Paper No. ____
Filed: August 1, 2018

Filed on behalf of: Medtronic, Inc.

By: Naveen Modi (PH-Medtronic-Niazi-IPR@paulhastings.com)
Paromita Chatterjee (PH-Medtronic-Niazi-IPR@paulhastings.com)
Paul Hastings LLP

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

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(continued)

Page(s)

Statutes

Other Authorities

LIST OF EXHIBITS

No.	Description
1001	U.S. Patent No. 6,638,268 ("the '268 patent")
1002	U.S. Provisional Application No. 60/195,701
1003	File History of U.S. Patent No. 6,638,268 (U.S. Patent Application No. 09/828,502)
1004	Assignment record of the '268 patent from USPTO assignment database
1005	Declaration of Dr. Ronald David Berger, M.D., Ph.D.
1006	Curriculum Vitae of Dr. Ronald David Berger, M.D., Ph.D.
1007	U.S. Patent No. 6,562,049 to Norlander et al. ("*Norlander*")
1008	U.S. Provisional Application No. 60/185,996 ("the '996 provisional")
1009	International Publication No. WO 99/49773 to Payne et al. ("*Payne*")
1010	Reserved
1011	Reserved
1012	U.S. Patent No. 5,423,772 to Lurie ("*Lurie*")
1013	Angelo Auricchio et al., *Transvenous Biventricular Pacing for Heart Failure: Can the Obstacles Be Overcome?*, 83 The Am. J. of Cardiology 136D, 136D-42D (1999) ("*Auricchio 1999*")
1014	Christine Alonso et al., *Six Year Experience of Transvenous Left Ventricular Lead Implantation for Permanent Biventricular Pacing in Patients with Advanced Heart Failure: Technical Aspects*, 86 Heart 405, 405-10 (2001) ("*Alonso*")
1015	Jean-Jacques Blanc et al., *A Method for Permanent Transvenous Left Ventricular Pacing*, 21 Pacing and Clinical Electrophysiology 2021, 2021-2042 (1998) ("*Blanc*")
1016	U.S. Patent No. 5,488,960 to Toner ("*Toner*")

1017	U.S. Patent No. 5,775,327 to Randolph et al. ("*Randolph*")
1018	U.S. Patent No. 6,277,107 to Lurie et al. ("*Lurie*")
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*")
1023	U.S. Patent No. 5,846,229 to Berg ("*Berg*")
1024	U.S. Patent No. 5,876,385 to Ikari et al. ("*Ikari*")
1025	Steven W. Werns et al., *Review of Hardware for PTCA*, J. of Interventional Cardiology, vol. 1, no. 3, 209-219 (1988) ("*Werns*").
1026	U.S. Patent No. 4,898,591 to Jang et al. ("*Jang*")
1027	Excerpt from *The New Manual of Interventional Cardiology*, (Mark Freed, MD, et al. eds., 1996).

I. INTRODUCTION

Medtronic, Inc. ("Petitioner") requests *inter partes* review of claims 15 and 27 ("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)[1]. 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 are directed to an "outer catheter" configured for use with an "inner, pliable catheter" that is "substantially question mark-shaped." (*See, e.g., id.*, 8:14-28, 8:31-33, 9:16-10:20, 10:23-25.) The claimed subject matter, however, was not new at the time of the '268 patent.

As the '268 patent acknowledges and the prior art cited herein demonstrates, 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; Ex. 1019, Abstract.) The use of a double catheter to implant a lead in a lateral branch vein of the coronary sinus was described in U.S. Patent No. 6,562,049 to Norlander et al. ("*Norlander*") and its related provisional application,

[1] On February 12, 2018, Petitioner filed petitions, IPR2018-00609 and IPR2018-00610, challenging claims 1, 10-14, 18, 19, and 23-26 of the '268 patent.

which predate the earliest effective filing date of the '268 patent. Further, the use of "substantially question mark-shaped" catheters in the heart was known and obvious prior to the challenged claims' earliest effective filing date. (*See* Exs. 1023, FIG. 1; Ex. 1024, FIG. 1.) 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 filed petitions, IPR2018-00609 and IPR2018-00610, challenging claims 1, 10-14, 18, 19, and 23-26 of the '268 patent on February 12, 2018, which were the claims asserted against Petitioner by Patent Owner in the Western District of Wisconsin litigation. After the Western District of Wisconsin case was dismissed without prejudice, Patent Owner filed a new case against Petitioner on November 14, 2017, in the District of Minnesota. Petitioner filed its petitions challenging claims of the '268 patent, and after those petitions were filed, Patent Owner served infringement contentions in the District of Minnesota case asserting claims 15 and 17 for the first time in the litigation. Claims 15 and 27 are being challenged herein.

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.[2]

[2] The dismissal without prejudice of the Western District of Wisconsin case nullifies the effect of service of the complaint and, as a consequence, that complaint does not bar Petitioner from pursing this IPR. *Oracle Corp. et. al. v. Click-to-Call Tech. IP*, IPR2013-00312, Paper No. 26 at 16 (P.T.A.B. Oct. 30, 2013).

V. PRECISE RELIEF REQUESTED AND GROUNDS RAISED

Petitioner requests review of claims 15 and 27 of the '268 patent and cancellation of these claims as unpatentable in view of the following grounds[3]:

- **Ground 1**: Claims 15 and 27 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,562,049 to Norlander *et al.* ("*Norlander*") (Ex. 1007), International Publication No. WO 99/49773 to Payne *et al.* ("*Payne*") (Ex. 1009), and U.S. Patent No. 5,846,229 to Berg ("*Berg*") (Ex. 1023).
- **Ground 2**: Claims 15 and 27 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,935,160 to Auricchio *et al.* ("*Auricchio*") (Ex. 1019), U.S. Patent No. 5,775,327 to Randolph *et al.* ("*Randolph*") (Ex. 1017), and U.S. Patent No. 5,876,385 to Ikari *et al.* ("*Ikari*") (Ex. 1024).

[3] 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).

VI. BACKGROUND

The ’268 patent was filed as U.S. Application No. 09/828,502 (“the non-provisional application”) on April 6, 2001. (Ex. 1001.) It issued on October 28, 2003, and purportedly claims priority to U.S. Provisional Application No. 60/195,701 (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.)

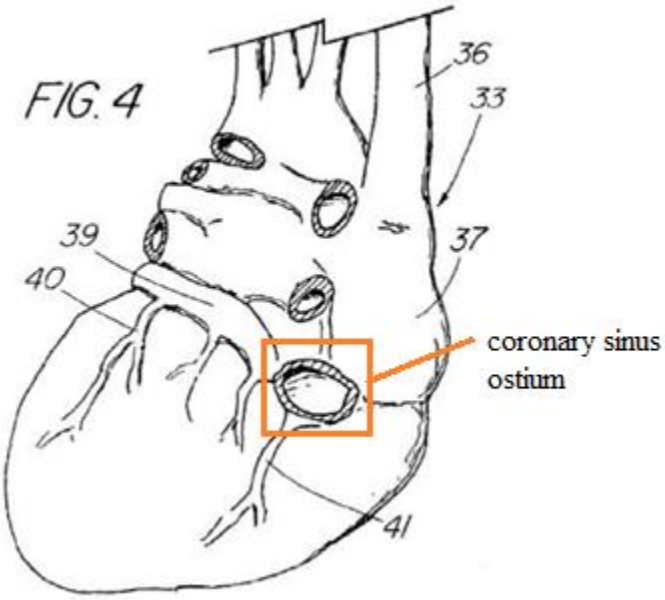
Heart failure occurs due to a structural or functional cardiac disorder that impairs the ability of a ventricle to fill with or eject blood commensurate with the needs of the body. (*Id.*, ¶18.) When the heart does not circulate blood normally, it can lead to the build-up of fluid in the lungs and the 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. (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. (*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 to stimulate the free wall of the left ventricle. (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 (annotated).) The coronary sinus ostium (or orifice) (annotated above) 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[4] of the coronary sinus merges into the great cardiac vein. (Ex. 1005, ¶21.) Antero-lateral, lateral,

[4] 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.)

and postero-lateral veins are also frequently found; however, the size, number, and location of these veins vary between patients. (*Id*.) At the time of the alleged invention, it was known that the appropriate branch veins for LV lead placement included branches that extended along and drain the lateral portion of the free wall ("lateral wall of the left ventricle"), as well as branches of the middle cardiac vein and the great cardiac vein that extended to the lateral wall of the left ventricle. (Ex. 1005, ¶22; Ex. 1014, 406.)

Physicians initially implanted leads without the use of any catheter delivery system. (Ex. 1005, ¶23; Ex. 1013, 139D.) By the late 1990s, however, it was common for physicians to use a catheter[5] to access the coronary sinus, including for lead implantation. (Ex. 1005, ¶24; Ex. 1014, 406; Ex. 1015, 2022.) 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 curve to direct a distal end of the catheter toward the coronary sinus ostium. (Ex.

[5] 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.)

1005, ¶24; Exs. 1012, 1016-1018.) In addition, a variety of shaped catheters were used in other procedures in the heart. (Ex. 1025, 210-11; Ex. 1026, Fig. 4; Ex. 1027, 11-20.) Some physicians used these well-known, shaped catheters to access the coronary sinus. (Ex. 1005, ¶24; Ex. 1021, J7.)

By the time of the alleged invention, pacing leads specifically designed for the coronary sinus had been developed, including open lumen leads that tracked over a guide wire. (Ex. 1005, ¶23; Ex. 1013, 139D-142D.) Physicians used various techniques to implant the available leads.[6] (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.)

[6] The 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.)

Once the outer catheter was positioned within the coronary sinus, the inner member might be removed and the anatomy of the coronary sinus would then be visualized by injecting contrast media through the lumen of the catheter under fluoroscopy, with the assistance of a blocking balloon catheter, to obtain a venogram and thereby visualize the surrounding vasculature. (Ex. 1005, ¶26; Ex. 1013, 139D; Ex. 1022, 158K.) 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, 3:26-28, 8:49-52.)

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." (Ex. 1007, 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, ¶¶28-33.) The '268 patent discloses a double catheter 10 used to place a pacing lead in a lateral branch of the coronary sinus. (Ex. 1001, 2:41-44, 2:62-63, 3:9-10, 4:35-62.) The double catheter includes an outer catheter 11 and an inner catheter 12. (*Id.*, 3:9-22.) Outer catheter 11 has a hook-shaped distal end with 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.[7] (*Id.*, 4:8-17, FIGS. 1-2.) The specification

[7] 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)).)

states that "[t]hese ranges refer to the angle formed by the straight segments adjacent each bend when the catheter is in an undistorted state." (*Id.*, 4:17-19.) The specification explains that "[t]he undistorted shape of outer catheter 11 can be varied" and describes an embodiment in which the outer catheter can have a first bend with an angle that equals 180°, which is "no bend," and an embodiment in which the outer catheter includes a first bend to form "a question mark shape," which is shown inverted in figures 1 and 2 below. (*Id.*, 4:26-31; Ex. 1005, ¶ 31.)

