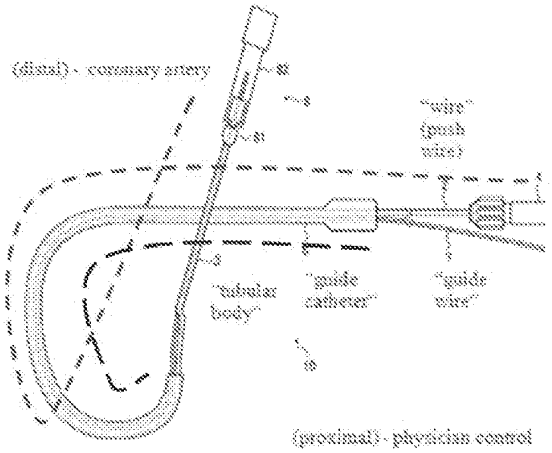
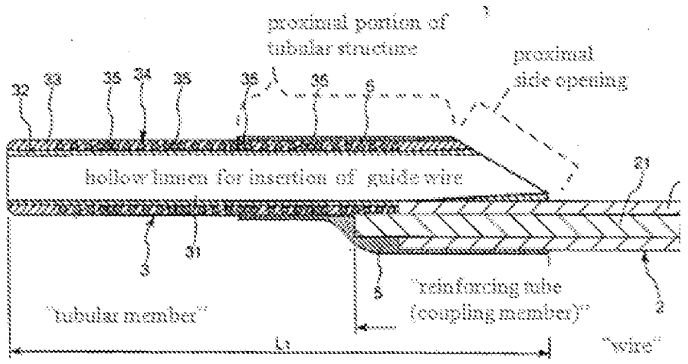
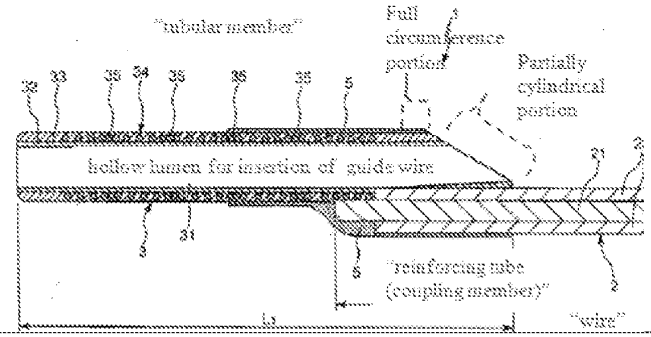
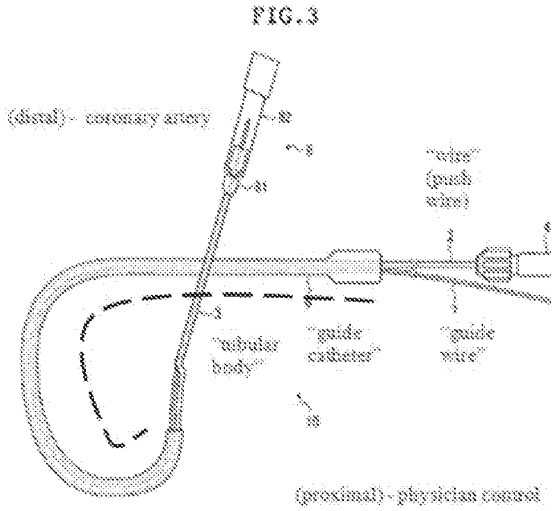
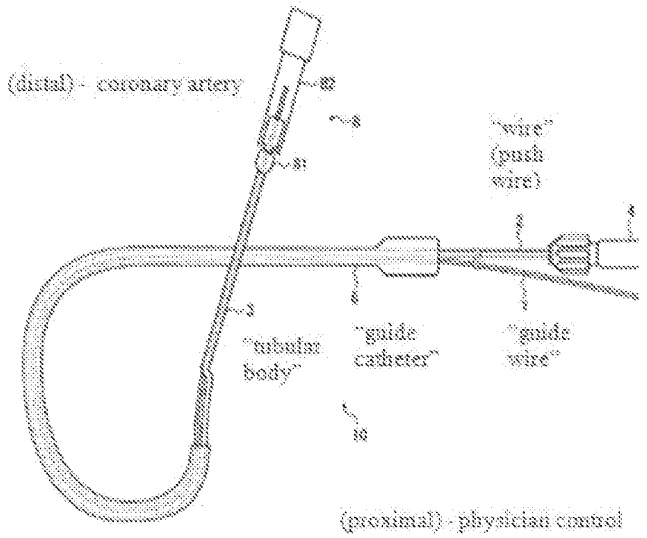
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	FIG.3  *Compare* 1006, [0092]: ("the guiding catheter 6 (Heart Rail 6, produced by Terumo Corp.; having an inner diameter of 1.8 mm and a length of 100 cm)"), *with* [0034] ("The entire length of the catheter 1 is not particularly limited, but preferably in the range of 900 to 1700 mm, and more preferably in the range of 1100 to 11500 mm"); *see* [0073]-[0075] ("Length of the wire 2: 1060 mm[;] Length of L2: 10 mm[;] Length of L1: 250 mm")
2. The system of claim 1, wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,	Mihara discloses the device of claim 1 (*see above*)

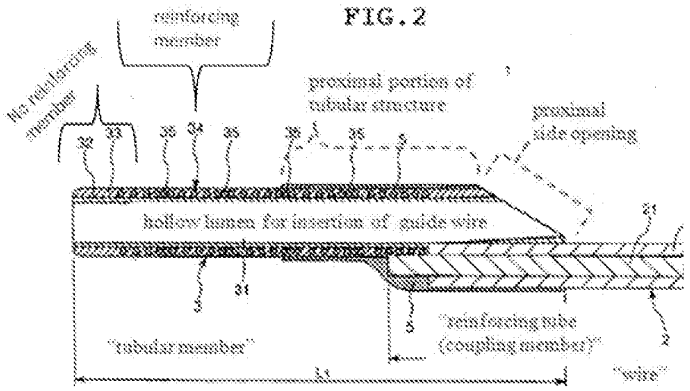
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	"As shown in Table 1, it was confirmed that the catheter of the present invention (Example 1) has a high striking resistance and an excellent push-in property, compared with the catheter with the guide wire lumen formed over the entire length of the catheter (Comparative Example)." (Exh. 1009, [0100]). "An object of the present invention is to provide a catheter excellent in push-in property, capable of easily and rapidly penetrating a stenotic lesion…." (Exh. 1009, [0010]). "As described below, the catheter of the present invention has an excellent push-in property. Therefore, a push-in force applied from a proximal end side is transmitted to a distal end portion exactly, and as a result, the catheter can penetrate a stenotic lesion occurred in a lumen in the human body easily and rapidly." (Exh. 1009, [0024]).
3. The device of claim 2	Mihara discloses the device of claim 2. (*see above*)
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a proximal side opening extending for a distance along the longitudinal axis and accessible from a longitudinal side defined transverse to the longitudinal axis. (Exh. 1009, Fig. 1).

