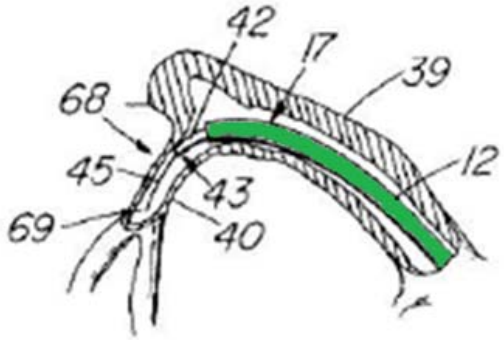
FIG. 1

Norlander teaches that outer introducer sheath 11 is introduced over a wire guide 45 through the subclavian vein 34 and into the right atrium 37 to the coronary sinus ostium 38. (*See* Ex. 1007, 6:17-28, 7:15-16, 7:52-57, FIG. 3; Ex.

1008, 8:24-8:26, 10:9-10, 10:25-11:1, FIG. 3; ¶56.) Outer introducer sheath 11 "is designed to be placed at the opening to, or within the coronary sinus" and includes at least one preformed bend 20 that "helps in the navigation of the sheath to the target site." (Ex. 1007, 2:51-52; Ex. 1008, 3:20-22.) In the exemplary embodiment shown in FIG. 1, outer introducer sheath 11 includes a bend 48 having "a tight[] radius in order to provide posterolateral access to the coronary sinus ostium." (Ex. 1007, 6:26-28, FIG. 1; Ex. 1008, 9:2-3, FIG. 1.) *Norlander* also teaches the use of a "steerage member," e.g., a dilator, obturator, or deflectable tip device, etc., to assist with the introduction and placement of outer introducer sheath 11. (Ex. 1007, 7:36-39; *see also* Ex. 1008, 10:25-11:9; Ex. 1005, ¶57.)

Once outer introducer sheath 11 is positioned within the coronary sinus 39, inner introducer sheath 12 (identified in green) is advanced over the wire guide to a second target site 68 which, in the illustrative example depicted in FIG. 4a below, is in posterior vein 40. (Ex. 1007, 2:60-64, 8:17-21, FIG. 4a; Ex. 1008, 3:28-4:2, 11:13-16, FIG. 4a; Ex. 1005, ¶58.)

FIG. 4a



Norlander explains that "it is often desirable to be able to inject contrast media to improve visualization under fluoroscopy" and teaches injecting contrast media through a passageway of inner introducer sheath 12. (*See* Ex. 1007, 3:53-56, 9:55-58, FIG. 5; Ex. 1008, 5:14-16, 14:3-6, FIG. 5.) Once the inner introducer sheath 12 is advanced to a second target site 68, the lead is advanced through the inner introducer sheath 12. (Ex. 1007, 8:19-26; Ex. 1008, 11:16-20, FIG. 4a.) The sheaths 11, 12 are then split and removed from around the lead, leaving the lead behind in the branch vein of the coronary sinus, as intended. (*See* Ex. 1007, 8:26-29, 8:38-43; Ex. 1008, 11:20-22, 12:1-5; Ex. 1005, ¶59.)

2. *Payne*

Payne published October 7, 1999. (Ex. 1009.) Because the challenged claims are not entitled to any priority date earlier than the filing date of the '268 patent, i.e., April 6, 2001 (*see supra* Section IX), *Payne* is prior art under pre-AIA 35 U.S.C. § 102(b). Even if the challenged claims of the '268 patent were entitled to the date of its provisional application, *Payne* would still be prior art under 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, ¶¶60-61.) 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 "delivery catheters 11 and 12 can be proximally manipulated and positioned relative to each other by translation and rotation to achieve a desired position and angular orientation during a procedure." (*Id.*, 12:17-21.)

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.) *Payne* teaches an embodiment of first delivery catheter 11, shown in Figure 5, which "has a shaped distal shaft section 13 with a first segment 53 and a second segment 57." (*Id.*, 17:1-3.)

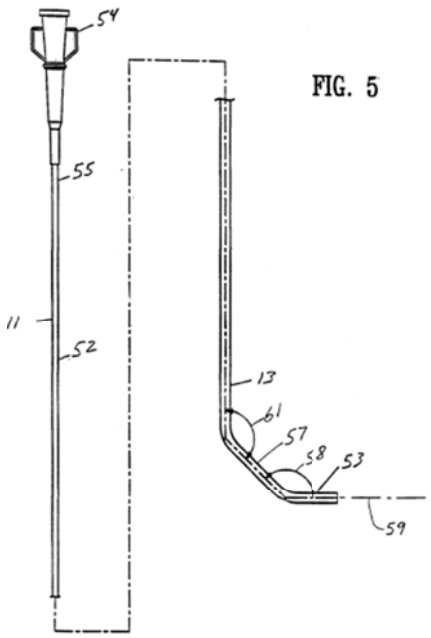


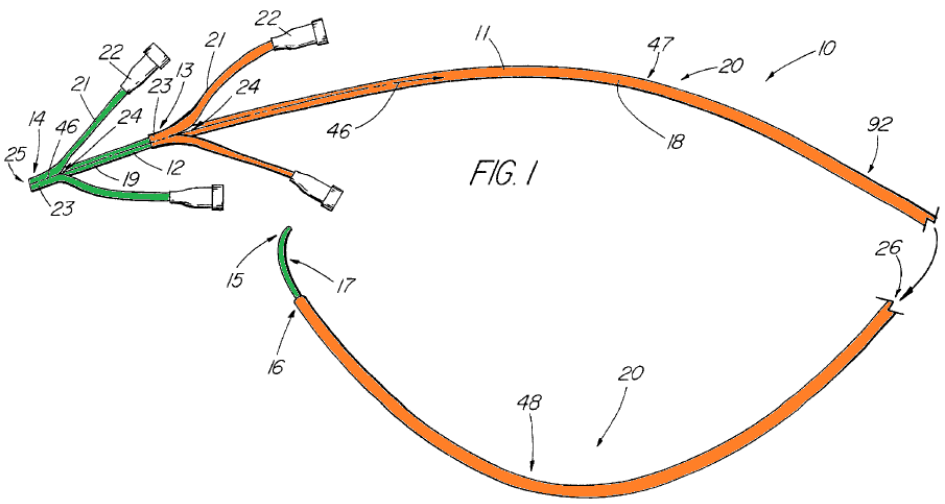
FIG. 5

According to *Payne*, "first 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." (*Id.*, 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.)