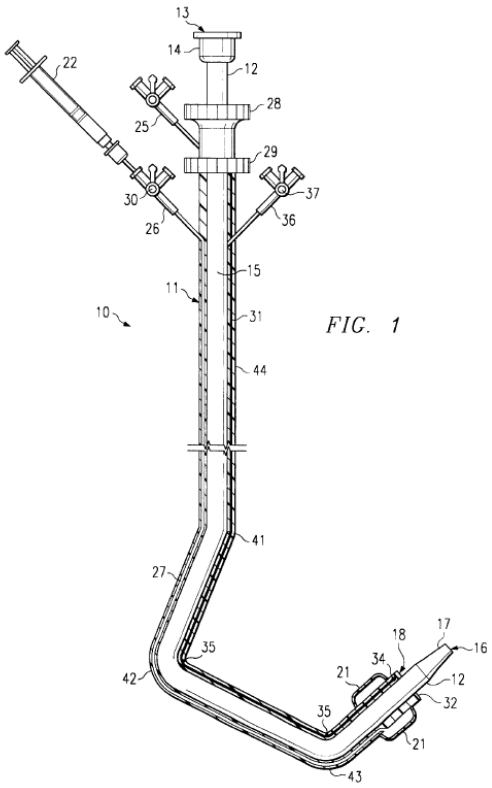


FIG. 1

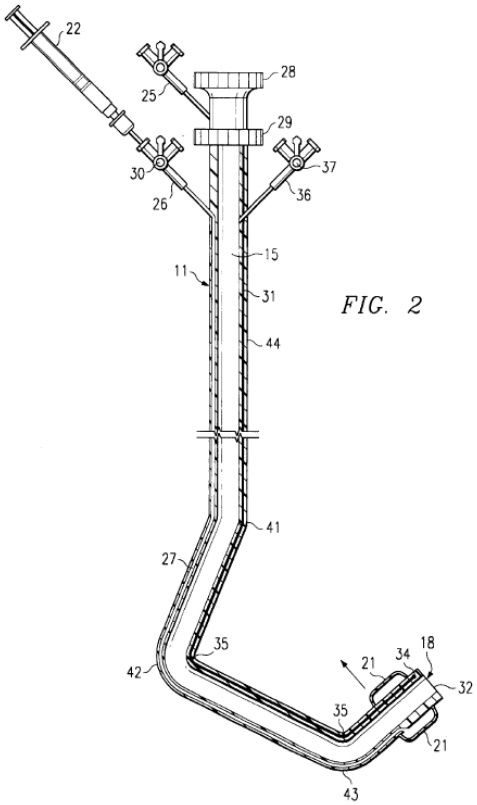


FIG. 2

C. Overview of the '268 Patent Claims

The '268 patent has 27 claims, but this petition only requests review of claims 15 and 27. Claim 15 depends from independent claim 13. (Ex. 1001, 8:14-

28, 8:31-33.) Claim 27 depends from claim 25, which depends from independent claim 24. (*Id.*, 9:16-10:12, 10:13-25.) As demonstrated in Section IX, claim 27 is not entitled to claim a right of priority to U.S. Provisional Application No. 60/195,701 because of its dependency from claim 24. In other words, claim 27 has an effective filing date of no earlier than April 6, 2001, the filing date of the non-provisional application that led to the ’268 patent.

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 argued, and the Examiner agreed, that the prior art cited by the examiner did not disclose the claimed angles of the outer catheter or describe the claimed methods for leaving a lead wire in a branch vein. (*Id.*, 72, 82.)[8]

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the art (PHOSITA) at the time of the alleged invention of the ’268 patent would have been a cardiologist, cardiac electrophysiologist, or interventional cardiologist having experience using catheters (or introducers or sheaths) in the heart, including catheters used for

[8] 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.

placement of, for example, leads.[9] (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"), but the claims are unpatentable under the BRI claim construction standard or the *Phillips* standard. Petitioner provides a construction for one phrase recited in independent claim 24 discussed below. The remaining terms should be interpreted in accordance with their plain and ordinary meaning.[10]

---

[9] Petitioner submits the declaration of Dr. Ronald David Berger, M.D., Ph.D. (Ex. 1005), an expert in the field of the '268 patent (Ex. 1005, ¶¶ 3-10; Ex. 1006).

[10] Because of the different claim interpretation standards used in this proceeding and in district courts, any claim interpretations herein are not binding upon

Claim 27 depends from claim 25, which depends from claim 24. (Ex. 1001, 9:16-10:20, 10:23-25.) The preamble of independent 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." (*Id.*, 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, while the body of claim 24 and the claims dependent from claim 24 do recite "inserting the catheter into the coronary sinus," they 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, the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" 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

---

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.

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 were 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.) In any event, as discussed below, for purposes of the prior art here, the Board may not need to 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").

IX. THE EFFECTIVE PRIORITY DATE OF CLAIM 27 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").

The provisional application does not provide adequate written support for at least the method of independent claim 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. This step requires that the guide wire be in place when the inner catheter is advanced into the branch vein. 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 before advancing the inner catheter into the branch vein. Nor does it disclose that the inner catheter is to be advanced into the branch vein, and certainly does not disclose advancing the inner catheter ***over*** the guide wire into the branch vein. 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, ¶¶37-39.)

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, ¶40.) The non-provisional application explicitly states that, in this new 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, claim 24 is not entitled to a priority date any earlier than April 6, 2001, the filing date of the '268 patent.

Claim 27 depends from claim 24 and incorporates all of the features of claim 24 and intervening claim 25. (Ex. 1001, 9:16-10:20, 10:23-25.) For at least the reasons discussed above, the provisional application does not provide adequate support for claim 27. (Ex. 1005, ¶41.) Therefore, claim 27 is also not entitled to a priority date earlier than April 6, 2001. However, as explained below, the references relied on in the grounds of this petition are prior art under either priority date applied to claim 27. (*See infra* Section X.A.)

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

The challenged grounds rely on a combination of prior art references, none 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 at least claim 27 is 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 to claim 27 under pre-AIA 35 U.S.C. § 102(e) as of its filing date, November 9, 2000. *Norlander* is also prior art to claim 27 and claim 15 under pre-AIA 35 U.S.C. § 102(e) as of its provisional filing date, March 1, 2000.

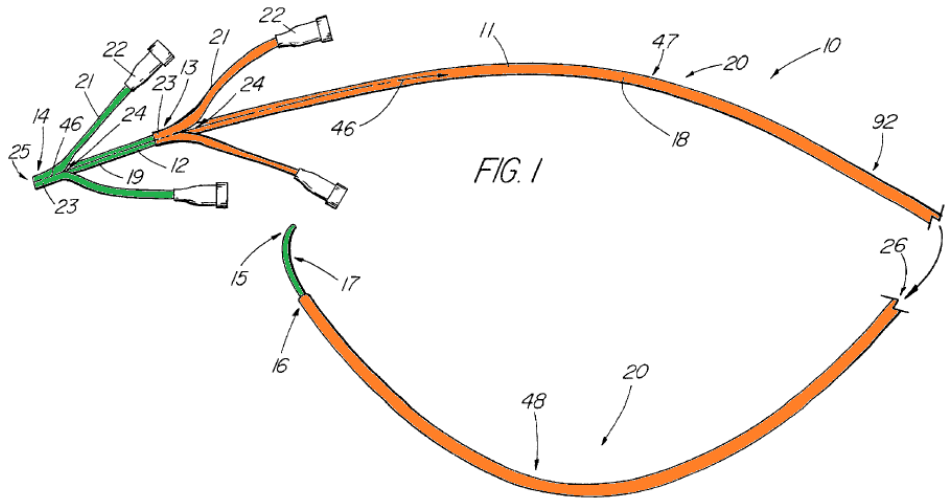
Specifically, *Norlander* claims priority to U.S. Provisional Application No. 60/185,996 ("the '996 provisional") (Ex. 1008), filed March 1, 2000. (Ex. 1007.) *Norlander* was filed within one year of its '996 provisional filing, names at least one inventor in common, and includes a specific reference to the '996 provisional. (*Id.*) Petitioner submits that at least claim 1 of *Norlander* is fully supported and enabled by the '996 provisional, and provides the following exemplary mapping:

Claim Language	**Support in '996 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, ¶42.) Moreover, as detailed throughout this petition by way of citations to both *Norlander* and the '996 provisional, the teachings that Petitioner relies upon were carried forward from the '996 provisional to *Norlander*. Thus, *Norlander* is entitled to claim a right of priority under 35 U.S.C. § 119(a) to the '996 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, *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); *Polaris Industries Inc. v. Arctic Cat Inc.*, IPR2016-01713, Paper No. 9, 12-13 (P.T.A.B. Feb. 27, 2017); *Cisco Sys., Inc. v. Capella Photonics, Inc.*, IPR 2014-01276, 2016 WL 783545, *9, n.9 (P.T.A.B. Feb. 17, 2016) (citing *Dynamic Drinkware*, 800 F.3d at 1375). Accordingly, subject matter in *Norlander* described in the '996 provisional is prior art under pre-AIA 35 U.S.C. § 102(e), with an effective filing date of March 1, 2000.

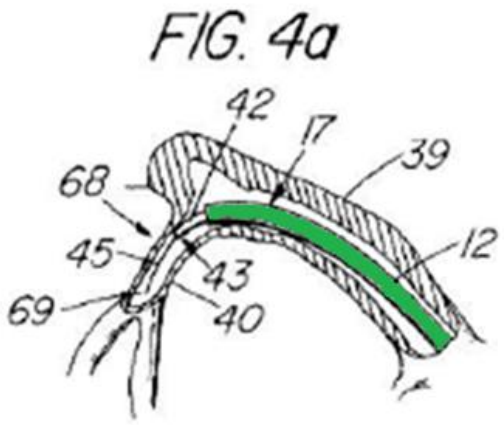
Norlander discloses an introducer apparatus 10 used for placement of a pacemaker or defibrillator lead into a branch vein of the coronary sinus to stimulate the left side of the heart. (Ex. 1007, 2:34-36; *see also* Ex. 1008, 3:3-5, 3:11-14, 3:25-4:2, 8:2-8; Ex. 1005, ¶43.) As shown below in FIG. 1, 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, 4:48-52; Ex. 1008, 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, ¶¶44-45.) The sheaths 11, 12 are splittable to facilitate its removal from the patient without disturbing the lead. (Ex. 1007, 4:52-58, 6:50-61; Ex. 1008, 7:14-19, 9:16-20.)