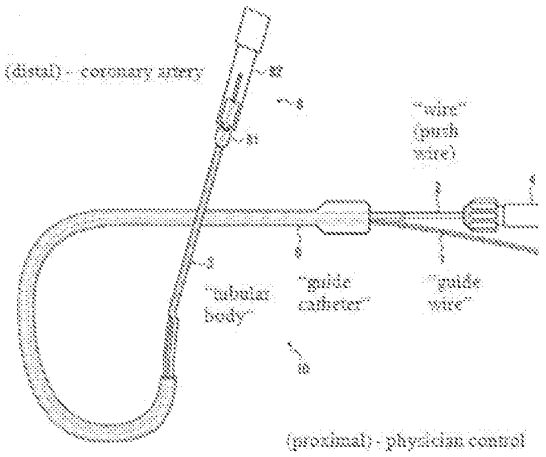
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	FIG. 2 
to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	"The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049]).
4. The system of claim 3	Mihara discloses the device of claim 3. (*see above*)
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion: FIG. 2 
12. A system for use with interventional cardiology	**[1]** To the extent that the preamble is a limitation, Mihara discloses a device for use with "guiding

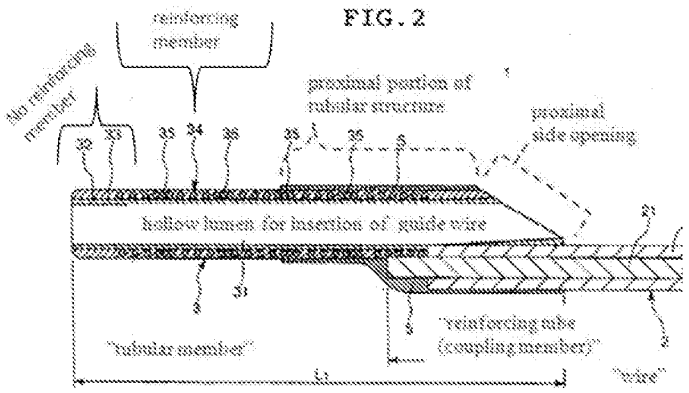
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	catheter 6" (*see* dashed blue line in annotated Fig. 3 below) having a continuous lumen extending for a predefined length from a proximal end to a distal end adapted to be placed in a branch artery:  "First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery." (Exh. 1009, [0092]). **[2]** As shown in annotated Fig. 3 above, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. "First the guiding catheter 6…having an inner diameter of 1.8 mm…was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7…was

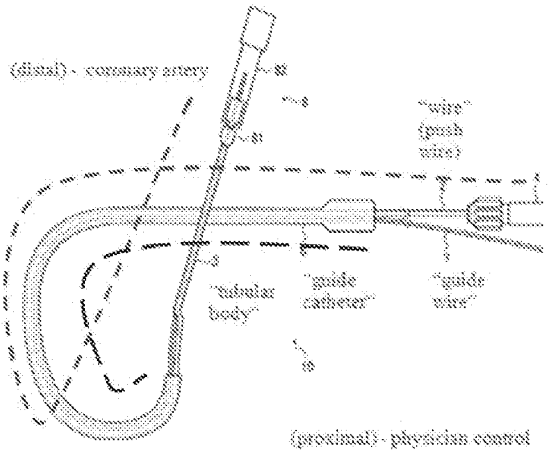
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093]). "First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery." (Exh. 1009, [0092]). **[2]** As shown in annotated Fig. 3 below, the guide catheter 6 used with the Mihara device has a continuous central lumen FIG. 3  **[4]** As shown in annotated Fig. 3 below, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. "First the guiding catheter 6 … having an inner

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	diameter of 1.8 mm…was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7…was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093]).
an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,	Mihara discloses that the combined length of the wire 2 and tubular body 3 is longer than the guide catheter lumen. (*See* Fig. 3 below). As shown in Fig. 3, catheter is longer that the continuous lumen of the guide catheter 6 as the wire 2 extends beyond the proximal end of the catheter and tubular body 3 extends beyond the distal end of the guide catheter 6.
the elongate structure including: a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	Annotated Fig. 2 of Mihara (below) discloses an elongate structure 1 including a flexible tip portion defining a tubular body 3 wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being "preferably formed of a flourine resin such as polytetrafluoroethylene (PTFE)." (Exh. 1009, [0051]). The outer layer 33 is further described as being preferably "composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof." (*Id.*, [0052]).

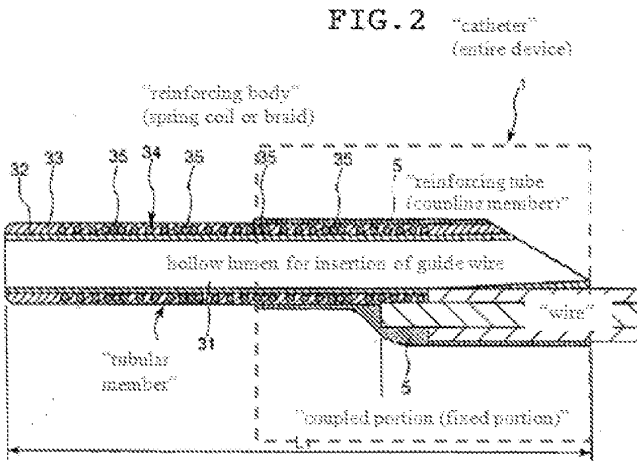
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	FIG. 2  **[2]** The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm." (Exh. 1009, [0056]). **[3]** "Although the length of the tubular body 3 … is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm." (Exh. 1009, [0057]).
the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;	**[1]** Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm): "Outer diameter of a portion between 0 and 90 mm from the proximal end side of the tubular body 3: 0.87 mm." (Exh. 1009, [0081]). "First, the guiding catheter 6 … having an inner diameter of 1.8 mm…." (Exh. 1009, [0092]). **[2]** As shown in annotated Fig. 3 below, Mihara discloses that the flexible tube ("tubular body 3") is placed coaxially relative to the guide catheter 6:

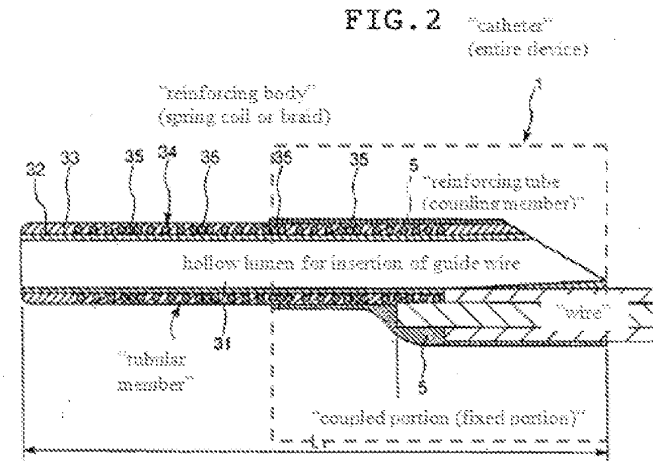
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	FIG. 3  **[3]** "As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end of the wire 2" (Exh. 1009, [0033]). "The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049]).
a reinforced portion proximal to the flexible tip portion; and	As shown in annotated Fig. 1 below: "The tubular body 3 has an inner layer 32 positioned on an inner circumferential side, an outer layer 33 formed on an outer circumferential side of the inner layer 32, and a reinforcing body (reinforcing member) 34 placed between the inner layer 32 and the outer layer 33." (Exh. 1009, [0050]). "In this embodiment, the reinforcing body 34 is a spiral coil composed of tungsten. The reinforcing body 34 is placed in such a manner that the reinforcing body 34 is buried in the

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	outer layer 33 (or the inner layer 32). The reinforcing body 34 is not limited to a spiral coil, and may be a braided body (net-shaped body), a bar-shaped body, or the like." (*Id.*, 0053]); Its material is not limited to tungsten. The reinforcing body 34 may be made of stainless steel or the like. "the reinforcing body 34 composed of a spiral coil at several portions." (*Id.*, [0059]). FIG. 2 
a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: "As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed." (Exh. 1009, [0036]). "The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	1 (tubular body 3) exactly by the wire 2." (Exh. 1009, [0037]).
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,	Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip: "The outer diameter of the wire 2 in the proximal portion . . . is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm." (Exh. 1009, [0048]). "[T]he outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm." (Exh. 1009, [0055]).
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	As shown in annotated Fig. 3 below, Mihara discloses that when at least a distal portion of the tubular body 3 is extended distally of the distal end of the guide catheter 6 with at least proximal portion of the rigid push wire 2 remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally in common with a guide wire 7 that is insertable into the guide catheter. (Exh. 1009, Fig. 3). FIG.3 
14. The system of claim 11	Mihara discloses the system of claim 11 (*See* cl. 11

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	"The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion). Therefore high coupling strength can be obtained, and the enlargement of the distal end portion of the catheter 1 can be prevented." (Exh. 1009, [0061]). "Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5. . . . [t]he overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process." (Exh. 1009, [0062]). Annotated Fig. 2 (below) depicts that the proximal side opening (that includes a partially cylindrical portion) to the hollow device lumen 31 of the reinforcing tube 5 surrounding the overlapped portion of the wire 2 and tubular body 3 is skived or cut at an angle,forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	FIG. 2  "the wire 2 is provided with appropriate rigidity (flexural rigidity and torsional rigidity), which enhances a push-in property and transmittance of a torque." (Exh. 1009, [0043]).
that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	"The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049]).
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	Annotated Fig. 2 (below) of Mihara discloses a proximal opening extending substantially along at least a portion of a length of the substantially rigid portion.