B. Ground 1: Claims 1, 10, 11, 12, and 24 Are Anticipated By *Norlander*

1. Claim 1

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

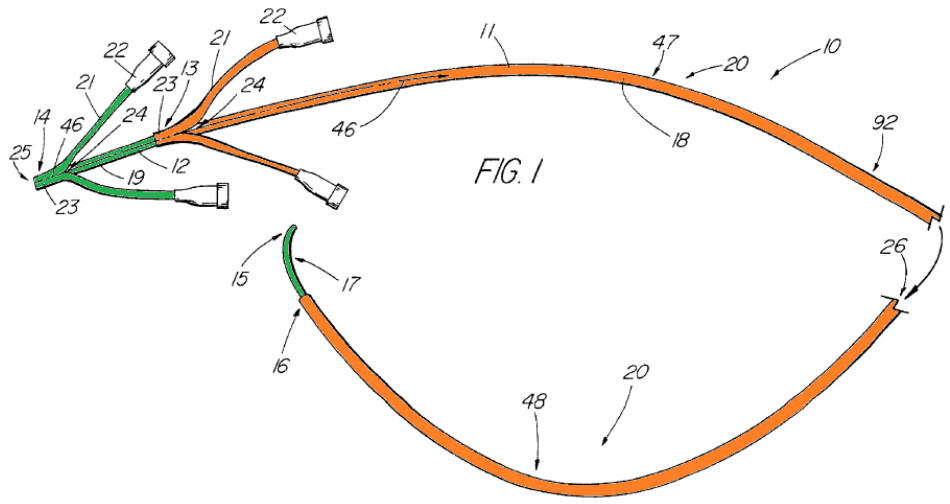


To the extent the preamble is limiting, *Norlander* describes an introducer apparatus 10 ("a double catheter") formed of co-extending introducer sheaths 11, 12. (Ex. 1007, Abstract, 2:18-26, 4:48-52, 4:58-5:1, FIG. 1; Ex. 1008, 3:11-14, 7:11-14, FIG. 1; *see also infra* Sections X.B.1.ii-vi; Ex. 1005, ¶¶62-63.) As shown in FIG. 1 above, introducer apparatus 10 includes an outer introducer sheath 11 (identified in orange) and an inner introducer sheath 12 (identified in green). (Ex.

1007, 4:48-52, 5:20-23, FIG. 1; Ex. 1008, 7:11-14, FIG. 1.) Outer introducer sheath 11 and inner introducer sheath 12 are co-axially arranged with inner introducer sheath 12 extending beyond a distal end 16 of outer introducer sheath 11 to reach a target site in the coronary vasculature that is otherwise difficult to access. (*See* Ex. 1007, 2:22-26, 2:39-43, FIG. 1; *see also* Ex. 1008, 3:14-18, FIG. 1; Ex. 1005, ¶63.)

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;"

Norlander's introducer apparatus 10 includes an outer introducer sheath 11 ("an outer, resilient catheter") identified in orange in FIG. 1 reproduced below.



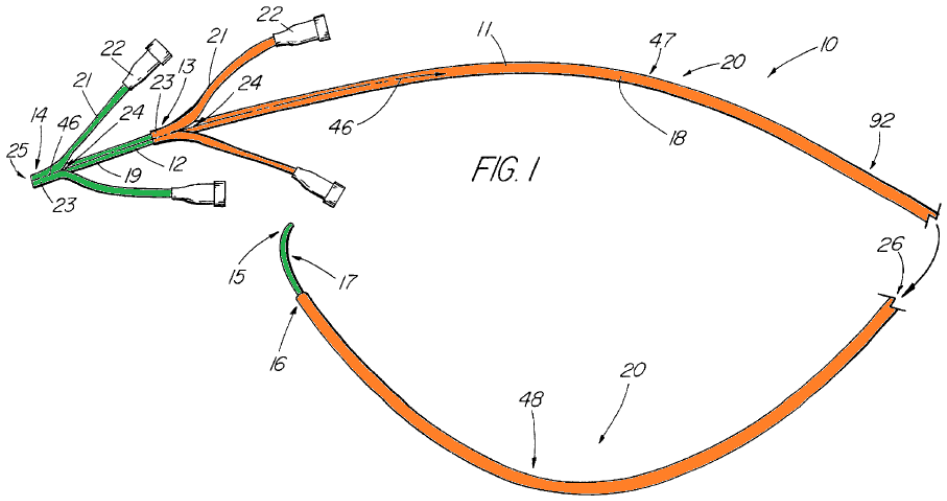
(Ex. 1007, 4:48-52, 5:20-23, FIG. 1; Ex. 1008, 7:11-14, FIG. 1.) *Norlander* discloses that outer introducer sheath 11 can be made from any splittable polymer and teaches that, in one embodiment, outer introducer sheath 11 is formed of a molecularly oriented (non-isotropic) polytetrafluroroethylene (PTFE). (Ex. 1007,

2:44-46, 6:67-7:6; Ex. 1008, 3:18-20, 9:22-27.) Outer introducer sheath 11 is resilient as it can navigate the curves and bends of the anatomical pathway to the coronary sinus. (*See* Ex. 1007, 6:20-26, FIG. 3; Ex. 1008, 8:24-9:3, FIG. 3; Ex. 1005, ¶64.) It is also resilient as it can be deflected using a steerable/deflectable device 74. (*See* Ex. 1007, 9:8-13; Ex. 1008, 13:1-6.) In fact, *Norlander* explains that outer introducer sheath 11 can be elastically deformed. (*See* Ex. 1007, 8:9-14.)

A PHOSITA would have understood outer introducer sheath 11 to have shape memory as it is formed with at least one preformed bend 20 and would return to this shape when undistorted. (Ex. 1007, 5:64-6:5; Ex. 1008, 8:9-13; Ex. 1005, ¶64.) In the exemplary embodiment shown in FIG. 1, outer introducer sheath 11 includes a preformed bend 20 at distal end 16 having a "hook-shaped" configuration. (Ex. 1007, FIG. 1; Ex. 1008, FIG. 1; Ex. 1005, ¶64.) This shape is formed by a distal bend or curve 48 having "a tight[] radius in order to provide posterolateral access to the coronary sinus ostium." (Ex. 1007, 6:12-16, 6:26-28, FIG. 1; Ex. 1008, 8:21-24, 9:2-3, FIG. 1.) *Norlander* teaches that distal end 16 of outer introducer sheath 11 is configured for cannulation of the coronary sinus. (Ex. 1007, 2:49-52, 6:12-16, 6:26-28; Ex. 1008, 3:20-22, 8:21-24, 9:2-3.)

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"

Norlander's introducer apparatus 10 includes an inner introducer sheath 12 ("an inner, pliable catheter") identified in green in FIG. 1 reproduced below.