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; Ex. 1005, ¶46.) 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, ¶47.)

Once outer introducer sheath 11 is positioned within the coronary sinus 39, inner introducer sheath 12 (identified in green) is advanced over wire guide 45 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, ¶48.)



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, ¶49.)

2. *Auricchio*

Auricchio issued August 10, 1999, and is thus prior art to both challenged claims under pre-AIA 35 U.S.C. § 102(a).[11] (Ex. 1019.) It discloses a transvenous coronary vein lead 10 designed for pacing the left ventricle from one of the heart's posterior veins, middle veins, or great vein and describes methods for delivering the lead to a preselected vein. (Ex. 1019, 5:25-29, 2:26-31, 2:41-44, 3:12-38, 8:21-

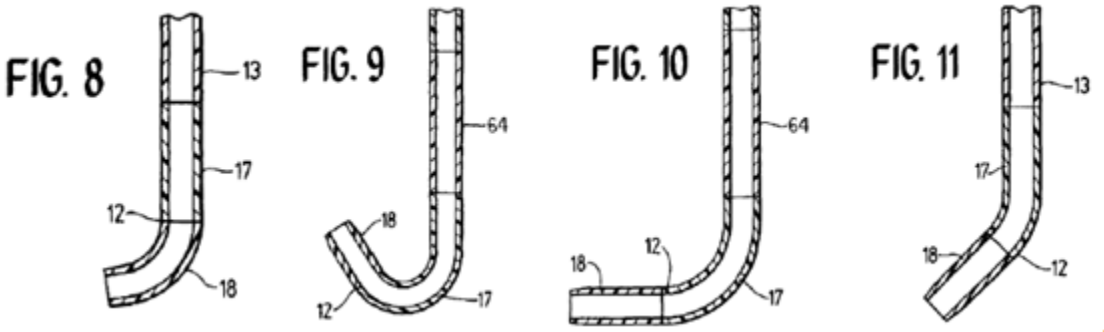
[11] Because at least claim 27 is not entitled to any priority date earlier than the filing date of the '268 patent, i.e., April 6, 2001 (*see* supra Section IX), *Auricchio* is also prior art to claim 27 under pre-AIA 35 U.S.C. § 102(b).

53, FIG. 17; Ex. 1005, ¶¶50-51.) *Auricchio* discloses that, in one embodiment, "[t]he method of positioning the coronary vein lead at a desired position within a preselected coronary vein may include the use of a guide catheter, guide wire and support catheter." (Ex. 1019, 2:41-44.) In this embodiment, a guide catheter is first inserted through the superior vena cava into the ostium of the coronary sinus, and a guide wire is then inserted into the guide catheter and advanced to the desired position within a preselected coronary vein. (*Id.*, 3:22-28.) "Once the guide wire is in position, a thin walled support catheter is advanced over the guide wire to the distal end of the guide wire" and used to position the coronary vein lead 10 within a preselected coronary vein. (*Id.*, 3:26-28, 8:52-53.) *Auricchio* teaches that after the lead is positioned at a desired site, the support catheter is retracted or peeled away from the lead body, leaving the lead in place. (*Id.*, 3:35-38.)

3. *Randolph*

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

various shapes for the distal shaft section of the guiding catheter, including hook-shaped curves. (*Id.*, 3:57-59, 4:49-55, FIGS. 8-11; Ex. 1005, ¶52.)



4. *Payne*, *Berg*, and *Ikari*

Payne published October 7, 1999, and is prior art to both challenged claims under pre-AIA 35 U.S.C. § 102(a)[12]. (Ex. 1009.) *Berg* issued December 8, 1998, and is thus prior art to both challenged claims under pre-AIA 35 U.S.C. § 102(b). (Ex. 1023.) *Ikari* issued March 2, 1999, and is thus prior art to both challenged claims under pre-AIA 35 U.S.C. § 102(b). (Ex. 1024.) *Payne*, *Berg*, and *Ikari* are secondary references relied upon in the obviousness grounds in Sections X.B-C, and demonstrate that the claimed catheter shapes were well-known in the art at the time of the alleged invention. (Ex. 1005, ¶¶53-57.)

[12] Because at least claim 27 is 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 also prior art to claim 27 under pre-AIA 35 U.S.C. § 102(b).

B. Ground 1: Claims 15 and 27 Are Obvious Based on *Norlander*, *Payne*, and *Berg*

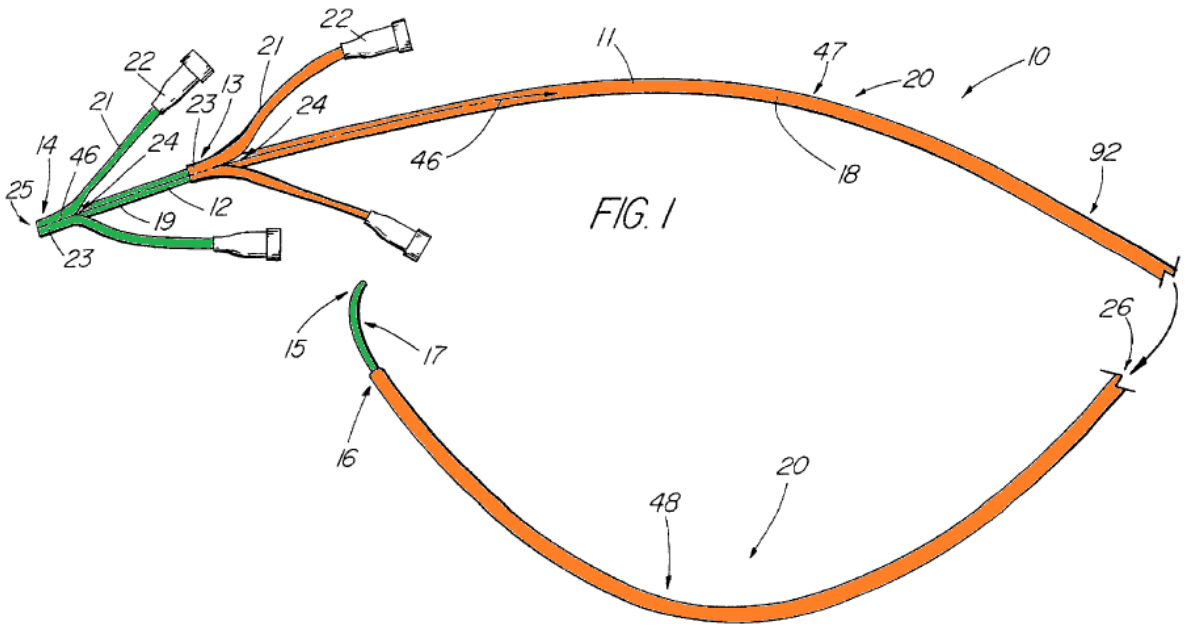
Because claims 15 and 27 depend from other claims (e.g., claims 13, 24, or 25), Petitioner first addresses these other claims before addressing claims 15 and 27.

1. Claim 13

Challenged claim 15 depends from independent claim 13 and incorporates all of the limitations of claim 13, which are disclosed by the combination of *Norlander* and *Payne*.

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,"

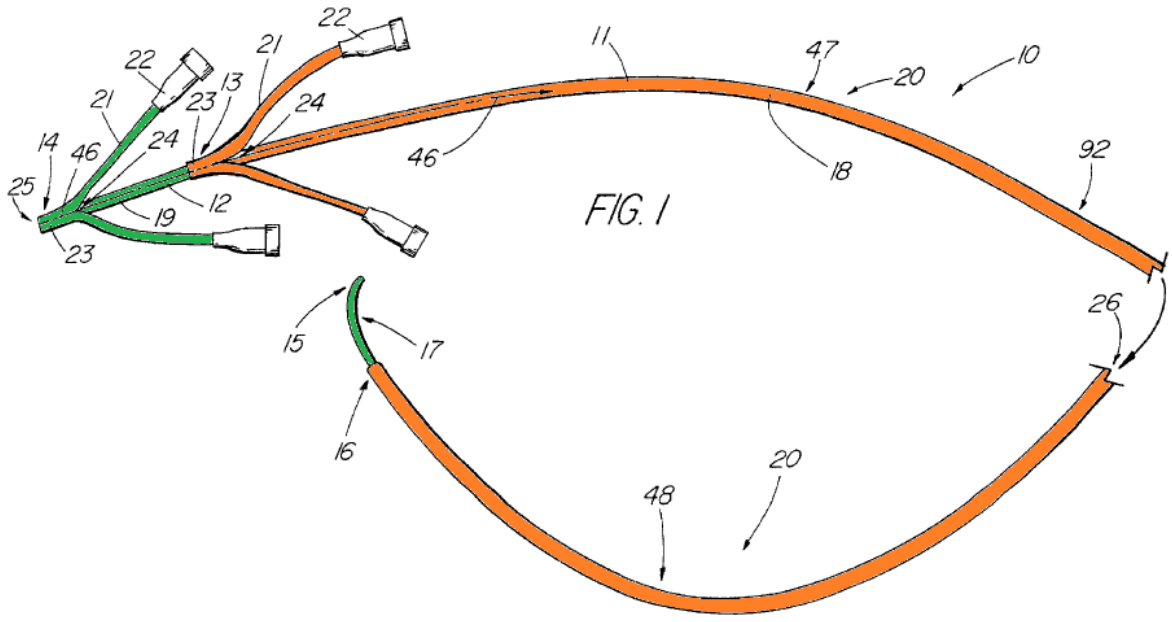
Norlander discloses an outer introducer sheath 11 ("outer catheter"; identified in orange below) configured for use with an inner introducer sheath 12 ("inner, pliable catheter"; identified in green below). (Ex. 1007, 4:48-52, 5:20-23, FIG. 1; Ex. 1008, 7:11-14, FIG. 1; Ex. 1005, ¶¶58-59; *see infra* Section X.B.1.ii-iv.)



(Ex. 1007, FIG. 1; Ex. 1008, 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; Ex. 1005, ¶59.) 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 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, 7:11-14, 8:2-8, 11:14-16, FIG. 1.)

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"

Norlander discloses that its outer introducer sheath ("outer catheter") comprises "a resilient tube having shape memory." (Ex. 1005, ¶60.) *Norlander*'s outer introducer sheath 11 is 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.) A PHOSITA would have understood outer introducer sheath 11 to be a resilient tube as it can navigate the curves and bends of the anatomical pathway to the coronary sinus. (Ex. 1007,

6:20-26, FIG. 3; Ex. 1008, 8:24-9:3, FIG. 3; Ex. 1005, ¶60.) 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 also 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, ¶60.)

Norlander 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. (Ex. 1007, 2:49-52, 6:26-28; Ex. 1008, 3:20-22, 9:2-3.) 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, ¶60.) 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 of outer introducer sheath 11 into a distal coronary sinus. (*Id*.)