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	FIG. 2 

B. Claims 1-4, 8, 12, 14 And 17 Are Obvious Under 35 U.S.C. § 103 Over Pub. No. U.S. 2007/0260219

As discussed above, all challenged claims of the '850 patent are, at best, only entitled to an effective filing date of January 26 2012, which is the filing date of the '850 patent. The publication of U.S. Patent Application 11/416,629 (the application of the'032 patent), Pub. No. U.S. 2007/0260219 (Exh. 1012), was publicly available more than one year before the filing date of the '850 patent and thus constitutes prior art under §102(b). While the disclosure set forth in Pub. No. U.S. 2007/0260219 has insufficient written description to support a claim of priority for the reasons discussed above, it would have been obvious to replace a 'monorail' tube—which has a lumen with the stiffening element or advancement member of a "rail without a lumen" because stiff proximal low profile structures

for pushing the tubular structure of a rapid exchange catheter through to the treatment site were known to be necessary for the delivery of monorail rapid exchange devices. (Exh. 1003 ¶ 53-54).

C. Claims 1-4, 12, and 14 Are Obvious Under 35 U.S.C. § 103 Over Mihara In View of the Knowledge of a Person of Ordinary Skill in the Art

To the extent that the Board concludes that the order and intended use limitations of claims 1, 2, 3, 4, 12, and 14 are not expressly or inherently disclosed by Mihara, Petitioner asserts that those characteristics should be deemed obvious based on Mihara alone. All of the structural recitations of the claims are expressly disclosed by Mihara as discussed above, and therefore, Petitioner references the analysis and claim charts for those elements as part of its obviousness analysis here. *See Intellectual Ventures Mgmt., LLC v. Xilinx*, IPR2012-00020, 9 (Feb. 11, 2014) ("A reference need not teach every feature for it to render a claimed invention obvious….[A]n obviousness determination takes into account what a person of ordinary skill in the art would have known at the time of the invention and is not limited to what is contained within the four corners of a parent or printed publication."); *see Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

D. Claims 1-4, 8, 12, 14 and 18 Are Obvious Under 35 U.S.C. § 103(a) Over Mihara In View Of Takahashi

As shown below, each element recited in claims 1-4, 8, 12, 14 and 18 is obvious over Mihara in view of Takahashi. Although Takahashi was cited during prosecution of the '032 Patent, it was not discussed in any Office Action or considered in combination with Mihara.

Mihara, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Mihara and Takahashi. (1003, ¶ 36).

Claims 8 and 18 require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." Takahashi satisfies the limitations of claims 8 and 18 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter such that the cross-sectional inner diameter of the 5 French catheter is not more than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner diameter of the outer guide catheter, and would recognize that this teaching of Takahashi's 5-in-6 system could be applied to any coaxial catheter directed to insertion through a standard guide catheter for purposes of providing backup support during interventional

cardiology procedures, such as Mihara, and would have been motivated to do so. (Ex. 1003 ¶¶ 92-94).

In 2004, the same year in which the Mihara publication was filed and published on behalf of assignee Terumo (and within which the Terumo Heartrail is expressly discussed as being used during testing of the Mihara support catheter), the Takahashi article disclosed use of Terumo's Heartrail guide catheter in teaching the advantages of minimizing differences in diameter for purposes of achieving the functionality of both a support catheter (enhanced pushability and backup support) and a guide catheter (working channel between the site of vascular access and the target vessel).

A POSA reviewing the device disclosed by Mihara at the time of the claimed invention would, therefore, have been motivated by Takahashi to achieve the advantages of having minimal difference in diameter by practicing the invention of Mihara within the claimed range of not more than one French with the predictable and expected results of allowing for the insertion of larger devices through the creation of a larger working channel. (*See* Exh. 1003 ¶¶64-65 and 86-97.

Claim Chart A-2: Cl. 8, 18	
The '850 Patent	**Mihara (Exh. 1009) in view of Takahashi (Exh. 1021)**
8. The system of claim 1,	Mihara discloses the system of claim 1 (*See* A-1, above).

Claim Chart A-2: Cl. 8, 18	
The '850 Patent	**Mihara (Exh. 1009) in view of Takahashi (Exh. 1021)**
wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	"The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A)." (Exh. 1021 at 452). "The inner lumen of the 5 Fr Heartrail catheter is 0.059' in diameter…. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter…." (*Id*). "In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter…." (*Id*. at 453) "Only inserting the 5 Fr guiding catheter into the 6 Fr catheter increased backup support…." (*Id*). "A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter." (*Id*. at 454).
18. The system of claim 12	Mihara discloses the device of claim 11. (*See above*).
wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	*See* Takahashi disclosures set forth in claim 8. (*See above*).

IX. CONCLUSION

Based on the foregoing, it is clear that claims 1-4, 12, and 14 of the '850 Patent define subject matter that is anticipated by Mihara and that claims 1-4, 8, 12, 14, and 18 of the '850 patent define subject matter that is obvious in view of

Mihara combined with the teachings of Takahashi. Mihara and the prior art combination cited above were never considered by the Examiner; if they had been, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '850 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

ARNOLD & PORTER LLP

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 16, 2014, to the USPTO correspondence address of record listed below:

Patterson, Thuente, Petersen, PA
4800 IDS Center
80 South 8th Street
Minneapolis, MN 55402-2100

Courtesy copies were also shipped to counsel for patent owner at the following address:

J. Thomas Vitt
Heather Redmond
Shannon Bjorklund
Forrest Tahdooahnippah
Dorsey & Whitney
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402
Telephone: (612) 340-2600

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

ATTACHMENT C

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,142,413 B2

Attorney Docket No. 0025216-00057

PETITION FOR INTER PARTES REVIEW
UNDER 37 C.F.R. § 42.100

TABLE OF CONTENTS

Page

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)) 5
A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) 5
B. Related Matters (37 C.F.R. § 42.8(b)(2)) 5
C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a)) 6
D. Service Information (37 C.F.R. § 42.8(b)(4)) 6

II. PAYMENT OF FEES (37 C.F.R. § 42.103) 6

III. SUMMARY OF RELEVANT TECHNOLOGY AND '413 PATENT 6
A. Overview Of Interventional Cardiology Procedures 7
B. Description Of The Alleged Invention Of The '413 Patent 8
C. Summary of the Prosecution History of the '413 Patent 10

IV. REQUIREMENTS FOR INTER PARTES REVIEW 12
A. Grounds for Standing Under 37 C.F.R. § 42.104(a) 12
B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested 12
C. Claims for Which *Inter Partes* Review Is Requested 12
D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2) 12
E. Construction Of The Challenged Claims 13
1. "rail structure without a lumen" 14
2. "interventional cardiology device(s)" 16
F. The Prior Art References 16
1. Adams '292 17
2. Klein 18
3. Adams '452 18
4. Mihara 19
5. Steinke 19
6. Takahashi 20
G. How The Construed Claim(s) Are Unpatentable 20
H. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5) 21