(Ex. 1007, 4:48-52, 5:20-23, FIG. 1; Ex. 1008, 7:11-14, FIG. 1.) *Norlander* describes inner introducer sheath 12 as pliable as it is "smaller," "less stiff," and has "increased flexibility" as compared to outer introducer sheath 11. (Ex. 1007, 2:28-32, 4:64-5:1, 6:35-37; Ex. 1008, 4:3-6, 9:9-10; *see also* Ex. 1005, ¶65.) Inner introducer sheath 12 is co-axially disposed within outer introducer sheath 11 and of greater length than outer introducer sheath 11 so that a distal end portion 17 of inner introducer sheath 12 can be extended or retracted from a distal end 16 of

outer introducer sheath 11 to vary the overall length of introducer apparatus 10. (*See* Ex. 1007, 2:39-43, 4:48-52, 5:52-60, 8:15-21, FIG. 1; Ex. 1008, 3:14-18, 7:11-14, 8:2-8, 11:14-16, FIG. 1.)

Norlander discloses that inner introducer sheath 11 includes an internal lumen or passageway 25 configured for the introduction of contrast media and a pacing lead.[9] (Ex. 1007, 7:44-47, 11:6-11, 11:58-65, FIG. 6; *see also* Ex. 1008, 16:5-8, 17:17-23; Ex. 1005, ¶65.) *Norlander* teaches that passageway 25 is configured for the introduction of a lead as it discloses that a lead is advanced through inner introducer sheath 12 to a second target site 68 in the coronary vasculature. (*See* Ex. 1007, Abstract, 8:21-26; Ex. 1008, 11:16-20.) The passageway 25 is also configured for the introduction of contrast media which is injected into the vasculature from distal portion 17 of inner introducer sheath 12 to

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[9] *Norlander* also includes an embodiment in which inner introducer sheath 12 includes passageway 25 and a second passageway 52. (Ex. 1007, 11:6-11, FIG. 6; Ex. 1008, 16:5-8, FIG. 6.) In this embodiment, passageway 25 is the "primary" passageway and second passageway 52 is incorporated in sheath wall 65 and is only "used as an inflation lumen or if made larger, could accommodate an ancillary device 54." (Ex. 1007, 11:6-11, FIG. 6; Ex. 1008, 16:5-8.)

visualize the anatomy under fluoroscopy. (*See* Ex. 1007, 3:53-56, 9:55-58, 10:63-64, FIG. 5; Ex. 1008, 5:14-16, 14:3-6, 15:26-27, FIG. 5.)

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 discussed 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.A.) *Norlander* discloses the recited function and also discloses at least one of the structures disclosed in the '268 patent corresponding to the recited function or its equivalents as explained below. (Ex. 1005, ¶66.) To the extent the Board determines that this phrase is not a means-plus-function term, *Norlander* still discloses this limitation under its plain and ordinary meaning for the reasons discussed below. (*Id.*)

Norlander discloses changing the curvature of the distal end 16 of outer introducer sheath 11 using a steerable/deflectable device 74. (Ex. 1007, 9:2-13; Ex. 1008, 13:1-6.) *Norlander* teaches that device 74 can be used with an outer introducer sheath 11 having one or more preformed bends. (Ex. 1007, 9:34-40.) Steerable/deflectable device 74 can be inserted or incorporated into outer introducer sheath 11 which "permits the tip of the sheath to be deflected into the

optimum position for advancing the sheath to the target area or providing an improved position such that the inner introducer sheath 12 can be then advanced to the target site." (Ex. 1007, 9:2-13; Ex. 1008, 13:1-6.) *Norlander* teaches that steerable/deflectable device 74 is operable from the proximal end of outer introducer sheath 11 as it includes a deflection control means 75, such as a flexible rod, wire, suture, etc., that is attached to the distal end of device 74 and extends proximally to a control handle that affects the degree of deflection of distal end of outer introducer sheath 11. (Ex. 1007, 9:21-28; Ex. 1008, 13:11-17.)

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."

As discussed above, the '268 patent discloses three alternative structures "for changing the curvature of the hook shaped distal end." (*See supra* section VIII.A.) Claim 10 specifies one of these structures.

As discussed above for claim 1, outer introducer sheath 11 includes a hook-shaped distal end 16. (*See supra* Section X.B.1.ii.) *Norlander* teaches that the curvature distal end 16 can be reduced by insertion of inner introducer sheath 12 through outer introducer sheath 11. (Ex. 1007, 8:9-14; Ex. 1005, ¶67.) In particular, *Norlander* explains that "it is possible for the preformed inner member,

such as a dilator 27, obturator, ***or inner introducer sheath 12, to either elastically or plastically deform the outer member***, such as an introducer sheath 11, 12, depending on the physical properties of inner and outer members." (*Id.* (emphasis added).)[10]

To the extent that Patent Owner argues that the subject matter of claim 10 is supported by Niazi's provisional application, teachings included in the '966 provisional and carried forward to *Norlander* also inherently disclose the subject matter of claim 10. *Norlander* and its '966 provisional teach that inner introducer sheath 12 is introduced through outer introducer sheath 11 and of greater length

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[10] The teachings Petitioner relies upon are prior art as of *Norlander*'s November 9, 2000 filing. As discussed above, the Niazi provisional application does not provide support for at least two of the structures corresponding to the claimed function recited in the "mechanism for" term of claim 1. For this reason, claim 1 is not entitled to a priority date earlier than April 6, 2001 and claim 10, which incorporates all of the features of claim 1, is also not entitled to a priority date earlier than April 6, 2001. Therefore, *Norlander* is prior art as of its November 9, 2000 filing. To the extent that Patent Owner argues and the Board finds that claim 10 is entitled to an earlier priority date (which Petitioner does not agree), *Norlander* is still prior art as of the filing date of the '966 provisional.

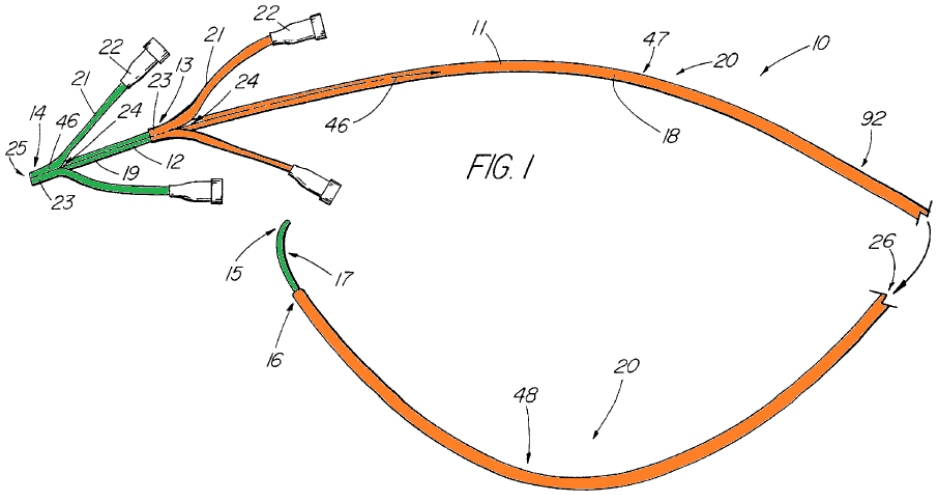
than outer introducer sheath 11 so that a distal end portion 17 of inner introducer sheath 12 can be extended or retracted from a distal end 16 of outer introducer sheath 11. (Ex. 1007, 2:39-43, 4:48-52, 5:52-60, 8:15-21, FIG. 1; Ex. 1008, 3:14-18, 8:2-8, 11:14-16, FIG. 1.) To the extent that Patent Owner argues that Niazi's provisional application teaches that "a portion of the inner catheter" is "configured to reduce the curvature of the hook shaped distal end when inserted in the outer catheter", insertion of inner introducer sheath 12 through distal end 16 of outer introducer sheath 11 would also reduce the curvature of distal curve 48 when extended through distal end 16 of outer introducer sheath 11. (Ex. 1005, ¶67.)