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 [] 130° to 175°."

Norlander in combination with *Payne* teaches this limitation. (Ex. 1005, ¶61.) *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, a distal portion of outer introducer sheath 11 includes a distal bend 48 having "a tight[] radius" to form a hook-shaped distal end 16. (Ex. 1007, 6:12-28, FIG. 1; Ex. 1008, 8:21-9:3, FIG. 1; Ex. 1005, ¶61.) *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, ¶61.) 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. (Ex.

1009, 12:12-15.) *Payne* discloses that first (outer) delivery catheter 11 has a shaped distal end. (*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. (*Id.*, 17:1-6, FIG. 5.) The first segment 53 is shaped at an angle 58 with respect to second segment 57, and second segment 57 is shaped at an angle 61 with respect to main shaft section 52. (*Id.*, 17:3-6, FIG. 5.)

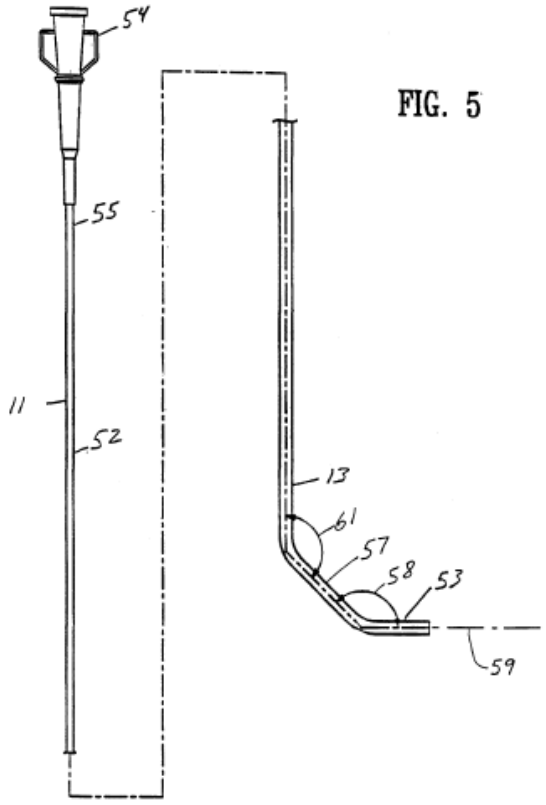


FIG. 5

The embodiment of first delivery catheter 11 shown in FIG. 5 teaches a hook-shaped distal shaft section 13 with bends having angles that fall within the claimed ranges. (Ex. 1005, ¶61.) 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 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 ¶61.) A PHOSITA would have understood angle 61 of *Payne* 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).[13] (Ex. 1005, ¶61.) 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, ¶61.)

Payne discloses ranges of angles for the bends shown in FIG. 5 that overlap with the claimed ranges. (Ex. 1005, ¶61.) *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

[13] 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.

90 to about 160°." (*Id.*, 17:6-8.) "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 id.* 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 does not teach 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 modify the shape of *Norlander*'s outer introducer sheath 11 to have a hook-shaped distal end with three bends having angles that fall within the claimed ranges, including a first bend adjoining a straight, proximal portion that is 180° (*i.e.*, no bend), as taught in *Payne*. (Ex. 1009, 17:1-12, FIG. 5; Ex. 1005, ¶61.) *Norlander* provides express motivation for this modification as it discloses that outer introducer sheath 11 can be shaped with multiples bends to "help[] in the navigation of the sheath to the target site." (Ex. 1007, 5:65-6:5; Ex. 1008, 8:9-15.) A PHOSITA would have had a reason to shape the outer sheath to have the bends and bend angles described in *Payne* to match the size and shape of the patient's heart and to orient the outer introducer sheath 11

when it is in the patient's heart. (Ex. 1005, ¶61; Ex. 1007, 5:65-6:12; Ex. 1008, 8:9-21; Ex. 1009, 9:22-25.)

Moreover, 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, ¶61.) *See KSR Int.'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). A variety of catheter shapes designed for use within the heart, including in the coronary sinus, were known. (Ex. 1005, ¶61; Exs. 1012, 1016-1018; Ex. 1027, 11-20.) As demonstrated by *Payne*, the claimed shape was also known and used in other cardiac procedures at the time of the alleged invention. (Ex. 1009, Abstract, 17:1-12, FIG. 5; Ex. 1005, ¶61.) 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 accessing the coronary sinus. (Ex. 1005, ¶61; Ex. 1013, 139D.)

A PHOSITA would have considered the specific teachings of *Payne* because, like *Norlander*, it also discloses a telescoping catheter system for use in a cardiac procedure. (Ex. 1007, 4:48-58, FIG. 1; Ex. 1008, 7:11-14, FIG. 1; Ex. 1009, Abstract, 12:12-15; Ex. 1005, ¶61.) 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, ¶61.) For these additional reasons, a PHOSITA would have been motivated

to modify *Norlander*'s outer introducer sheath 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, ¶61.)

2. Claim 15

As explained below, the combination of *Norlander*, *Payne*, and *Berg* teaches all of the limitations of claim 15. (Ex. 1005, ¶62.)

i. "The catheter of claim 13, wherein the first bend is in the range of 130-175°, rendering the outer catheter substantially question mark-shaped."[14]

As explained above for claim 13, *Norlander* in combination with *Payne* teaches an outer introducer sheath ("outer catheter") with a hook-shaped distal end having bends with angles that fall within the ranges of claim 13. (*See supra* Section X.B.1.iii; Ex. 1005, ¶62.) Claim 15 requires that "the first bend is in the range of 130-175°, rendering the outer catheter substantially question mark-shaped." (Ex. 1001, 8:31-33.) But such a difference would have been obvious based on the combined teachings of *Norlander*, *Payne*, and *Berg*. (Ex. 1005, ¶62.)

[14] The claim language provides that a "question mark-shaped catheter" is defined by a first bend having an angle in the range of 130-175°. To the extent the claimed shape requires something more; it raises indefiniteness issues that cannot be raised in this proceeding.

First, *Norlander* in combination with *Payne* teaches an outer sheath with a hook-shaped distal end having three bends, including a first bend that renders the sheath substantially question mark-shaped. (Ex. 1005, ¶62.) In particular, *Norlander* describes that a distal portion of outer introducer sheath 11 includes a proximal bend 47 that is bent in a direction opposite to distal bend 48. (Ex. 1007, 6:12-28, FIG. 1; Ex. 1008, 8:21-9:3, FIG. 1; Ex. 1005, ¶62.) For the reasons discussed above for claim 13, it would have been obvious to combine the teachings of *Norlander* and *Payne* to shape the outer sheath to have a hook-shaped distal end with a first bend that is bent in a direction opposite to a second bend, as taught in *Norlander*, and with second and third bends that are bent in the same direction and have angles that fall within the claimed ranges, as taught by *Payne*. (*See supra* Section X.B.1.iii; Ex. 1005, ¶62.)

Further, *Berg* discloses a catheter with a proximal shaft section 11 that is "substantially straight" and a shaped distal shaft section 12. (Ex. 1023, 2:61-65, 3:51-54, 3:58-67, 4:12-14, FIG. 1.) As shown in FIG. 1 below, distal shaft section 12 includes a primary curve 13, a secondary curve 14, and a tertiary curve 15.

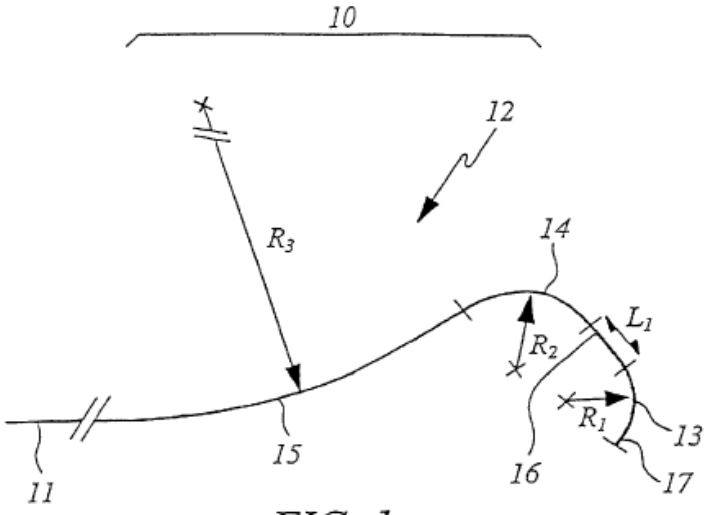


FIG. 1

(*Id.*, 3:58-66, FIG. 1.) A PHOSITA would have understood tertiary curve 15 to be similar to the first bend of the sheath in the *Norlander-Payne* combination. (Ex. 1005, ¶62.) *Berg* teaches that tertiary curve 15 is a "relatively shallow curve." (Ex. 1023, 5:5-6.) As noted above, the claimed angles refer to "angle[s] formed by the straight segments adjacent each bend." (*See supra* Section VI.B.) Tangents to tertiary curve 15 intersect to form a similar angle and the measure of that angle formed by the tangents is related to the arc angle of the curve (e.g., it is 180° minus the arc angle). (Ex. 1005, ¶62.) *Berg* teaches that tertiary curve 15 has an arc angle "of about 15 to 90°", which would result in a bend angle that falls within the range of 130-175° recited in claim 15. (Ex. 1023, 1:66-67, 2:9-13, 4:17-30; Ex.

1005, ¶62.)[15] Like the bends of the sheath in the *Norlander-Payne* combination, *Berg* discloses that tertiary curve 15 is curved in an opposite direction than that of secondary curve 14 of distal section 12. (Ex. 1023, 3:58-66.) A PHOSITA would have appreciated that this configuration renders *Berg*'s catheter "substantially question-mark shaped." (*Compare* Ex. 1023, FIG. 1 *with* Ex. 1001, FIGS. 1-2; Ex. 1005, ¶62.)

Based on the combined teachings of *Norlander*, *Payne*, and *Berg*, it would have been obvious to modify the outer sheath of the *Norlander-Payne* combination in view of *Berg* to have a first bend with an angle in the range of 130-175°, rendering the sheath "substantially question mark shaped." (Ex. 1005, ¶62.) A PHOSITA would have had a reason to shape the sheath in the *Norlander-Payne* combination to have *Berg*'s catheter design to "help[] in the navigation of the sheath to the target site." (Ex. 1007, 6:2-6:5; Ex. 1008, 8:13-15; Ex 1005, ¶62.) A PHOSITA would have also been motivated to use *Berg*'s catheter design to accommodate certain patient anatomies that may be difficult to navigate with common catheter designs for accessing the coronary sinus. (Ex. 1005, ¶62.) A PHOSITA would have understood that such a modification would have required

[15] Petitioner reserves the right to argue in the litigation that a curved arc is not a "bend" as used in the '268 patent.

nothing more than providing a first bend with a "relatively shallow curve," as taught in *Berg*, and thus was well within the capabilities and knowledge of a PHOSITA at the time of the alleged invention, especially in view of *Berg*'s disclosure that "[t]he distal end of the catheter may be thermally formed to virtually any desired shape." (Ex. 1023, 3:38-41; Ex. 1005, ¶62.)