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4) 21
A. Claims 1 And 13 Are Anticipated Under 35 U.S.C. §102(b) By Adams'292 21
1. Claim 1 22

2. Claim 13 24
B. Statement Of Non-Redundancy: Skived Proximal Opening Disclosures in Klein, Adams '452, Mihara, And Steinke 31
C. Claims 1, 4, 9, And 10 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of The Knowledge Of One Of Ordinary Skill In The Art 33
D. Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Klein 35
E. Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Adams '452 40
F. Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Mihara 45
G. Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Steinke 50
H. Claim13 Is Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of The Knowledge Of One Of Ordinary Skill In The Art 55
I. Claims 1 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Takahashi 57
VI. CONCLUSION 59

Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,142,413

Exhibit Description	Exhibit No.
U.S. Patent No. 8,142,413 to Root, et al.	1001
File History for U.S. Patent No. 8,142,413	1002
Declaration of Ronald Jay Solar, Ph.D., with attached Appendix1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,048,032 to Root, et al.	1004
U.S. Patent No. 8,292,850 to Root, et al.	1005
File History for U.S. Patent No. 8,048,032	1006
File History for U.S. Patent No. 8,292,850	1007
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1008
U.S. Patent No. 6,638,268 to Niazi	1009
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1010
U.S. Publication No. 2004/0127927 to Adams	1011
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1012
U.S. Patent No. 5,527,292 to Adams et al.	1013
U.S. Patent No. 5,776,141 to Klein et al.	1014
U.S. Patent No. 7,232,452 to Adams et al.	1015
U.S. Patent No. 5,328,472 to Steinke et al.	1016
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," *Catherization and Cardiovascular Interventions* 63:452-456 (2004)	1017
U.S. Patent No. 5,690,613 to Verbeek	1018
U.S. Patent No. 5,156,594 to Keith	1019
U.S. Patent No. 5,102,403 to Alt	1020
Kucklick, Theodore R., The Medical Device R&D Handbook (2006)	1021
Amended Complaint filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (May 28, 2013)	1022
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1023
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1024

Exhibit Description	Exhibit No.
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (July 28, 2013)	1025
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (December 19, 2013)	1026
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed December 27, 2013	1027
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed January 3, 2014	1028
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir.) filed January 7, 2014	1029
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir.) filed January 29, 2014	1030
Declaration of Anthony Vrba In Support of Boston Scientific Opposition to Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (July 8, 2013)	1031
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir.) filed February 3, 2014	1032
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir.)	1033
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1034
Joint Claim Construction Statement filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (February 21, 2014)	1035
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1036
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1037
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1038
U.S. Patent No. 5,267,958 to Buchbinder et al.	1039
U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1040

Inter partes review is respectfully requested for claims 1, 4, 9, 10, and 13 of U.S. Patent No. 8,142,413 B2 ("the '413 Patent") (Exh. 1001).

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '413 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 12-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of U.S. Patent No. 8,048,032 B2 (the "'032 patent") and U.S. Patent No. 8,292,850 (the "'850 patent") in four petitions being filed concurrently herewith. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and directed generally to the same subject matter. The '850 patent is a divisional of application No. 12/824,734, which issued as the '413 patent, and the '413 patent is a divisional of application No. 11/416,629, which issued as the '032 patent. The claims challenged in the

concurrently filed petitions are apparatus ('032 patent) and system ('850 patent) versions of the method claims of the '413 patent challenged herein.

C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

Lead Counsel	Back-Up Counsel
David R. Marsh (Reg. No. 41,408) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5068 Facsimile: 202.942.5999 Email: david.marsh@aporter.com	Kristan L. Lansbery (Reg. No. 53,183) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5186 Facsimile: 202.942.5999 Email: kristan.lansbery@aporter.com

D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to service by email to lead and backup counsel at xBSC_VSI_IPRService@aporter.com.

II. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 50-2387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF RELEVANT TECHNOLOGY AND '413 PATENT

A. Overview Of Interventional Cardiology Procedures

The claims of the '413 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (*See* Exh. 1001, 1:21-44). During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.; see* Declaration of Ronald Jay Solar, Ph.D. ("Solar Declaration") ¶ 8 (Exh. 1003)). The physician introduces the treatment device into the patient's vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id.*) Often, to create a passage for such treatment devices, physicians insert a "guide catheter" earlier in the procedure. (*Id.*) In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id.*) The '413 patent is directed to methods for delivering an apparatus through a standard guide

catheter, extending beyond the ostium, to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (*See, e.g.*, Exh. 1001, 2:51-55).

B. Description Of The Alleged Invention Of The '413 Patent

The '413 Patent contains 14 method claims, including one independent claim (claim 1). The specification of the '413 patent states that it relates "generally to catheters used in interventional cardiology procedures," and "[m]ore particularly, ... methods … for increasing backup support for catheters inserted into the coronary arteries of the aorta." (Exh. 1001, 1:13-17).

The challenged claims of the '413 patent are not straightforward; they are replete ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Independent claim 1 of the '413 patent recites:

> 1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:
>
> inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;
>
> positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,

further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;

advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and

inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.

Dependent claim 4 of the '413 patent depends from independent claim 1 and recites a method "further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof."

Dependent claim 9 of the '413 patent depends from independent claim 1 and recites a method "further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter."

Dependent claim 10 of the '413 patent (depending from claim 9) recites a method "further comprising extending the interventional cardiology device through the proximal side opening; advancing the interventional cardiology device through structure defining a full circumference portion; and advancing the interventional cardiology device through structure defining a partially cylindrical portion."

Dependent claim 13 of the '413 patent depends from independent claim 1 and recites a method "further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter."

C. Summary of the Prosecution History of the '413 Patent

The '413 Patent was filed as U.S. App. Serial No. 12/824,734 on June 28, 2010 (*see* Exh. 1002, paper 1) and claims priority to application No. 11/416,629, filed on May 3, 2006, which issued as the '032 patent.

Claims 1-7 were rejected as obvious over U.S. Patent 6,638,268 ("Niazi") in view of U.S. Patent Application Publication No. 2005/0004523 to Osborne, *et al.*, ("Osborne"). The Examiner found that Niazi disclosed all but "a rigid portion proximal to the reinforced portion and at least a portion of the reinforced portion extending out of the distal end of the guide catheter and into the second blood vessel." (Non Final Office Action (Aug. 1, 2011) at 3-4 (Exh. 1002, at 70-71). The element missing from Niazi was, however, disclosed by Osborne: "a reinforcing portion 52 and a stiffening cannula 50 within inner cannula 20 to avoid kinking (Paragraph 36) and provide stiffening (Paragraph 35). Therefore, it would have been obvious ... to include a reinforcing portion and stiffening portion as taught by Osborne to the device of Niazi to provide kind resistance and stiffening." (*Id.* at 4.)

Regarding claim 4, the Examiner asserted that "[a] side port exists in the side of catheter 52 for contrast media (5:25-28). The part of the catheter along the same longitudinal length as the side port is partially cylindrical and the surrounding areas are fully cylindrical." (*Id.* at 4).

In response, Applicant amended claims 1-3, 5, and 7 (corresponding to claims 1-6 of the '413 patent) and cancelled claim 6.

A Notice of Allowance was mailed January 17, 2012, and the '413 Patent issued on March 27, 2012.

IV. REQUIREMENTS FOR INTER PARTES REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '032 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '413 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

The precise relief requested by Petitioner is that claims 1, 4, 9, 10, and 13 of the '413 Patent be found unpatentable.

C. Claims for Which *Inter Partes* Review Is Requested

Pursuant to 37 C.F.R. § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1, 4, 9, 10, and 13 of the '413 Patent.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

This Petition, supported by the grounds set forth below and the Solar Declaration (Ex. 1003), demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C.