3. 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:"

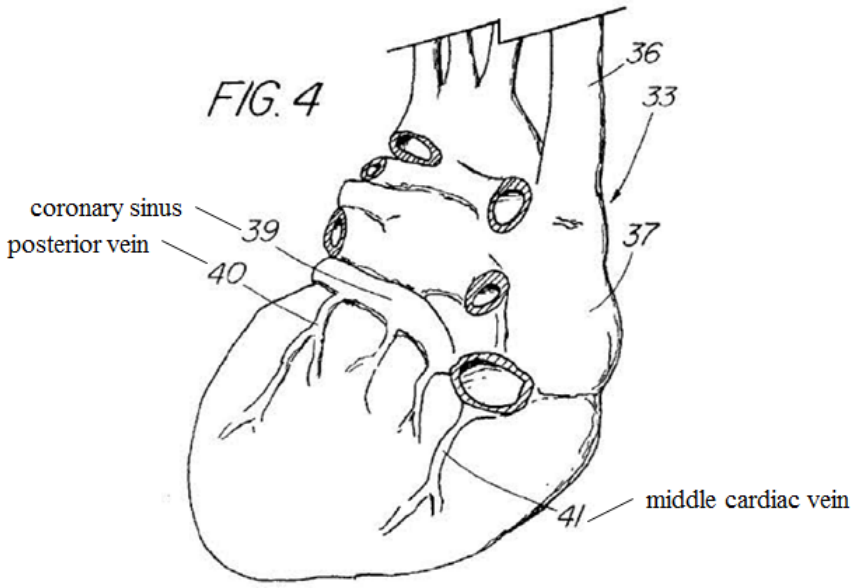
To the extent the preamble is limiting, *Norlander* discloses a method for placing a pacemaker lead—which is an electrical lead—in a lateral branch vein of the coronary sinus using an introducer apparatus 10 ("double catheter"). (*See, e.g.*, Ex. 1007, 7:15-8:43, FIGS. 3, 3a, 4, 4a; Ex. 1008, 10:9-12:5, FIGS. 3, 3a, 4, 4a; *see also infra* Sections X.3.ii-vi; Ex. 1005, ¶¶68-69.) Introducer apparatus 10 includes an outer introducer sheath 11 ("an outer catheter", identified in orange)

and an inner introducer sheath 12 ("an inner catheter", identified in green). (Ex. 1007, 4:48-52, FIG. 1; Ex. 1008, 7:11-14, FIG. 1.)



Inner introducer sheath 12 is slidably disposed within outer introducer sheath 11. (Ex. 1007, 2:39-42, 5:52-60, 8:15-21, FIG. 1; Ex. 1008, 3:14-18, 8:2-8, 11:14-16, FIG. 1.)

Figure 4 from *Norlander* (reproduced below) is an illustration of the left side of the heart from a posterior view, which shows the coronary sinus 39 and its venous branches, including the posterior vein 40 and the middle cardiac vein 41. (Ex. 1007, 7:31-35, FIG. 4; Ex. 1008, 10:22-25, FIG. 4.)



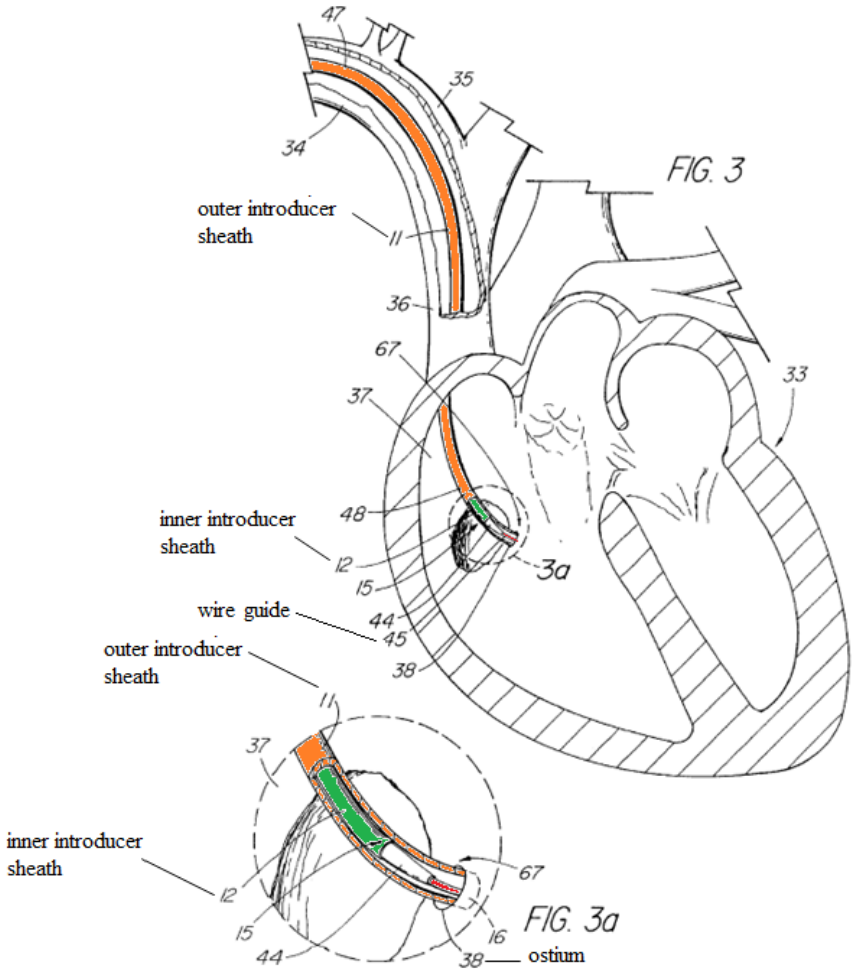
Norlander describes that introducer apparatus 10 is used to place a lead within a lateral branch of a coronary sinus vein such as, for example, the posterior vein 40. (Ex. 1007, Abstract, 2:49-3:4, 5:20-38, 7:15-8:43, FIGS. 3, 3a, 4, 4a; Ex. 1008, 3:20-4:7, 7:19-25, 10:9-12:5, FIGS. 3, 3a, 4, 4a.) A PHOSITA would have understood the posterior vein 40 to include branches that extend along and drain the lateral wall of the left ventricle. (Ex. 1005, ¶¶22, 69.) *Norlander* also contemplates placing the lead in the middle cardiac vein 41, which can include branches that extend to the lateral wall of the left ventricle. (Ex. 1007, 7:29-35; Ex. 1008, 10:20-25; Ex. 1005, .)