Moreover, a PHOSITA would have appreciated at the time of the alleged invention that a catheter would have been selected for accessing the coronary sinus in part by the size and shape of the patient's heart. (Ex. 1005, ¶62.) In addition, a PHOSITA would have appreciated that a catheter would have been selected based on the back-up support required to prevent the catheter from disengaging from the coronary sinus ostium during a lead placement procedure. (*Id.*) It was known that a catheter for accessing the coronary sinus derives back-up support from contacting the wall of the right atrium opposite of the coronary sinus ostium. (*Id.*) The back-up support enables the catheter to counteract any forces that would otherwise cause the catheter to disengage from the coronary sinus ostium. (*Id.*)

While common catheter designs at the time of the alleged invention provided adequate back-up support in normal sized right atriums, these shapes were known to provide inadequate backup support in selected patients with dilated right atriums where, because of the dimensions of the right atrium, the catheter may not sufficiently contact the right atrium wall. (*Id.*) For these selected patients, a

PHOSITA would have had reason to consider a catheter shaped like *Berg*'s catheter that is designed to provide "excellent back-up support." (*Id*.; Ex. 1023, Abstract, 1:59-2:3, 4:53-5:24, FIG. 2.) A PHOSITA would have recognized that a catheter having a hook-shaped distal end with three bends including a first bend that is bent in a direction opposite of the second and third bends, like *Berg*'s catheter, would have enabled a portion of the catheter to contact the right atrium wall for back-up support while the portion of the catheter spanning the second and third bends crosses the right atrium to engage the coronary sinus ostium. (Ex. 1005, ¶62.) The back-up support would prevent the catheter from disengaging from the coronary sinus ostium. (*Id.*) A PHOSITA would have also understood that with such a configuration, the catheter would remain in a stable and fixed position within the coronary sinus ostium while an inner catheter and/or lead is advanced through the outer catheter. (*Id.*) Given such understandings, a PHOSITA would have found it obvious to configure the outer sheath of the *Norlander-Payne* combination into a shape similar to that disclosed in *Berg*. (*Id.*)

Furthermore, 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. (*Id*.) *See KSR*, 550 U.S. at 421. As demonstrated by *Berg* and other references, the claimed shape was known and used in other cardiac procedures at

the time of the alleged invention. (*See, e.g.*, Ex. 1023, 3:58-67, FIG. 1; Ex. 1024, 3:65-4:11, FIG. 1; Ex. 1025, 211 (FR 3.5 ALT in Figure 1); Ex. 1026, FIG. 4 (top catheter); Ex. 1005, ¶62.) 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 accessing the coronary sinus. (Ex. 1005, ¶62.) A PHOSITA, which would have included interventional cardiologists, would have had familiarity with catheters like *Berg*'s angioplasty catheter. (*Id*.) *Berg* states that "[t]hose skilled in the art will recognize the benefits of applying the present invention to similar fields not discussed herein." (Ex. 1023, 1:8-10) The prior art literature shows that a PHOSITA at the time of the alleged invention would have appreciated that catheters patterned after angioplasty devices, like *Berg*'s catheter, provide a solution to the problem of navigating and placing leads in veins of the coronary sinus (Ex. 1013, 139D, 142D).

For all of the reasons discussed above, the combined teachings of *Norlander*, *Berg*, and *Payne* teach the claimed "outer catheter" with a first bend "in the range of 130-175°, rendering the outer catheter substantially question mark-shaped." (Ex. 1005, ¶62.)

3. Claim 24

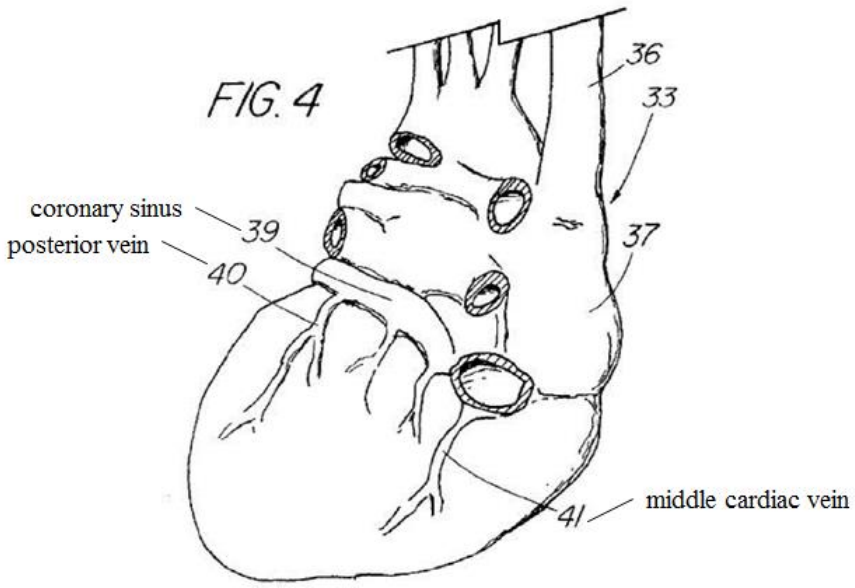
Challenged claim 27 depends from claim 25, which depends from independent claim 24. Claim 27 incorporates all of the limitations of claim 24, which are disclosed or rendered obvious by *Norlander*.

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:"

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") including an outer introducer sheath 11 ("an outer catheter") and an inner introducer sheath ("an inner . . . catheter"). (*See*, *e.g.*, Ex. 1007, 4:48-52, 7:15-8:43, FIGS. 1, 3, 3a, 4, 4a; Ex. 1008, 7:11-14, 10:9-12:5, FIGS. 1, 3, 3a, 4, 4a; *see also infra* Sections X.B.3.ii-vi; Ex. 1005, ¶¶63-64.) As discussed for claim 13, *Norlander*'s outer introducer sheath 11 comprises a resilient tube having shape memory and sufficient stiffness to cannulate the coronary sinus and having a hook-shaped distal end 16.

(*See supra* Sections X.B.1.ii-iii; Ex. 1005, ¶64.) As noted above, the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" is not a limiting requirement of the preamble. (*See supra* Section VIII.B.) Even if it were limiting, 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 for the same reasons discussed above for claim 13. (*See supra* Section X.B.1.ii; Ex. 1005, ¶64.) As also discussed for claim 13, inner introducer sheath 12 is pliable and slidably disposed in outer introducer sheath 11 and of greater length than the outer introducer sheath 11 so that a distal portion 17 of inner introducer sheath 12 can be extended or retracted from distal end 16 ("a distal end opening") of outer introducer sheath 11 to vary the overall length of introducer apparatus 10. (*See supra* Section X.B.1.i; Ex. 1005, ¶64.)

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 posterior vein 40 and middle cardiac vein 41. (Ex. 1007, 7:31-35, FIG. 4; Ex. 1008, 10:22-25, FIG. 4.)



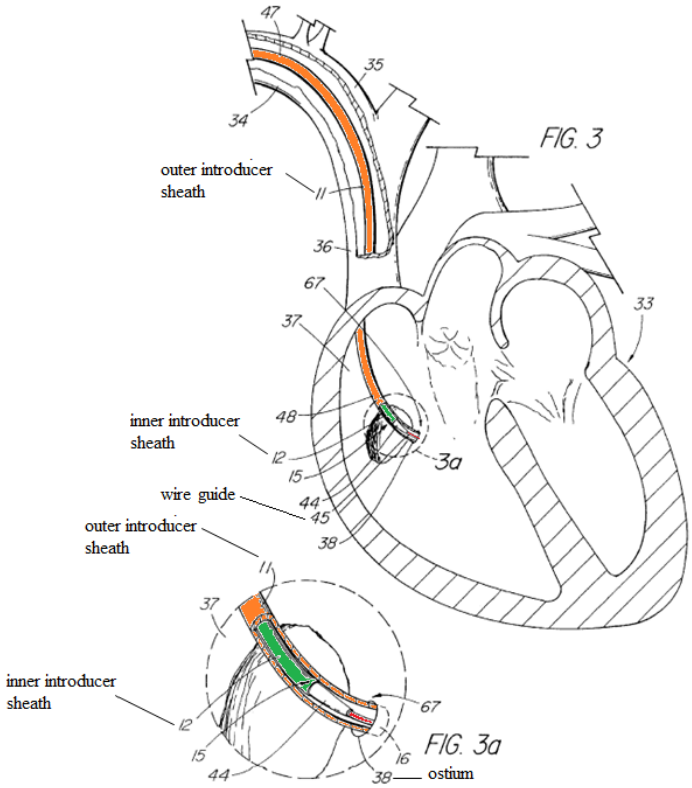
Norlander describes that introducer apparatus 10 is used to place a lead within a lateral branch of a coronary sinus vein such as, for example, the posterior vein 40. (Ex. 1007, Abstract, 2:49-3:4, 5:20-38, 7:15-8:43, FIGS. 3, 3a, 4, 4a; Ex. 1008, 3:20-4:7, 7:19-25, 10:9-12:5, FIGS. 3, 3a, 4, 4a.) A 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, 64.) *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, ¶¶22, 64.)

ii. [24.b] "inserting the catheter[16] into the coronary sinus;"

Norlander discloses inserting introducer apparatus 10 ("the catheter") 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, ¶65.) 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.

[16] Claim 24 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.

1007, Abstract, 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, ¶65.)

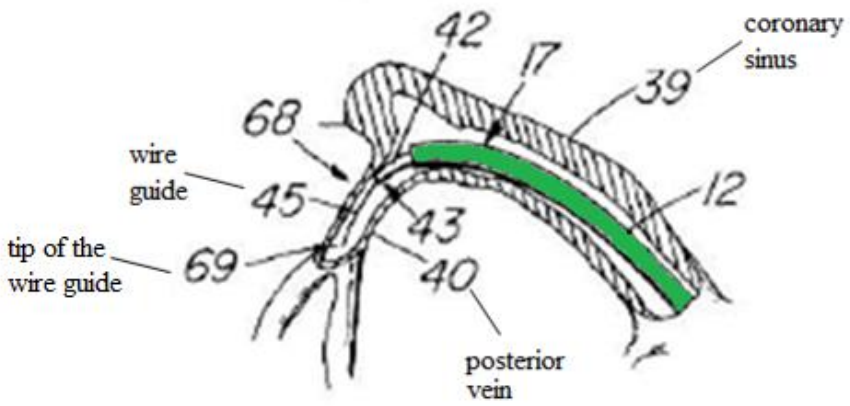


iii. [24.c] "advancing a guide wire through the catheter into a coronary sinus lateral branch vein;"

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, ¶66.) *Norlander* teaches that wire guide 45 is advanced "into a coronary sinus lateral branch vein" as it discloses that wire guide 45 is guided into the ostium 38 of the coronary sinus 39 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.)