§ 314(a). *Inter partes* review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103.

No.	Grounds
1	Claims 1 and 13 are anticipated by US 5,527,292 ("Adams '292")
2	Claims 1, 4, 9, 10 and 13 are obvious over Adams '292 in view of knowledge of one of ordinary skill in the art
3	Claims 1, 4, 9, 10 and 13 are obvious over Adams '292 in view of US 5,776,141 ("Klein")
4	Claims 1, 4, 9, 10 and 13 are obvious over Adams '292 in view of US 7,232,452 ("Adams '452")
5	Claims 1, 4, 9, 10 and 13 are obvious over Adams '292 in view of US Pub. 2004/0236215 ("Mihara")
6	Claims 1, 4, 9, 10 and 13 are obvious over Adams '292 in view of US 5,328,472 ("Steinke")
7	Claim 13 is obvious over Adams '292 in view of knowledge of one ordinary skill in the art
8	Claim 13 is obvious over Adams '292 in view of "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," 2004, Takahashi Online Article ("Takahashi")

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

E. Construction Of The Challenged Claims

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to inter partes review shall receive the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." *See* I*n re Swanson*, 540 F.3d 1368, 1377-78 (Fed. Cir. 2008); *In re Trans Texas Holding* Corp., 498 F.3d 1290, 1298 (Fed. Cir. 2007) (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984). Because the standards of claim interpretation used by the Courts in patent litigation differ from

those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation ("BRI") in light of the patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.[1]

1. "rail structure without a lumen"

Because the '413 patent does not disclose any structure for the "rail structure without a lumen" limitation of independent claim 1, it is invalid under 35 U.S.C. § 112, ¶ 2. The word "rail" appears in the specification of the '413 patent only twice. *First*, the Summary of the Invention refers to a "guidewire rail segment," defined as "permit[ing] delivery without blocking the use of the guide catheter." (Exh. 1001, 2:62). *Second*, Fig. 17 is described as "a plan view of a coaxial guide catheter having a longer rail segment," without any guidance as to which portion(s) of Figure 17 constitute the "rail segment." Neither of these references discloses any

[1] Petitioner reserves the right to challenge the validity of the '413 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

meaning for "rail" in the claim term "rail structure without a lumen." (Exh. 1003, ¶ 67). Moreover, nothing in the specification suggests that the rail structure consists of the "tapered inner catheter," "full circumference portion," "cutout potion," "reinforced portion," "hemicylindrical portion," "second full circumference portion," "arcuate portion," "braid or coil reinforcement," "most proximal portion of braid or coil reinforcement," "relief cut," "hemi-tube portion," "single cuts," "double cuts," "connector hub," "funnel portion," "grip portion," to name a few, nor would be so read by a POSA. (*Id.*)

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent claim 1 under 35 U.S.C. §§ 102 and 103[2], and claims 4, 9, 10, and 13 depending therefrom, Petitioner submits that, a POSA would understand "rail structure" to refer to a pushing or advancement structure. "Monorail" or rapid exchange catheters are characterized by a relatively guide wire lumen; this cannot be the "rail structure" for purposes of the claim, however, because the claimed structure must be "without a lumen." (Exh. 1003 ¶ 68). A POSA would therefore

[2] All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing dates of the patents at issue.

understand the "rail structure" to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id.* ¶ 69). Accordingly, the term "rail structure without a lumen" can be construed for purposes of this Petition to mean a "pushing or advancement structure without a lumen." (*Id.*)

2. "interventional cardiology device(s)"

The specification of the '413 patent expressly defines the term "interventional cardiology devices": "For the purposes of this application, the term 'interventional cardiology devices is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters." (Exh. 1001, 1:23-26). A person of ordinary skill in the art would understand the term "interventional cardiology devices" to include other thin, flexible treatment devices used in treating a blockages (occlusions) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions, such as embolic protection devices, such as filters. (Exh. 1003 ¶ 70).

F. The Prior Art References

As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under §102(b), some of which also constitute prior art under §102(a), as set forth below.[3]

1. Adams '292

U.S. Patent No. 5,527,292 to Adams, *et al.* ("Adams '292") (Exh. 1013) matured from an application filed on September 9, 1994, prior to the earliest filing date the benefit of which is claimed by the '032 patent and is therefore available as prior art to the '032 patent under 35 U.S.C. § 102(b). Adams '292 describes a guide catheter extension: "The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter" (Exh. 1013, 4:35-38; Exh. 1003 ¶ 72), and discloses, *inter alia*:

> An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery. The device also including a push rod attached to a proximal end of the flexible tube to facilitate placement of the flexible tube within the coronary artery requiring treatment.

---

[3] All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

(Exh. 1013 at Abstract). A benefit of the device disclosed in Adams '292 is the ability to extend the flexible tube beyond the distal tip of the guide catheter so that it is deep-seated beyond the ostium to anchor the guide catheter during treatment:

> A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond….

(Exh. 1013, 9:12-24; *see* Exh. 1003 ¶¶ 31 and 72).

2. Klein

U.S. Patent No. 5,776,141 to Klein ("Klein") (Exh. 1005) matured from an application filed on August 26, 1996, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under §102(b). Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter and a proximal shaft attached to the proximal end of the tubular catheter body. (Exh. 1003 ¶ ¶ 33 and 75).

3. Adams '452

U.S. Patent No. 7,232,452 to Adams ("Adams '452") (Exh. 1015) matured from an application filed on July 12, 2002, prior to the earliest filing date the benefit of which is claimed by the '032 patent, and thus qualifies as prior art under § 102(b). The Adams '452 patent discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large

enough to allow passage of a catheter used to deliver … an expandable filter or balloon." (Exh. 1015, 8:47-50; Exh. 1003 ¶¶ 34 and 78). Adams '452 further discloses "A proximal wire or other control means…." (Exh. 1013, 8:27-30). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1003 ¶ 78). The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*Id.* ¶ 34).

4. Mihara

Patent Application Publication No. US 2004/0236215 A1 to Mihara, *et al.* ("Mihara") (Ex. 1040) was filed on March 12, 2004, prior to the earliest filing date the benefit of which is claimed by the '413 patent and, thus, qualifies as prior art under § 102(b). Mihara discloses "a linear wire" and "a tubular body placed on a distal end side of the wire allowing a guide wire to be inserted through its hollow portion." (Exh.1040, ¶¶ [0013], [0014]). The proximal opening to the hollow tube is skived or cut at an angle. (*Id.*, FIG. 2).

5. Steinke

U.S. Patent No. 5,328,472 to Steinke ("Steinke") (Ex. 1016) matured from an application filed on July 27, 1992, prior to the earliest filing date the benefit of

which is claimed by the '032 patent and, thus, qualifies as prior art under § 102(b). Steinke discloses "a catheter which allows rapid exchange" where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1016, 3:1-2; Exh. 1003, ¶ 35)

6. Takahashi

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions, 63:452-456 ("Takahashi") (Exh. 1017) is an article published in 2004 and, thus, qualifies as prior art under § 102(b). In fact, Takahashi is admitted to be prior art on the face of the '413 patent. Takahashi describes method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶¶ 36 and 84). The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is less one French or less. (*Id.*)

G. How The Construed Claim(s) Are Unpatentable

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1, 4, 9, 10, and 13 of the '413 patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section

V below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration.

H. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below in Section V and the corresponding claim charts set forth therein. Dr. Solar, an expert with thirty-seven years of academic and industry experience in the field of interventional cardiology devices, has reviewed the claim charts submitted in the '413 Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein. (*See generally* Exh. 1003).