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

Norlander discloses inserting introducer apparatus 10 into the coronary sinus. (*See, e.g.*, Ex. 1007, 2:34-43, 2:49-64, 7:15-8:26, FIGS. 3, 3a, 4, 4a; Ex. 1008, 3:11-18, 3:20-4:1, 8:21-9:3, 10:9-11:20, FIGS. 3, 3a, 4, 4a; Ex. 1005, ¶70.) Figures 3 and 3a "depict the device of FIG. 1 being used in the coronary sinus" with outer and inner introducer sheaths 11, 12 (identified in FIGS. 3 and 3a reproduced below) being advanced over a wire guide 45 into the coronary sinus ostium 38. (Ex. 1007, 4:12-13, FIGS. 3, 3a; Ex. 1008, 6:11-12, FIGS. 3, 3a.) *Norlander* teaches that introducer sheaths 11, 12 co-extend within the coronary sinus during the procedure with outer introducer sheath 11 "placed at the ostium to, or just within the coronary sinus" and inner introducer sheath 12 "advanced over [a] wire guide though the outer sheath and maneuvered to a second, more distal target site where the lead or other device is to be placed." (Ex. 1007, Abstract,

[11] Claim 11 lacks antecedent basis for "the catheter." For purposes of this petition, however, Petitioner assumes that this term refers to the "double catheter" mentioned in the preamble. As detailed in this section, *Norlander* teaches that introducer apparatus 10, including the inner and outer introducer sheaths 11, 12, are inserted into the coronary sinus.

2:18-21, 2:49-64, 4:58-5:1; *see also* Ex. 1008, 3:11-14, 3:20-4:1, 7:11-14, 7:19-25; Ex. 1005, ¶70.)

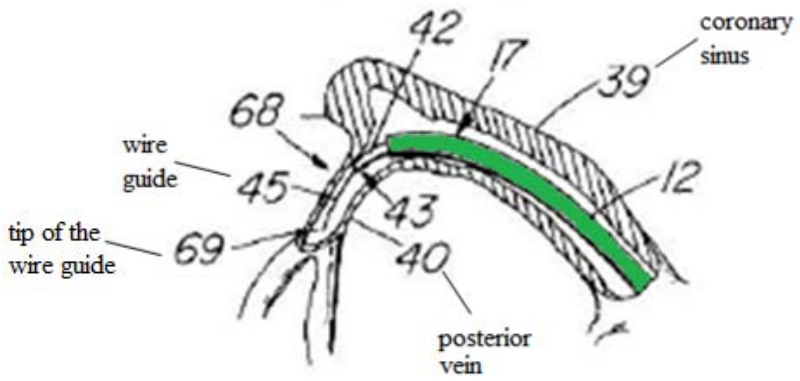


iii. [11.c] "advancing a guide wire through the catheter into a coronary sinus lateral branch vein;"

Norlander states that "introducer apparatus 10 is normally introduced over a wire guide" and thus discloses "advancing a guide wire through the catheter." (Ex. 1007, 7:15-16, FIGS. 3, 3a, 4a; Ex. 1008, 10:9-10, FIGS. 3, 3a, 4a; Ex. 1005, ¶71.) *Norlander* teaches that wire guide 45 is guided into the ostium 38 of the coronary

sinus 39, which represents a first target site 67, and is then advanced through the coronary sinus 39 down a cardiac vein branching from the coronary sinus 39. (Ex. 1007, 7:21-24, 7:26-35; Ex. 1008, 10:14-16, 10:18-25.) In the exemplary embodiment shown in FIG. 4a below, a tip 69 of wire guide 45 is positioned within posterior vein 40. (Ex. 1007, 7:29-37, FIG. 4a; Ex. 1008, 10:20-25, FIG. 4a.)

FIG. 4a

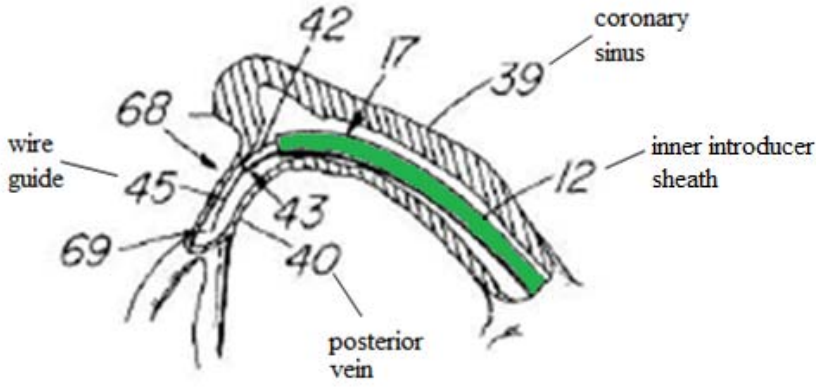


iv. [11.d] "advancing the inner catheter out of a front end opening of the outer catheter along the guide wire into the branch vein;"

Norlander discloses advancing inner introducer sheath 12 ("the inner catheter") out of a front end opening 16 of outer introducer sheath 11 ("the outer catheter") along wire guide 45 ("the guide wire") to a distal end 69 of wire guide 45 located within posterior vein 40 ("the branch vein"). (*See, e.g.*, Ex. 1007, 2:61-3:4, 8:15-21, FIG. 4a; Ex. 1008, 3:27-4:2, 11:11-16, FIG. 4a; Ex. 1005, ¶72.) *Norlander* teaches that inner introducer sheath 12 "is advanced over the wire guide ***through the outer sheath*** and maneuvered to a second, more distal target site

where the lead or other device is to be placed." (Ex. 1007, 2:61-64; Ex. 1008, 3:28-4:2 (emphasis added).) *Norlander* discloses that inner introducer sheath 12 (identified in green below) is "protected by the larger outer introducer sheath during its initial path to the first target site," i.e., the coronary sinus ostium 38 and is then "advanced from the distal tip of the outer introducer sheath," as shown in FIG. 4a below, to second target site 68, which is located within posterior vein 40 ("the branch vein") in FIG. 4a. (Ex. 1007, 2:64-3:4, 7:26-35, 8:21-26, FIG. 4a; Ex. 1008, 4:3-6, 10:20-25, 11:11-16, FIG. 4a.)