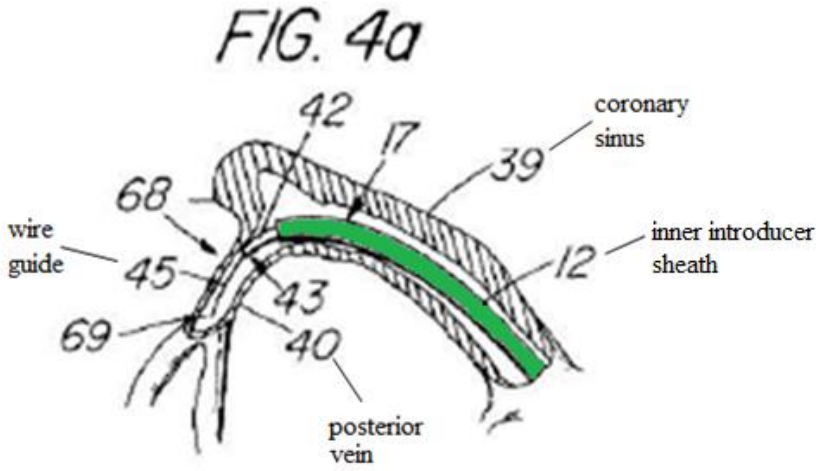
FIG. 4a



iv. [24.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, ¶67.) *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" along the wire guide 45 to second target site 68, which is located within the posterior vein 40 ("the branch vein") in FIG. 4a below. (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.)



v. [24.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, ¶68.) *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. [24.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, ¶69.)

4. Claim 25

Challenged claim 27 depends from claim 25 and incorporates all of the limitations of claim 25, which are disclosed by the combination of *Norlander* and *Payne*.

i. "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°."

Claim 25 recites limitations that track those recited in claim 13. (*Compare* Ex. 1001, 10:13-20 *with id.*, 8:22-27.) Thus, the combination of *Norlander* and

Payne teaches the limitations of claim 25 for the same reasons discussed above for claim 13. (*See supra* Section X.B.1.iii; Ex. 1005, ¶70.)

5. Claim 27

i. "27. The method of claim 25, wherein the first bend is in the range of 130-175°, rendering the outer catheter substantially question mark-shaped."

Claim 27 recites limitations that track those of claim 15. (*Compare* Ex. 1001, 10:23-25 *with id.*, 8:31-33.) Thus, for the same reasons discussed above for claim 15, the combination of *Norlander, Payne* and *Berg* teaches the limitations of claim 27. (*See supra* Section X.B.2; Ex. 1005, ¶71.)

C. Ground 2: Claims 15 and 27 Are Obvious Based on *Auricchio*, *Randolph*, and *Ikari*

1. Claim 13

Challenged claim 15 depends from independent claim 13 and incorporates all of the limitations of claim 13, which is disclosed by the combination of *Auricchio, Randolph*, and *Ikari*.

i. Claim element 13.a[17]

Auricchio discloses a guide catheter ("outer catheter") configured for use with a support catheter ("inner . . . catheter"). (Ex. 1019, 2:41-44, 3:22-28, 8:50-

[17] Petitioner does not repeat the language of claims 13, 15, 24, 25, and 27, which are provided above in Ground 1.

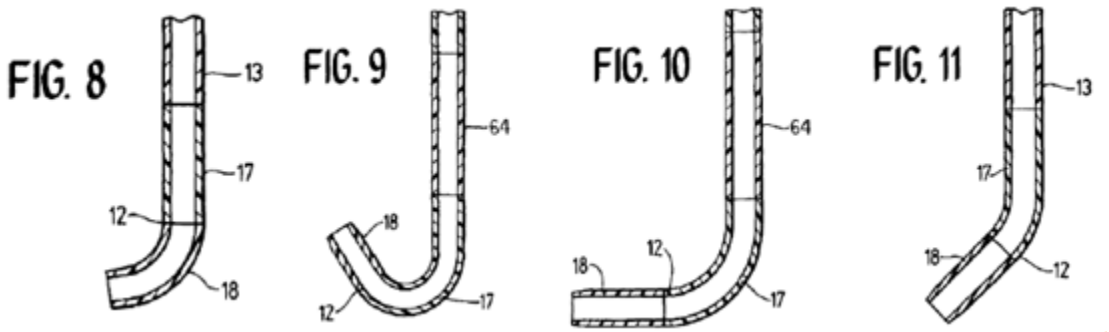
53; Ex. 1005, ¶¶72-73; *see infra* Sections X.C.1.ii-iii.) *Auricchio* describes the support catheter as "thin walled"; therefore, a PHOSITA would have understood the support catheter to be pliable. (Ex. 1019, 3:27; Ex. 1005, ¶73.) *Auricchio* discloses that the support catheter is slidably disposed inside the outer guide catheter as it states that "[the] guide catheter may be used to direct a guide wire which is used to guide [the] support catheter" (Ex. 1019, 8:50-53) and also that the "support catheter is advanced over the guide wire to the distal end of the guide wire" *(id.,* 3:26-28). Indeed, a PHOSITA would have understood that "support catheter" refers to a small diameter catheter that is inserted into a guide catheter. (Ex. 1005, ¶73.) *Auricchio* teaches that the support catheter is advanced to a "distal end of the guide wire" positioned within a preselected coronary vein, and thus teaches that the support catheter is of greater length than the outer guide catheter so that a distal end portion of the support catheter can be extended or retracted from a distal end opening of the outer guide catheter. (Ex. 1019, 3:24-28; Ex. 1005, ¶73.)

ii. Claim element 13.b

Auricchio in combination with *Randolph* teaches this limitation. (Ex. 1005, ¶74.) *Auricchio* discloses an outer guide catheter having sufficient stiffness to permit advancement into a distal coronary sinus (Ex. 1019, 3:11-37, 8:28-53, FIG. 17), but does not describe the catheter as "a resilient tube having shape memory."

Randolph, however, teaches these features. As discussed in detail below, a PHOSITA would have combined the teachings of *Auricchio* and *Randolph* and would have had a reasonable expectation of success in doing do. (*Id.*)

Randolph discloses a guiding catheter designed for accessing a branch vein of the coronary sinus. (Ex. 1017, 1:66-2:5, FIG. 7.) *Randolph* teaches that its guiding catheter is formed of thermoplastic polymer materials that are resilient and have shape memory. (*Id.*, 2:20-31, 4:55-65.) FIGS. 8-11 illustrate various conventional shapes of the guiding catheter. (*Id.*, 3:57-59, 4:49-55, FIGS. 8-11; Ex. 1005, ¶74.)

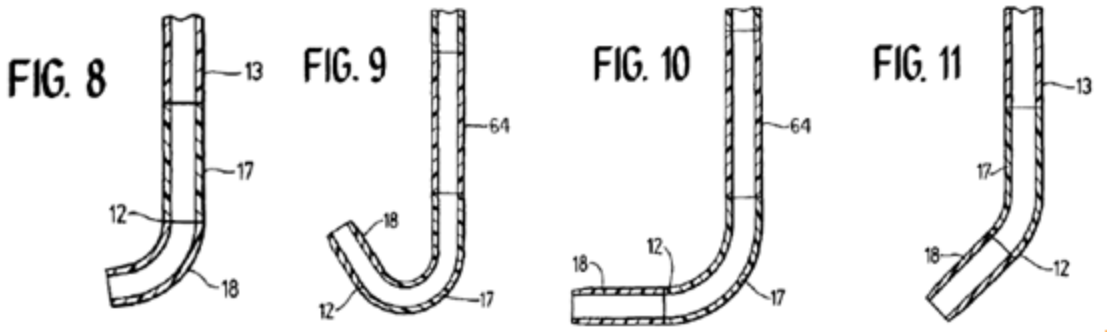


It would have been obvious to a PHOSITA to combine the teachings of *Auricchio* and *Randolph* by using a catheter like *Randolph*'s guiding catheter for the catheter disclosed in *Auricchio*. (Ex. 1005, ¶74.) Given that *Auricchio* and *Randolph* describe coronary sinus catheters for introduction of a device into the coronary sinus, a PHOSITA would have looked to *Randolph* and would have combined the disclosures to result in an improved outer guide catheter for use with a support catheter for delivering a pacing lead into a branch vein of the coronary

sinus. (*Id*.) A PHOSITA would have had reason to use a catheter, like *Randolph*'s catheter, with physical properties to facilitate rapid access into the coronary sinus for delivering a lead into a coronary vein, as disclosed in *Auricchio*. (*Id*; Ex. 1017, 1:61-63; Ex. 1019, 1:14-17, 2:41-44.) Given that there were only a limited number of materials from which a guide catheter could be made, selecting a shaped guide catheter, like *Randolph*'s catheter, with physical properties that render the catheter resilient and having shape memory, as the guide catheter of *Auricchio* would have been a routine design choice to a PHOSITA. (Ex. 1005, ¶74.) The substitution of the guide catheters of *Auricchio* and *Randolph* would also be the predictable use of prior art elements according to their established functions. *See KSR*, 550 U.S. at 417.

iii. Claim element 13.c

Auricchio in combination with *Randolph* and *Ikari* teaches these limitations. (Ex. 1005, ¶75.) For the reasons discussed above, it would have been obvious to a PHOSITA to use a catheter, like *Randolph*'s guiding catheter, for the outer guide catheter disclosed in *Auricchio*. (*Id*.) *Randolph* teaches that its guiding catheter for use in the coronary sinus can be formed with straight, proximal, or intermediate shaft sections 13, 64 and a distal section 12 with various hook-shaped curves to assist with locating and entering the coronary sinus. (Ex. 1017, 4:49-55; Ex. 1005, ¶75.)



(Ex. 1017, 4:49-55, FIGS. 8-11 (illustrating "various conventional shapes").) While *Randolph* discloses a shaped guiding catheter, it does not explicitly disclose a catheter having a hook-shaped distal end with three 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, ¶75.) For the reasons discussed below, a PHOSITA would have found it obvious to combine the teachings of *Auricchio*, *Randolph*, and *Ikari*, and would have had a reasonable expectation of success in doing so. (*Id.*)

Ikari describes a catheter having a hook-shaped distal segment 13. (Ex. 1024, Abstract, 2:29-41, 3:58-61, 3:65-4:11, FIG. 1; Ex. 1005, ¶75.) Like the '268 patent, *Ikari* teaches that distal segment 13 includes curved portions 131, 133, 135, and 137 that are separated by substantially straight portions 132, 134, 136, and 138, as shown in figure 1 below.