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4)

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to achieve predictable results, all of which were well known to persons of ordinary skill in the art in the field of interventional cardiology procedures at the time to which the '413 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

A. Claims 1 And 13 Are Anticipated Under 35 U.S.C. §102(b) By Adams'292

As shown below, each element recited in claims 1 and 13 is anticipated by Adams '292, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '413 patent. (An unrelated application by a different inventor with the last name "Adams" was disclosed). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *E.g.*, *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

1. Claim 1

Claim 1 of the '413 patent discloses: "[a] method of providing backup support for an interventional cardiology device … adapted to be passed through a standard guide catheter…." (Exh. 1001, 10:28-30); Adams '292 similarly, teaches: "For use in combination with a guide catheter for insertion and advancement of a coronary treatment device … an anchoring device…." (Exh. 1013, 22:35-40). Claim 1 of the '413 patent discloses "inserting the standard guide catheter into a first artery over a guidewire; a POSA would understand that the guide catheter is advanced over a guidewire. (Exh. 1003 ¶ 97). Claim 1 of the '413 patent further discloses "inserting the flexible tip portion of a coaxial guide catheter defining a tubular structure having ... a length that is shorter than the … length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. (Exh. 1001, 10:45-49); Adams '292 similarly discloses "a

relatively flexible tube having … an outer diameter … sized for insertion through the central lumen of the guide catheter …" (Exh. 1013, 23:37-40) and "[t]he length of the flexible tube 32 is preferably approximately 6 to 10 inches" (*id.*, 5:61-63), which a POSA would understand to be shorter than the length of a standard guide catheter—approximately 40 inches. (*See* Exh. 1003 ¶ 100). Claim 1 of the '413 patent also discloses: "a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion … defining a rail structure without a lumen …" (Exh. 1001, 10:50-55); Adams '292 similarly teaches that a "shaft 19 or push rod is attached to a proximal end of the elongated flexible tube 32" (Exh. 1013, 6:1-2) and that "[o]ne embodiment is shown in FIG. 2 and the shaft 19 or push rod is defined by an elongated wire." (*Id.*) Claim 1 of the '413 patent discloses that the combined length of the substantially rigid portion and the distal tip portion is greater than the length of the guide catheter; Adams '292 similarly discloses that the combined length of the push rod and the flexible tube is preferably 50.5 inches to 51.5 inches, while a POSA would understand that a standard guide catheter is approximately 40 inches. (Exh. 1003 ¶ 103). Finally, claim 1 of the '413 patent requires "advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter" while "at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve" (Exh. 1001, 10:62-

67); likewise, Figure 1 of Adams '292 shows the flexible tube 32 extending beyond the distal tip of the guide catheter 12, while the push rod 19 extends proximally through the channel leg of the manifold 17 (where the hemostatic valve is located). Thus, Adams '292 discloses every element of claim 1 of the '413 patent.

2. Claim 13

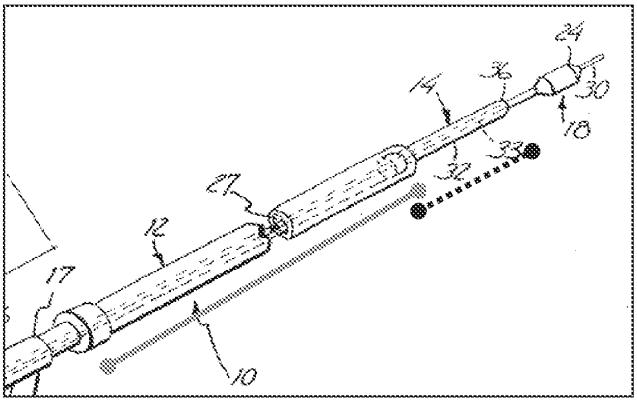
Claim 13 (depending from claim 1) of the '413 patent requires "selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter." The Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube; a POSA would understand that the largest tubes within that range would have an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1001, 5:64-67). In disclosing a range overlapping or touching the claimed range, the Adams '292 thereby anticipates the claimed range with sufficient specificity. *See, e.g., ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

The '413 Patent	**Claim Chart A-1: Claim 1 in view of Adams '292**
1. A method of providing backup support for **[1]** an	"For use in combination with a guide catheter for insertion and advancement of a coronary treatment

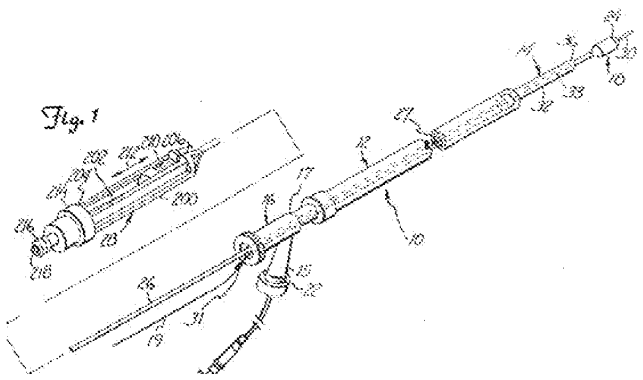
The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
interventional cardiology device for use in the coronary vasculature, **[2]** the interventional cardiology device being adapted to be passed through a standard guide catheter, **[3]** the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, **[4]** the continuous lumen of the guide catheter having a circular cross sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	device through a coronary vessel having an ostium to a treatment site, the guide catheter having a central lumen, a distal end and a distal opening, an anchoring device comprising: a relatively flexible tube sized for insertion through the central lumen of the guide catheter into the coronary vessel, the flexible tube being concentrically aligned with the guide catheter …" (Exh. 1013, 22:35-43.) **[1]** "An intravascular device…." (*Id.*, Abstract.) "The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter." (*Id.*, 4:36-37.) **[2]** "... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for insertion through the central lumen of the guide catheter...." (*Id.*, 23:36-44.) **[3]** "The guide catheter 12 is an elongated, flexible, tubular member defining a first guide catheter lumen 27 therethrough." (*Id.*, 5:30-32.) "Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or other angioplasty device is disposed and guided to a stenosis or obstruction. The guide catheter manifold 54 is mounted at a proximal end of the guide catheter 52, and preferably comprises a Y-shaped structure having a primary channel leg 51 and an extension leg 55 with a guide catheter port 58…. A hemostatic valve (not shown) on the primary channel leg 51 provides hemostatic control for the guide catheter. (*Id.*, 11:20-30; *see id.*, 5:6-29.)

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
	"the guide catheter 287 is manipulated until ***a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium*** so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary, artery requiring treatment." (*Id.*, 16:9-44 (emphasis added).) **[4]** "The diameter of the first guide catheter lumen 27 in the guide catheter 12 and the second guide catheter lumen 33 in the guide catheter extension 32 are larger than the outer diameters of the hollow balloon catheter shaft 26 and balloon 24 (deflated) which are advanced therethrough." (*Id.*, 8:40-45.) "... a guide catheter 287 is inserted into the patient and advanced until ***a distal end of the guide catheter*** 287 reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment." (*Id.*, 16:9-44 (emphasis added).)
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	"the guide catheter is inserted at the femoral artery and advanced through a patient's arterial system to the coronary ostium requiring treatment." (Exh. 1013, 4:56-58; *id.*, 16:9-44 ("... a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient").) "the angioplasty balloon catheter 18 may be

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
	advanced beyond ***the distal end of the guide catheter*** … with the assistance of the guide catheter extension…." (*Id.*, 9:2-5 (emphasis added).) "A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond ***the distal end of the guide catheter*** 12…." (*Id.*, 12:19-25 (emphasis added).) "... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for insertion through the central lumen of the guide catheter so that the distal end of the tube may be positioned beyond ***the distal end of the guide catheter*** to extend the flexible tube to a treatment site...." (*Id.*, 23:36-44 (emphasis added).)
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	"... a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment." (*Id.*, 16:9-44.)
[**1**] inserting **[2]** a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and **[3]** a length that is shorter than the predefined length of the continuous lumen of	**[1]** "... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for ***insertion through the central lumen of the guide catheter***...." (Exh. 1013, 23:36-44 (emphasis added).) "The outer diameter of the elongated flexible tube 32

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
the standard guide catheter, **[1]** into the continuous lumen of the standard guide catheter, and,	is smaller than the first guide catheter lumen 27 defined by the guide catheter 12 so that it may be slidably disposed therethrough and to permit ***insertion of the tube*** …" (*Id.*, 5:64-67 (emphasis added).) **[2]** "The guide catheter extension (distal extension) comprises an elongated flexible tube…." (Exh. 1013, 5:38-39.) "The intravascular device includes a relatively flexible tube…." (*Id.*, 2:50-51.) **[3]** Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). This is also depicted in Fig. 12 which shows flexible tube 255 is shorter than guide catheter 287.  "The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length." (*Id.*, 15:50-51.)
further **[1]** inserting a substantially rigid portion that is proximal of,	**[1]** "A push rod is attached to a proximal end of the tube for slidably positioning the tube…." (Exh. 1013, 2:48-50.)