FIG. 4a



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

Norlander discloses inserting the lead through outer and inner introducer sheaths 11, 12 ("the outer and inner catheters") to a target location in the posterior vein 40 ("the branch vein"). (*See, e.g.*, Ex. 1007, 2:49-64, 4:46-58, 8:21-26; Ex. 1008, 3:20-4:1, 7:11-19, 11:16-20; Ex. 1005, ¶73.) *Norlander* teaches that "[o]nce

the outer introducer sheath 11 is in place . . . the inner introducer sheath 12 is inserted therethrough" and further states that "[o]nce the inner introducer sheath 12 is advanced to the second target site 68 within the vasculature, . . . the pacing lead or other device is advanced through the inner introducer sheaths [*sic*] 12 to the second target site 68 or a more distal location" located within the posterior vein 40 in FIG. 4a. (Ex. 1007, 8:17-26, FIG. 4a; Ex. 1008, 11:11-20, FIG. 4a.)

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

Norlander discloses withdrawing introducer apparatus 10 ("the catheter") by splitting the inner and outer introducer sheaths 11, 12 to leave the lead in the branch vein. (*See, e.g.*, Ex. 1007, Abstract, 4:52-58, 6:50-61, 8:16-43; Ex. 1008, 7:14-19, 9:16-20, 11:20-12:5; Ex. 1005, ¶74.)

4. Claim 12

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

As discussed above for claim 11, *Norlander* discloses inserting introducer apparatus 10 into the coronary sinus 39. (*See* Section X.B.1.ii; Ex. 1005, ¶75.) *Norlander* discloses that distal end 16 of outer introducer sheath 11 is designed to be placed at the opening to or within the coronary sinus 39. (Ex. 1007, 2:49-52; Ex. 1008, 3:20-22.) To facilitate this, outer introducer sheath 11 includes at least one preformed bend 20 which helps in the navigation of the sheath to the target

site. (Ex. 1007, 5:65-6:12; Ex. 1008, 8:9-21.) In the exemplary embodiment shown in FIG. 1, outer introducer sheath 11 includes a distal curve 48 to "provide posterolateral access to coronary sinus ostium." (Ex. 1007, 6:12-16, 6:26-28, FIG. 1; Ex. 1008, 8:21-24, 9:2-3, FIG. 1.)

Norlander also teaches adjusting the curvature of outer introducer sheath 11 of introducer apparatus 10 in order to enter the coronary sinus 39 using a steerable/deflectable device 74. (Ex. 1007, 9:2-13, 9:34-40; Ex. 1008, 13:1-6; Ex. 1005, ¶75.) *Norlander* teaches that steerable/deflectable device 74 can be incorporated into outer introducer sheath 11 and used to deflect the tip of the sheath "into the optimum position for advancing the sheath to the target area or providing an improved position such that the inner introducer sheath 12 can be then advanced to the target site." (Ex. 1007, 9:2-13; Ex. 1008, 13:1-6.)

5. 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:"

As noted above, "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.) To the extent the remaining portions of the preamble are considered limiting, *Norlander* discloses these portions of the claimed method. (Ex. 1005, ¶77.) As discussed above for claim 11, *Norlander* discloses a method for placing a pacemaker lead ("an electrical lead") in a lateral branch of a coronary sinus vein such as, for example, posterior vein 40, using an introducer apparatus 10 ("a double catheter") including an outer introducer sheath 11 ("outer catheter") and an inner introducer sheath 12 ("inner catheter"). (*See supra* Section X.B.3.i.) As discussed above for claim 1, outer introducer sheath 11 comprises a resilient tube having shape memory with a hook-shaped distal end 16. (*See supra* Section X.B.1.ii.) As also discussed above for claim 1, *Norlander* teaches that inner

introducer sheath 12 is pliable and is co-axially disposed within outer introducer sheath 11 and of greater length than outer introducer sheath 11 so that a distal end portion 17 of inner introducer sheath 12 can be extended or retracted from a distal end 16 of outer introducer sheath 11 to vary the overall length of introducer apparatus 10. (*See supra* Section X.B.1.iii; *see also infra* Sections X.B.5.ii-vi; Ex. 1005, ¶¶76-77.)

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

As discussed above for claim 11, *Norlander* discloses inserting introducer apparatus 10 ("the catheter") into the coronary sinus 39. (*See supra* Section X.B.3.ii; Ex. 1005, ¶78.)

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

As discussed above for claim 11, *Norlander* discloses advancing a wire guide 45 ("guide wire") through introducer apparatus 10 ("the catheter") into a coronary sinus lateral branch vein. (*See supra* Section X.B.3.iii; Ex. 1005, ¶79.)

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 above for claim 11, *Norlander* discloses advancing inner introducer sheath 12 ("inner catheter") out of a distal end 16 of outer introducer sheath 11 ("outer catheter") along wire guide 45 ("guide wire") into the branch vein. (*See supra* Section X.B.3.iv; Ex. 1005, ¶80.)

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

As discussed above for claim 11, *Norlander* discloses inserting the lead through the outer and inner introducer sheaths 11, 12 to a target location in the branch vein. (*See supra* Section X.B.3.v; Ex. 1005, ¶81.)

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

As discussed above for claim 11, *Norlander* teaches withdrawing introducer apparatus 10 ("the catheter") leaving the lead in the branch vein. (*See supra* Section X.B.3.vi; Ex. 1005, ¶82.)

C. Ground 2: Claims 10 and 24 Are Obvious Based on *Norlander*

1. Claim 10

As discussed above for claim 10, the subject matter of claim 10 is expressly disclosed in *Norlander* and inherently disclosed by teachings in the '966 provisional carried forwarded to *Norlander*. (*See supra* Section X.B.2.) To the extent the Board finds otherwise, it would have been obvious to a PHOSITA to reduce the curvature of bend 48 forming the hook-shaped distal end 16 of outer introducer sheath 11 by inserting inner introducer sheath 11 through the outer introducer sheath 12. (Ex. 1005, ¶83.)