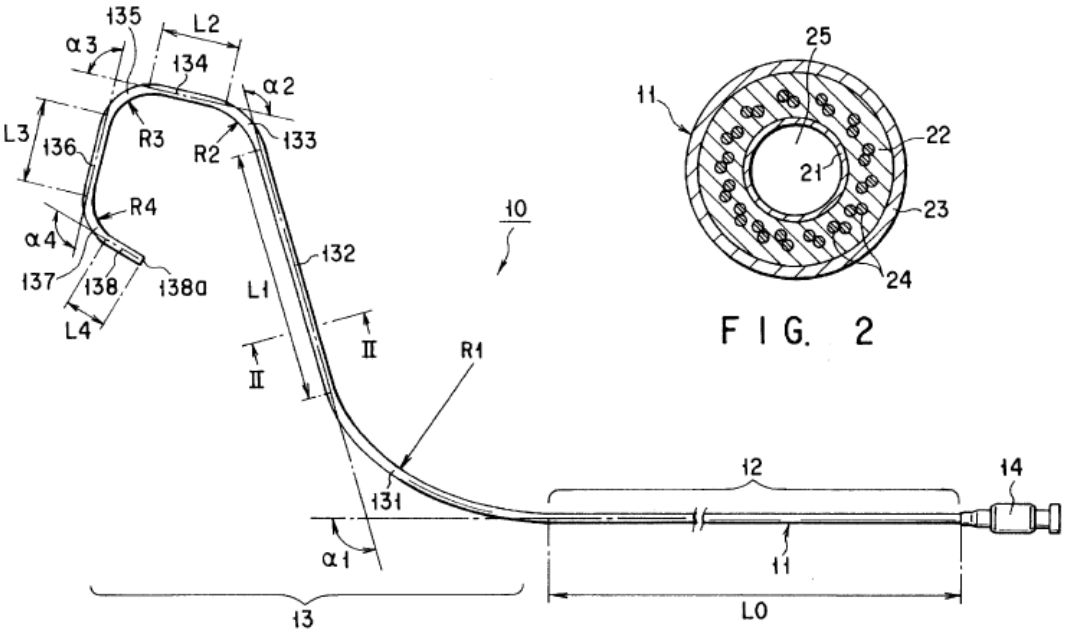
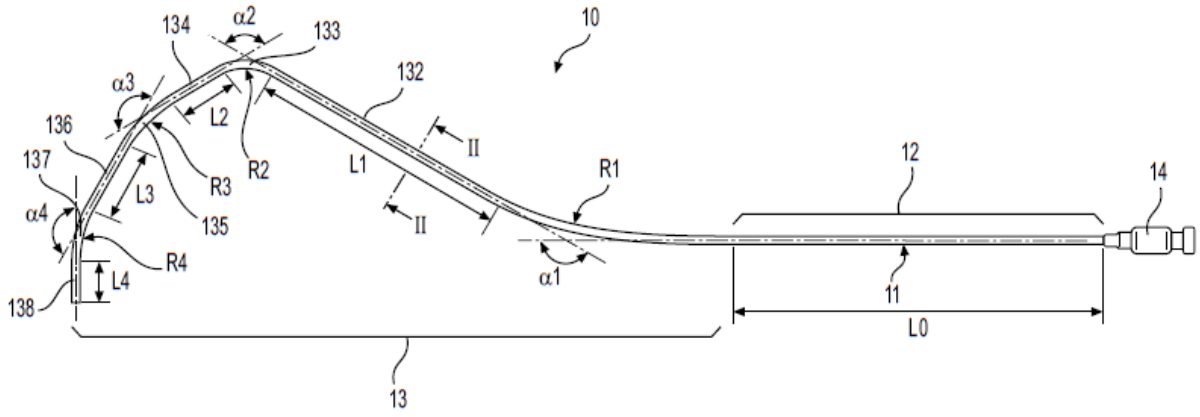


FIG. 2

FIG. 1

(Ex. 1024, 3:65-4:11, FIG. 1.) *Ikari* teaches that angle α1 of the first curved portion 131 falls within the range of about 90° to 150° and that the angles of the other curved portions fall within the range of about 30° to 150°. (*Id.*, 4:14-18, 4:50-55, 5:12-17, 5:35-40.) The demonstrative below illustrates the shape of *Ikari*'s catheter where angle α1 of the first curved portion 131, α3 of the third curved portion 135, and α4 of the fourth curved portion 137, are about 150°, as disclosed.



(*Id.*, 4:14-18, 5:12-17, 5:35-40; Ex. 1005, ¶75.) A PHOSITA would have appreciated the similarity between the shape of *Ikari*'s catheter and the catheter shown in figures 1 and 2 of the '268 patent. (*Id.*)

A PHOSITA would have also appreciated that the distal segment 13 of *Ikari*'s catheter forms the claimed "hooked shaped distal end" with at least three curved portions or bends having angles that overlap with the claimed ranges. (Ex. 1005, ¶75.) In particular, *Ikari* teaches that distal segment 13 includes a first curved portion 131 ("a first bend") adjacent a straight proximal segment 12 that is "bent under a free state", a second curved portion 133 ("a second, intermediate bend") that is bent in a direction opposite to the bending direction of the first curved portion 131, and a fourth curved portion 137 ("a third bend") nearest the distal end of the catheter that is bent in the same direction as second curved portion 133. (Ex. 1024, Abstract, 2:29-41, 3:58-61, 3:65-4:11, 4:12-14, 4:46-50, 5:31-35,

FIG. 1; Ex. 1005, ¶75.) *Ikari* teaches that angle α1 of first curved portion 131 can be in the range of about 90° to 150°. (Ex. 1024, 4:12-18.) *Ikari* teaches that angle α2 of the second curved portion 133 and angle α4 of the fourth curved portion 137 can be in the range of about 30° to 150°. (Ex. 1024, 4:50-55, 5:35-40.) Here, because the claimed ranges overlap with the ranges disclosed by the prior art, there is a strong presumption of obviousness. *See Ormco Corp.*, 463 F.3d at 1311.

It would have been obvious to a PHOSITA to modify the outer guide catheter in the *Auricchio-Randolph* combination in view of *Ikari*. (Ex. 1005, ¶75.) *Randolph* provides motivation for this combination as it teaches that catheters used to access the coronary sinus can have a variety of curved shapes. (*See* Ex. 1017, 4:49-55, FIGS. 8-11.) A PHOSITA would have had reason to shape the guide catheter in the *Auricchio-Randolph* combination to have a shape similar to that disclosed in *Ikari* to orient the tip of the catheter when it is in the patient's heart. (Ex. 1005, ¶75.)

Indeed, a PHOSITA would have appreciated at the time of the alleged invention that a catheter would have been selected for accessing the coronary sinus in part by the size and shape of the patient's heart. (*Id.*) In addition, a PHOSITA would have understood that a catheter would have been selected based on the back-up support required to prevent the catheter from disengaging from the coronary sinus ostium during a lead placement procedure. (*Id.*) It was known that a catheter

for accessing the coronary sinus derives back-up support from contacting the wall of the right atrium opposite of the coronary sinus ostium to keep the tip of the catheter engaged within the coronary sinus ostium. (*Id.*) A PHOSITA would have appreciated that the back-up support would enable the catheter to counteract any forces that would otherwise cause the catheter to disengage from the coronary sinus ostium. (*Id.*)

While common catheter designs at the time of the alleged invention provided adequate back-up support in normal sized right atriums, these shapes were known to provide inadequate backup support in selected patients with dilated right atriums where, because of the dimensions of the right atrium, the catheter may not sufficiently contact the right atrium wall. (*Id.*) For these selected patients, a PHOSITA would have had reason to consider a catheter like *Ikari*'s catheter which is shaped to impart a large back-up force by abutting against a wall of the aortic arch opposite of the entrance the left coronary artery. (Ex. 1024, 2:42-45, 4:65-5:5, 7:57-8:2, 8:30-40, FIGS. 1, 5; Ex. 1005, ¶75.) A PHOSITA would have recognized that a catheter having a hook-shaped distal end with at least three bends including a first bend that is bent in an opposite direction of the second and third bends, like *Ikari*'s catheter, would have enabled a portion of the catheter to contact the right atrium wall for back-up support while the portion of the catheter spanning the second and third bends crosses the right atrium to engage the coronary sinus

ostium. (Ex. 1005, ¶75.) A PHOSITA would have known that the back-up support would prevent the catheter from disengaging from the coronary sinus ostium. (*Id.*) Thus, the catheter would remain in a stable and fixed position within the coronary sinus ostium while an inner catheter and/or lead is advanced through the outer catheter. (*Id.*)

A PHOSITA would have considered the specific teachings of *Ikari* because it discloses a shaped catheter for use in a catheter-based cardiac procedure, like *Auricchio* and *Randolph*. (*See, e.g.*, Ex. 1024, 1:4-6, 2:12-17, FIG. 5; Ex. 1019, 8:30-33; Ex. 1017, Abstract; Ex. 1005, ¶75.) In addition, it has a hook-shaped design which resembles a known shape that matches the anatomical pathway to the coronary sinus ostium. (Ex. 1024, 3:65-4:11, FIG. 1; Ex. 1005, ¶75.) For these reasons, a PHOSITA would have found it obvious to configure the distal end of the catheter of the *Auricchio-Randolph* combination into a shape similar to that disclosed in *Ikari*. (Ex. 1005, ¶75.)

Furthermore, 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. (*Id.*) *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, ¶75; Exs. 1012, 1016-1018; Ex. 1027, 11-20.) As demonstrated by *Ikari*, the claimed

shape was known and used in other cardiac procedures at the time of the alleged invention. (Ex. 1024, 3:65-4:11, FIG. 1; Ex. 1005, ¶75.) A PHOSITA would have included interventional cardiologists who would have had familiarity with angioplasty catheters like *Ikari*'s catheter and would have adopted these catheters and/or catheter designs to access the coronary sinus. (Ex. 1005, ¶75.) The prior art literature shows that a PHOSITA at the time of the alleged invention would have appreciated that catheters patterned after angioplasty devices, like *Ikari*'s catheter, provide a solution to the problem of accessing the coronary sinus. (Ex. 1013, 139D, 142D.)

For at least these reasons, it would have been obvious to a PHOSITA to shape of the guide catheter of the *Auricchio-Randolph* combination to have a shape similar to that disclosed in *Ikari* with at least three bends having bend angles that fall within the claimed ranges. (Ex. 1005, ¶75.)