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and **[2]** having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	"the shaft 19 or push rod is defined by an elongated wire 34." (*Id.*, 6:15-16.) "The extension length of the elongated flexible tube 32 is lengthened by ***advancing the wire 34 distally into the guide catheter***…. (*Id.* 6:35-37.) "The use of the elongated wire 34 to adjust the extension length of the elongated flexible tube 32 provides several advantages." (*Id.*, 6:56-58.) **[2]** "The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length. The push rod is approximately 40.0 to 45.0 inches in length. The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches." (*Id.*, 15:50-54.)
[1] advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and **[2]** such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	**[1]** "... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for ***insertion through the central lumen of the guide catheter so that the distal end of the tube may be positioned beyond the distal end of the guide catheter to extend the flexible tube to a treatment site***...." (Exh. 1013, 23:36-44 (emphasis added).) "The elongated flexible tube 32 of the guide catheter extension 14 is designed to ***extend beyond a distal end of the guide catheter 12 into the coronary arteries***." (*Id.*, 6:8-11 (emphasis added).) **[2]** When the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
	catheter shaft:  "As seen in FIG. 1, shaft 19 or push rod … extends proximally … outside the guide catheter 12 so that it is accessible to the user…. The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12…." (*Id.*, 6:1-10.) 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. (*Id.*, 5:17-29.) 26 is a balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. (*Id.*, 17:3-7 ("The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient").)
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond	"The flexible tube has an inner diameter sized for ***insertion over an angioplasty device***." (Exh. 1013, 2:62-64 (emphasis added).) "the angioplasty balloon catheter 18 may be advanced beyond the distal end of the guide catheter 12 proximate to or across the stenosis or obstruction with the assistance of the guide catheter extension....)" (*Id.*, 9:2-5.)

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	"A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for ***guiding a coronary treatment device into the arteries beyond***…." (*Id.*, 12:19-25 (emphasis added).)
13. The method of claim 1,	Adams '292 discloses the method of claim 1 (*See* A-1, above).
further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	"The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the guide catheter…." (Exh. 1013, 5:64-67.)

B. Statement Of Non-Redundancy: Skived Proximal Opening Disclosures in Klein, Adams '452, Mihara, And Steinke

The grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 4, 9, and 10 are not redundant given the far reaching functional language of such claims. Although the alternative combinatory references of Adams '292 in view of either Klein, Adams '452, Mihara, or Steinke are encompassing of the functionality of each of the disclosed systems, (each of these references discloses systems for receiving an interventional cardiology device through a lumen having a skived proximal

opening), they are structurally different from each other in numerous other respects. Adams '452 explicitly discloses the insertion of devices through the skived proximal opening of its claimed device when a distal portion of the device is extended beyond the end of a guide catheter, and while the proximal portion is within the guide catheter lumen. Mihara discloses a support catheter directed to insertion beyond the ostium having a proximal skive with a rapid exchange design. Klein discloses the insertion of larger devices such as balloon catheters (in addition to guidewires), through its skived proximal opening, as was found by the Examiner during the prosecution of the '032 patent to which the '413 claims priority. Finally, Steinke discloses a proximal side "entry port" through which a guidewire is received, wherein the shape of the port clearly defines both full circumference and hemicylindrical portions.

If the PTAB determines that there is redundancy with respect to the grounds raised herein regarding obviousness of claims 4, 9, and 10 over Adams '292 in combination with either the knowledge of one of skill in the art, Klein, Adams '452, Mihara, or Steinke, Petitioner suggests institution on the grounds of Adams '292 in combination with either Mihara or Klein. Finally, to the extent that the Board finds redundant Petitioner's proposed grounds of unpatentability for the claimed range of "not more than one French" in claims 13 based on anticipation in view of substantial disclosure by Adams '292, obviousness over Adams '292 in

view of the knowledge of one of skill in the art, and Adams '292 in combination with the specific disclosure of the claimed range in the analogous art of Takahashi, Petitioner suggests institution by the Board on the basis of Adams '292 in combination with Takahashi.

C. Claims 1, 4, 9, And 10 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of The Knowledge Of One Of Ordinary Skill In The Art

Claims 1, 4, 9, and 10 are obvious over Adams '292 in view of the knowledge of one of ordinary skill in the art. As shown above, Claim 1 and is anticipated by Adams '292, which discloses every limitation of that claim. (Exh. 1003, ¶¶ 92-105). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been known or obvious to a POSA or could be found by a POSA in one or more other references or analogous art. (*Id.*, 109-110).

Dependent claim 4 of the '413 patent depends from claim 1, every element of which, as shown above, is disclosed in Adams '292. Claim 4 further requires "selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof." (Exh. 1001, claim 4). A POSA at the time of the '413 patent would know to use a skived or angled proximal lumen opening in rapid

exchange catheters. (Exh. 1003 ¶ 110). Such a skived or angled opening would define a partially cylindrical portion and a full circumference portion. (*Id.*)

Claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter." Adams '292 discloses extending the interventional cardiology device through a proximal opening in the tubular structure while the proximal portion remains within the lumen of the guide catheter. (*See* Exh. 1013, 9:36-52). A POSA at the time of the '413 patent would know that the proximal opening could be skived or angled, thereby defining a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure. (Exh. 1003 ¶ 110).

Claim 10 of the '413 patent further requires extending the interventional cardiology device through a full circumference portion and a partially cylindrical portion. Adams '292 discloses extending the interventional cardiology device through a proximal opening of the tubular structure. (Exh. 1003 ¶ 105). A POSA at the time of the '413 patent would know that the proximal opening could be skived

or angled, thereby defining a full circumference portion and a partially cylindrical portion. (Exh. 1003 ¶ 110).

D. Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Klein

Claims 1, 4, 9, 10, and 13 are obvious over Adams '292 in view of Klein, which was cited during prosecution of the '413 patent, but was not considered in combination with Adams '292. (Exh. 1003, ¶¶ 111-113). As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (*Id.*, ¶¶ 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Klein. (*Id.*, ¶¶ 111-113).

Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter. (*See, e.g.*, Exh. 1014, Fig. 28). This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires "selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof." (Exh. 1003 ¶ 112).

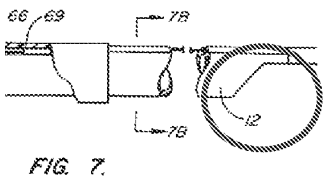
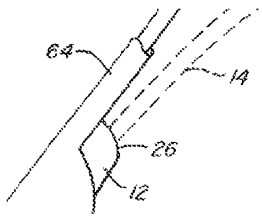
Dependent claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening" in the tubular structure while claim 10 (which depends from claim 9) requires "advancing" such device through the "full circumference" and the "partially cylindrical" portions of such opening.