As discussed above for claim 1, *Norlander* and its '966 provisional teach that outer introducer sheath 11 has shape memory as it is formed with a hook-shaped distal end. (*See supra* Section X.B.1.iii.) *Norlander* and its '966

provisional teach that inner introducer sheath 12 includes a straight shaft. (Ex. 1007, 6:32-35; Ex. 1008, 9:7-9.) *Norlander* and its '966 provisional further teach that inner introducer sheath 12 is introduced through outer introducer sheath 11 so that a distal end portion 17 of inner introducer sheath 12 can be extended from a distal end 16 of outer introducer sheath 11. (Ex. 1007, 2:39-43, 4:48-52, 5:52-60, 8:15-21, FIG. 1; Ex. 1008, 3:14-18, 8:2-8, 11:14-16, FIG. 1.) In view of these disclosures, it would have been obvious to a PHOSITA to have inserted the straight inner introducer sheath 12 through the outer introducer sheath 11 to reduce the curvature of its hook-shaped distal end. (Ex. 1005, ¶83.) A PHOSITA would have been motivated to use this approach to cannulate the coronary sinus as it would reduce the number of tools used during the procedure and could be advantageously used to cannulate a vein close to the coronary sinus ostium. (*Id*.)

Both outer and inner introducer sheaths 11, 12 are formed of a molecularly oriented (non-isotropic) polytetrafluroroethylene (PTFE). (Ex. 1007, 2:44-46, 6:67-7:6; Ex. 1008, 3:18-20, 9:22-27.) A PHOSITA would have known that an outer introducer sheath 11 made from PTFE can deform upon insertion of a structure based on the physical properties (e.g., outer diameter, inner diameter, thickness, etc.) of outer introducer sheath 11, and would have been motivated to use a sheath with the physical properties to allow the sheath shape to be adjusted during the procedure. (Ex. 1005, ¶83.) Given that there are only a limited number

of materials from which outer introducer sheath 11 can be made, selecting a sheath with physical properties that permit its shape to be adjusted upon insertion of a structure, like inner introducer sheath 12, would have been a routine design choice. (*Id*.) *See KSR Int.'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Likewise, a PHOSITA would have recognized that selecting an inner introducer sheath with a shape and sufficient stiffness to straighten any curvatures or bends formed in outer introducer sheath 11 would have also been a routine design choice. (Ex. 1005, ¶83.) *See KSR*, 550 U.S. at 421.

2. Claim 24

To the extent the Board deems the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" to be limiting, this limitation in combination with the other limitations would have been rendered obvious by *Norlander*. (Ex. 1005, ¶¶84-90.) *Norlander* discloses all of the features of claim 24 (*see supra* Section X.B.5), but does not expressly disclose that outer introducer sheath 11 has "sufficient stiffness to permit advancement of the outer catheter into a ***distal*** coronary sinus." *Norlander*, however, describes its outer introducer sheath 11 as having sufficient stiffness to ***cannulate*** (*i.e.* enter) the coronary sinus 39 (Ex. 1007, 2:49-52; Ex. 1008, 3:20-22). A PHOSITA would have understood that outer introducer sheath 11, having sufficient stiffness to navigate to and enter the coronary sinus ostium, also could be advanced distally to

a distal portion of the coronary sinus. (Ex. 1005, ¶85.) In fact, it was a well-known technique at the time of the alleged invention to advance an outer sheath into the distal coronary sinus to provide support to an inner sheath used to cannulate a branch vein for lead placement. (*Id*.) For at least this reason, it would have been obvious in view of *Norlander* to make outer introducer sheath 11 with sufficient stiffness to permit advancement to a distal portion of the coronary sinus. (*Id*.)

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

To the extent the preamble is limiting, *Norlander* discloses an outer introducer sheath 11 ("an outer catheter") configured for use with an inner introducer sheath 12 ("an inner catheter") that is pliable and is co-axially disposed within outer introducer sheath 11 and of greater length than outer introducer sheath 11 so that a distal end portion 17 of inner introducer sheath 12 can be extended or retracted from a distal end 16 of outer introducer sheath 11 as discussed above for claim 1. (*See* Sections X.B.1.i-iii; *see also infra* Sections X.D.1.ii-iii; Ex. 1005, ¶¶91-92.)

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 1, a PHOSITA would have understood *Norlander*'s outer introducer sheath 11 to be resilient tube having shape memory. (*See* Section X.B.1.ii; Ex. 1005, ¶93.) As discussed above for claim 24, a PHOSITA would have also recognized that it would have been obvious in view of *Norlander* to make an outer introducer sheath 11 with sufficient stiffness to permit advancement of outer introducer sheath 11 into a distal coronary sinus. (*See* Section X.C.2; Ex. 1005, ¶93.)

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 *Norlander* and *Payne* teaches this limitation. (Ex. 1005, ¶94.) *Norlander* teaches that outer introducer sheath 11 can have a shape with at least one preformed bend 20. (Ex. 1007, 5:65-6:12; Ex. 1008, 8:9-21.) In the exemplary embodiment shown in FIG. 1, outer introducer sheath 11 has a generally serpentine configuration 92 with a hook-shaped distal end 16. (Ex. 1007, 6:12-28, FIG. 1; Ex. 1008, 8:21-9:3, FIG. 1; Ex. 1005, ¶93.) *Norlander* does not

expressly disclose that outer introducer sheath 11 has a hook-shaped distal end with 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, ¶93.) For the reasons discussed below, a PHOSITA would have found it obvious to combine the teachings of *Norlander* and *Payne* and would have had a reasonable expectation in success in doing so. (*Id.*)

For example, *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.)

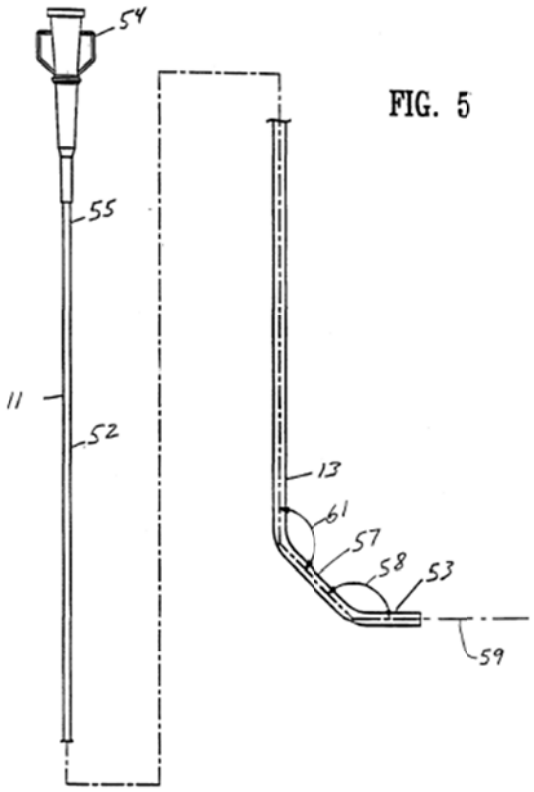


FIG. 5

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, ¶93.) A PHOSITA would have understood this embodiment of first delivery catheter 11 to have a hook-shaped distal shaft section 13. (Ex. 1009, FIG. 5; Ex. 1005, ¶93.) 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. *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 ¶93.) 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).[12] (Ex. 1005, ¶93.) 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, ¶93.)