2. Claim 15

As explained above for claim 13, the combination of *Auricchio*, *Randolph*, and *Ikari* teach the claimed "outer catheter" having a hook-shaped distal end with three bends that fall within the claimed ranges. (*See supra* Section X.C.1.iii; Ex. 1005, ¶76.) Claim 15 recites that "the first bend is in the range of 130-175°, rendering the outer catheter substantially question mark-shaped." (Ex. 1001, 8:31-33.) *Ikari*'s catheter has a distal segment 13 with at least three curved portions

including a first curved portion 131 ("the first bend") having an angle α1 in the range of 90° to 150° which overlaps with the claimed range. (Ex. 1024, 3:65-67, 4:12-18.) A PHOSITA would have appreciated that this configuration renders *Ikari*'s catheter "substantially question-mark shaped." (*Compare* Ex. 1024, FIG. 1 *with* Ex. 1001, FIGS. 1-2; Ex. 1005, ¶76.)

For the same reasons discussed above for claim 13, it would have been obvious to a PHOSITA at the time of the alleged invention to shape the catheter in the *Auricchio-Randolph* combination to have a shape similar to that disclosed in *Ikari*. (*See supra* Section X.C.1.iii; Ex. 1005, ¶76.) For instance, a PHOSITA would have been motivated to use *Ikari*'s catheter design in selected patients with dilated atriums where the catheter shape would have enabled a portion of the catheter to contact the wall of the right atrium and provide back-up support to keep the catheter engaged within the coronary sinus ostium during the procedure. (Ex. 1005, ¶76.) Moreover, *Ikari* and other references demonstrate the claimed "question mark" shape was well-known at the time of the alleged invention. (*See, e.g.*, Ex. 1023, 3:58-67, FIG. 1; Ex. 1024, 3:65-4:11, FIG. 1; Ex. 1025, 211 (FR 3.5 ALT in Figure 1); Ex. 1026, FIG. 4 (top catheter); Ex. 1005, ¶76.) As discussed above, 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 accessing the coronary sinus. (*See supra* Section X.C.1.iii; Ex. 1005, ¶76.) A

PHOSITA having familiarity with angioplasty catheters like *Ikari*'s catheter and would have adopted these catheters and/or catheter designs to access the coronary sinus. (Ex. 1005, ¶76; Ex. 1013, 139D, 142D).

3. Claim 24

Challenged claim 27 depends from claim 25, which depends from independent claim 24, and incorporates all of the limitations of claim 24, which is disclosed by the combination of *Auricchio* and *Randolph*.

i. Claim element 24.a

The combination of *Auricchio* and *Randolph* discloses this limitation. (Ex. 1005, ¶¶77-78; *see also infra* Sections X.C.2.ii-vi.) *Auricchio* teaches a method for placing a coronary vein lead 10 ("electrical lead") in a preselected coronary vein, including a lateral branch of a coronary sinus vein, using a double catheter formed of a guide catheter ("outer catheter") and a support catheter ("inner catheter"). (*See* Ex. 1019, 1:14-17, 2:41-44, 3:22-38, 5:25-29, 8:49-53, FIGS. 15, 17.) As explained above for claim 13, *Auricchio* teaches that the support catheter is a "pliable" catheter that is slidably disposed in the guide catheter and of greater length than the guide catheter so that a distal end portion of the support catheter can be extended or retracted from a distal end opening of the guide catheter to vary the overall length of the double catheter. (*See supra* Section X.C.1.i; Ex. 1005, ¶78.)

As noted above, the phrase "sufficient stiffness to permit advancement of the outer catheter into a distal coronary sinus" is not a limiting requirement of the preamble. (*See supra* Section VIII.) Even if it were limiting, *Auricchio* discloses that its outer guide catheter has sufficient stiffness to permit advancement into a distal coronary sinus (Ex. 1019, 3:11-37, 5:25-29, 8:28-53, FIG. 17.) *Auricchio* does not disclose that its guide catheter is a "resilient tube having shape memory" or that it has "a hook-shaped distal end." As discussed for claim 13, *Randolph* teaches these features. (*See supra* Section X.C.1.ii-iii; Ex. 1005, ¶¶52, 78.) Thus, for the same reasons discussed above for claim 13, it would have been obvious to a PHOSITA to use a catheter, like *Randolph*'s guiding catheter, for the outer guide catheter disclosed in *Auricchio,* and a PHOSITA would have had a reasonable expectation of success in doing do. (Section X.C.1.ii; Ex. 1005, ¶78.)

ii. Claim element 24.b

Auricchio discloses inserting the guide catheter and the support catheter of *Auricchio*'s double catheter into the coronary sinus. (*See* Ex. 1019, 3:12-14 ("[t]he method for pacing in accordance with the present invention begins with the physician inserting a guide catheter through the coronary sinus"), *id.*, 8:49-52 ("a guide catheter may be used to direct a guide wire which is used to guide a support catheter to a desired position within a preselected coronary vein"); Ex. 1005, ¶79.)

iii. Claim element 24.c

Auricchio discloses advancing a guide wire through the guide catheter of *Auricchio*'s double catheter into the lateral branch vein. (Ex. 1019, 3:22-30; Ex. 1005, ¶80.) Specifically, *Auricchio* teaches that "[a] guide wire is . . . inserted into the guide catheter and advanced to the desired position within . . . a preselected coronary vein." (Ex. 1019, 3:24-26.) Like the '268 patent, *Auricchio* teaches that "a guide catheter may be used to direct a guide wire which is used to guide a support catheter to a desired position within a preselected coronary vein." (*Compare* Ex. 1001, 5:46-58 *with* Ex. 1019, 8:49-52.)

To the extent it is found that the claim requires advancing the guide wire relative to both the "outer catheter" *and* the "inner catheter" of "the catheter," this step was well-known to a PHOSITA, and a PHOSITA would have found it obvious to perform this step in combination with the steps explicitly disclosed in *Auricchio*. (Ex. 1005, ¶80.) A PHOSITA would have understood the benefits of advancing a guide wire through both the guide catheter and support catheter, advancing the support catheter over it, and then using the support catheter to provide axial support as the guide wire is delivered to a desired position in the target vein. (*Id*.) To the extent the guide wire was displaced during the procedure, a PHOSITA would have also been motivated to advance the guide wire relative to both the support catheter and the guide catheter in order to reposition the guide

wire at the desired location within the preselected coronary vein. (*Id.*) Moreover, if a PHOSITA encountered difficulties inserting the support catheter within the preselected coronary vein because of the tortuosity of the vein, a PHOSITA would have performed this step in order to position the guide wire in a second branch vein. (*Id.*) For similar reasons, it would have been obvious to a PHOSITA to advance the guide wire relative to both the guide catheter and the support catheter, particularly in view of *Auricchio*'s disclosure that the guide wire is used to "guide a support catheter to a desired position within a preselected coronary vein." (Ex. 1019, 8:49-52; Ex. 1005, ¶80.)

iv. Claim element 24.d

Auricchio discloses advancing the support catheter ("inner catheter") out of the distal or front end of the guide catheter ("outer catheter") "to the distal end of the guide wire" which is positioned within a branch vein, and thus teaches advancing the support catheter along the guide wire into the branch vein. (Ex. 1019, 3:26-28, 8:49-52; Ex. 1005, ¶81.)

v. Claim element 24.e

Auricchio discloses a method in which "the coronary vein lead . . . is advanced through the support catheter to the desired site in the coronary vein." (Ex. 1019, 3:30-32.) While Auricchio teaches that "[t]he guide catheter and guide wire are . . . removed, leaving the support catheter in place" before inserting lead

10 through the support catheter (*id.*, 3:28-32), it would have been obvious to a PHOSITA to have kept the guide catheter in the coronary sinus while placing the lead, rather than removing it first. (Ex. 1005, ¶82.) A PHOSITA would have been motivated to leave the guide catheter in the coronary sinus because, as the guide catheter is withdrawn, there is a risk that the support catheter may be displaced from the preselected coronary vein. (*Id*.) In addition, this would avoid the need to recannulate the coronary sinus to exchange support catheters, if such exchange is needed. (*Id*.) By leaving the guide catheter in position within the coronary sinus, the support catheter could also be manipulated or withdrawn without repeatedly drawing the support catheter back and forth over the vessel wall. (*Id*.)

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

vi. Claim element 24.f

Auricchio describes removing both the guide catheter and the support catheter from the coronary sinus to leave the lead in the branch vein. (Ex. 1019, 3:28-30, 3:34-37, 8:28-29, 8:46-49; Ex. 1005, ¶83.) For example, *Auricchio* describes that the guide catheter is "the tear away type known to those skilled in the art" that is split as it is removed from the body. (Ex. 1019, 8:28-29, 8:46-49; Ex. 1005, ¶83.) *Auricchio* teaches that "the support catheter is retracted or peeled away from the lead body." (*Id.*, 3:35-38.) As discussed above for claim element 24.e, it would have been obvious to a PHOSITA to position the guide catheter within the coronary sinus so that the lead would be inserted through both the support catheter and the guide catheter to the desired location in the branch vein. (*See supra* section X.C.2.v; Ex. 1005, ¶83.) In this method, both the guide catheter and the support catheter would be retracted or peeled away from the lead body to leave the lead in the branch vein. (*Id*.)

4. Claim 25

Claim 25 recites limitations that track those recited in claim 13. (*Compare* Ex. 1001, 10:13-20 *with id.*, 8:22-27.) Thus, the combination of *Auricchio*, *Randolph*, and *Ikari* teaches the limitations of claim 25 for the same reasons discussed above for claim 13. (*See supra* Section X.C.1.iii; Ex. 1005, ¶84.)

5. Claim 27

Claim 27 recites limitations that track those of claim 15. (*Compare* Ex. 1001, 10:23-25 *with id.*, 8:31-33.) Thus, the combination of *Auricchio, Randolph*, and *Ikari* teaches the limitations of claim 27 for the same reasons discussed above for claim 15. (*See supra* Section X.C.2; Ex. 1005, ¶85.)

XI. CONCLUSION

For the reasons given above, Petitioner requests *inter partes* review and cancellation of claims 15 and 27 of the '268 patent.

Respectfully submitted,

Dated: August 1, 2018

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Paul Hastings LLP

Counsel for Medtronic, Inc.

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

The undersigned certifies that the foregoing Petition for *Inter Partes* Review contains 13,968 words according to the word count of the word-processing software used to prepare the petition.

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Paul Hastings LLP

Counsel for Medtronic, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition for *Inter Partes* Review and supporting materials were served on August 1, 2018, by express mail at the following address of record as listed on PAIR:

BOYLE FREDRICKSON S.C.
840 North Plankinton Avenue
Milwaukee, WI 53203

Dated: August 1, 2018

By: /Naveen Modi/
Naveen Modi (Reg. No. 46,224)
Paul Hastings LLP

Counsel for Medtronic, Inc.