Payne discloses ranges of angles for the bends shown in FIG. 5 that overlap with the claimed ranges. (Ex. 1005, ¶93.) *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

[12] 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.

F.3d at 131. Here, because, the claimed ranges overlap with the ranges disclosed 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 shape of outer introducer sheath 11 described in *Norlander* in view of *Payne*. (Ex. 1005, ¶93.) *Norlander* provides express motivation for this modification as it discloses that outer introducer sheath 11 can be shaped with multiple bends to "help[] in the navigation of the sheath to the target site." (Ex. 1007, 5:65-6:5; Ex. 1008, 8:9-15.) It would have been obvious to a PHOSITA to use the bend angles described in *Payne* so that the outer introducer sheath 11 disclosed in *Norlander* is preformed into a shape that would orient the outer introducer sheath 11 when it is in the patient's heart. (Ex. 1009, 9:22-25; Ex. 1005, ¶93.)

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, ¶93.) *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, ¶93; Exs. 1012, 1016-1018.) As demonstrated by *Payne*, the claimed shape was also 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, ¶93.) It was common practice at the time of the alleged invention to adopt catheters or design elements of catheters used in other cardiac procedures for navigating the coronary vessels. (Ex. 1005, ¶93; *see* Ex. 1013, 139D.)

A PHOSITA would have considered the specific teachings of *Payne* because it discloses a telescoping catheter system for use in a cardiac procedure like *Norlander*. (*See, e.g.,* Ex. 1009, Abstract, 12:12-15; Ex. 1007, 4:48-58, FIG. 1; Ex. 1008 at 7:11-14, FIG. 1; *see also* Ex. 1005, ¶93.) 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, ¶93.) For this additional reason, a PHOSITA would have been motivated to modify the shape of outer introducer sheath 11 described in *Norlander* in view of *Payne* as it would "orient[] the distal end 16 of introducer into a favorable position to access" the coronary sinus ostium. (Ex. 1007, 6:10-12; Ex. 1008, 8:20-21; Ex. 1005, ¶93.)

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 combination of *Norlander* and *Payne* disclose an outer introducer sheath 11 ("outer catheter") having a shape with a first

bend that equals 180°, rendering outer introducer sheath 11 substantially J-shaped. (*See supra* Section X.D.1.c (explaining that the main shaft section 52, shown in Figure 5 of *Payne*, is straight, and therefore has an angle of 180°); Ex. 1005, ¶94.)

3. Claim 18

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

To the extent the preamble is limiting, *Norlander* discloses an introducer apparatus 10 ("a double catheter") as discussed above for claim 1. (*See supra* Section X.B.1.i; *see also infra* Sections X.D.3ii-v; Ex. 1005, ¶¶96-97.)

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 1, a PHOSITA would have understood *Norlander*'s outer introducer sheath 11 comprises a resilient tube having shape memory. (*See supra* Section X.B.1.ii; Ex. 1005, ¶98.) As discussed above for claim 24, a PHOSITA would have also recognized that it would have been obvious to make outer introducer sheath 11 with sufficient stiffness to permit advancement of outer introducer sheath 11 into a distal coronary sinus. (*See* Section X.C.2.i; Ex. 1005, ¶98.)

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 *Norlander* and *Payne* teaches this limitation. (*See supra* Section X.D.1.iii; Ex. 1005, ¶99.)

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 1, *Norlander* discloses an inner introducer sheath 12 ("inner catheter") that is pliable and is co-axially disposed within outer introducer sheath 11 ("outer catheter") and of greater length than outer introducer sheath 11 so that a distal end portion 17 of inner introducer sheath 12 can be extended or retracted from a distal end 16 of outer introducer sheath 11 to vary the overall length of introducer apparatus 10 ("the double catheter"). (*See supra* Section X.B.1.iii; Ex. 1005, ¶100.)

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."

Norlander discloses that inner introducer sheath 12 has a passageway 25 suitable for the introduction of a fluid therethrough. (*See, e.g.*, Ex. 1007, FIG. 6; Ex. 1008, FIG. 6.) In one embodiment, inner introducer sheath 12 includes a hemostatic valve 55 "to prevent loss of blood during an intravascular procedure, especially procedures of long duration such as coronary sinus or cardiac defibrillator lead placement." (Ex. 1007, 11:54-58; Ex. 1008, 17:14-18.) Hemostatic valve 55 is molded into passageway 25 near a distal portion 17 of inner introducer sheath 12. (Ex. 1007, 11:59-61; Ex. 1008, 17:14-17.). It would have been obvious to a PHOSITA to modify to provide hemostatic valve 55 at a proximal end of *Norlander*'s inner introducer sheath 12 in order to minimize blood loss and reduce the possibility of an air embolism when a lead or wire is inserted through inner introducer sheath 12. (Ex. 1005, ¶101.) In fact, it was well-known to position a hemostatic valve at a proximal end of a sheath, and these sheaths were common at the time of the alleged invention. (*Id.*; Ex. 1009, 13:3-11.) As such, it would have been nothing more than a matter of design choice to modify *Norlander*'s sheath 12 in this way and a PHOSITA would have had a reasonable expectation of success in doing so. (Ex. 1005, ¶101.) *KSR*, 550 U.S. at 421.

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 *Norlander* and *Payne* teaches this limitation. (*See supra* Section X.D.2; Ex. 1005, ¶102.)

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 discussed above for claim 1, *Norlander* meets the recited function and also teaches at least one of the structures described in the '268 patent corresponding to the recited function or its equivalents. (*See supra* Section B.1.iv; Ex. 1005, ¶103.) To the extent the Board determines that this phrase is not a means-plus-function term, *Norlander* still discloses this limitation under its plain and ordinary meaning for the reasons discussed above for claim 1. (*See supra* Section B.1.iv; Ex. 1005, Ex. 1005, ¶103.)

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 *Norlander* and *Payne* teaches this limitation. (*See supra* Section X.D.1.iii; Ex. 1005, ¶104.)

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 *Norlander* and *Payne* teaches this limitation. (*See supra* Section X.D.2; Ex. 1005, ¶105.)

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

Petitioner has streamlined this petition and only presents multiple grounds for claims 10 and 24. The Board should adopt both grounds for claims 10 and 24 that take into account different possible priority dates and/or claim constructions. Petitioner is also filing another IPR petition challenging claims 1, 10-14, 18, 19, and 23-26 of the '268 patent concurrently with the filing of this petition based on different prior art references with earlier prior art dates. 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).

XII. 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 13,774 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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