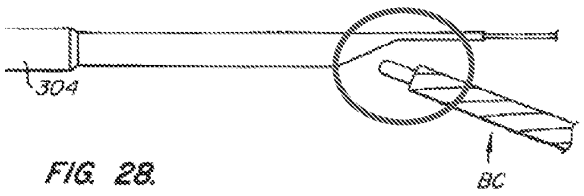
Adams '292 discloses the function of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003, ¶ 105). Klein discloses the claimed structure of a proximal side opening extending for a distance along a proximal portion of the tubular structure, defining a full circumference portion and a partially cylindrical portion. (*Id.* ¶ 112). Extending the interventional cardiology device through the proximal side opening would therefore entail advancing the device through structures defining a full circumference portion and a partially cylindrical portion.

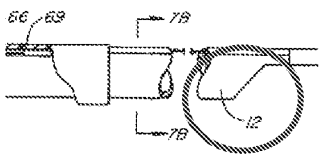
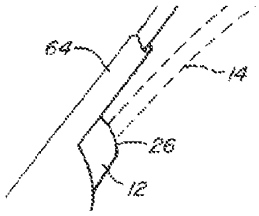
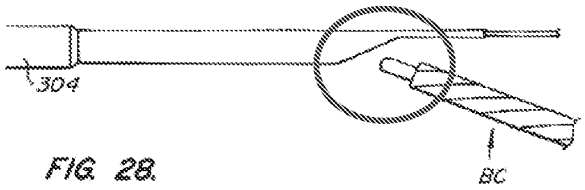
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 112-114), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Klein to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams '292 and Klein are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*Id.*, 71-77) Specifically, both Klein and Adams '292 disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. Accordingly, a POSA would have been motivated to combine the guide catheter extension disclosed by Adams '292 with the skived proximal

lumen opening of Klein. (*Id.*, 89-91). Indeed, Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1013, 6:24-34 (flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)).

Thus, Adams '292 and Klein show that using skived proximal openings for the delivery of interventional cardiology devices such as balloon catheters was well known by the time of the '413 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (Exh. 1003, 111-114).

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	**Adams '292 in view of Klein**
4. The method as claimed in claim 1	Adams '292 discloses the method of claim 1. (*See* A-1, above).
further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.	Annotated Figure 7 of Klein (below) shows that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof:  FIG. 7.  (Fig. 6.) 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	**Adams '292 in view of Klein**
	 FIG. 28. In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (*See also* Figs. 1, 8, 9, 9A, 10-15, 20-27.)
9. The method as claimed in claim 1	Adams '292 discloses the method of claim 1. (*See* A-1, above).
further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses extending the interventional cardiology device through a proximal opening in the tubular structure while the proximal portion remains within the lumen of the guide catheter. (*See* Exh. 1013, 9:36-52 ("The guide catheter extension 14 (distal extension) which is the subject of this invention provides a means for establishing a path proximate to or across the obstruction or stenosis and directing a substitute angioplasty balloon catheter thereto. Before the original angioplasty balloon catheter 18 is withdrawn, the elongated flexible tube 32 is positioned proximate to or across the lesion…. Then, the original angioplasty balloon catheter 18 is withdrawn and the new angioplasty balloon catheter is substituted therefor. During the insertion thereof, the guide catheter 12 and the guide catheter extension 14 cooperate to direct the new angioplasty balloon catheter to the stenosis."); *id.*, 15:57-16:13 ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ....").) Klein discloses a proximal side opening defined by the proximal portion of the tubular structure extending for a distance along the longitudinal axis of the proximal portion of the tubular structure which remains within the guide catheter. (Exh. 1014, 10:16-22 ("the entry port 26 will remain within the guiding catheter at all times").) Annotated Fig. 7 (below)

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	**Adams '292 in view of Klein**
	depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis of the tubular structure:  FIG. 7.  (Fig. 6.) 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.  FIG. 28. In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (*See also* Figs. 1, 8, 9, 9A, 10-15, 20-27.)
10. The method of claim 9,	Adams '292 and Klein disclose the method of claim 9. (*See* discussion of claim 9, above).
further comprising extending the interventional cardiology device through the proximal side opening;	As shown above, Adams '292 and Klein disclose extending the interventional cardiology device through the proximal side opening. (*See* discussion of claim 9.)
advancing the interventional cardiology device through structure defining a full circumference portion; and	As shown above, Klein discloses a proximal side opening with structure defining a full circumference portion. (*See* discussion of claim 9.)

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	**Adams '292 in view of Klein**
advancing the interventional cardiology device through structure defining a partially cylindrical portion.	As shown above, Klein discloses a proximal side opening with structure defining a partially cylindrical portion. (*See* claim 9, above.)

E. Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Adams '452

Claims 1, 4, 9, 10, and 13 are obvious over Adams '292 in view of Adams '452, neither of which was cited or considered, either alone or in combination, during prosecution of the '413 patent or the '032 patent, from which it claims priority. As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (Exh. 1003, 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Adams '452. (*Id.*, 109-110).

The Adams '452 patent discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." (Exh. 1015, 8:47-50). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis. (*See* Exh. 1003 ¶¶ 34 and 116). The guide seal 20 receives an interventional

device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*See id.* ¶ 78). This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires "selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof." (*See id.* ¶ 116).

Dependent claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening" in the tubular structure while claim 10 (which depends from claim 9) requires "advancing" such device through the "full circumference" and the "partially cylindrical" portions of such opening. Adams '292 discloses the functions of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003, ¶ 105). Extending the interventional cardiology device through the proximal side opening would therefore entail advancing the device through structure defining a full circumference portion.

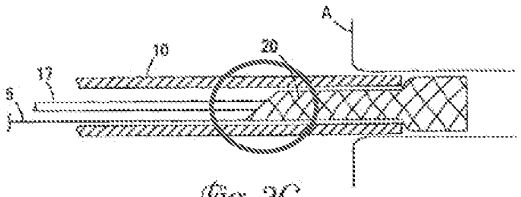
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 116-118), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams '292 and Adams

'452 are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*Id.*, ¶¶ 71-74 and 78-79). Specifically, both Adams '452 and Adams '292 disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. Accordingly, a POSA would have been motivated to combine the guide catheter extension disclosed by Adams '292 with the skived proximal lumen opening of Adams '452. Indeed, Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1013, 6:24-34 (flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)).

Notably, Adams '292 and Adams '452 were both issued to the same named inventor, Daniel O. Adams; the fact that the inventor of the Adams '292 device in 1992 included a skived proximal side opening when designing a similar device (Adams '292 is cited as prior art on the face of the Adams '452 patent) ten years later is further evidence that, by 2006, a POSA would routinely include a skived or angular side opening in such rapid exchange devices.

In sum, Adams '292 and Adams '452 show that using skived proximal lumen openings for the delivery of devices while the proximal opening is within the lumen of a guide catheter was well known by the time of the '413 patent and

employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (Exh. 1003, 89-91 and 115-118).

Claim Chart A-3: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Adams'452**
4. The method as claimed in claim 1	Adams '292 discloses the method of claim 1 (*See* A-1, above).
further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.	Adams '452 discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." (Exh. 1015, 8:47-50.) "A proximal wire … extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter." (*Id.*, 8:27-30.) The guide seal has a "portion which remains in the lumen of the guide catheter when the guide seal is deployed." (Exh.1015, 8:55-56.) The guide seal may be formed of braided wires with a polymer covering or membrane attached. (Exh. 1015, 9:11-46.) The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  *Fig. 2C* The proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the

Claim Chart A-3: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Adams'452**
	distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
9. The method as claimed in claim 1	As shown above, Adams '292 discloses the method of claim 1.
further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." (Exh. 1013, 15:57- 16:13.) As shown above, the Adams '452 patent discloses a proximal opening of a lumen in a catheter skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion.
10. The method of claim 9,	Adams '292 and Adams '452 disclose the method of claim 9 (*See* claim 9, above).
further comprising extending the interventional cardiology device through the proximal side opening;	As shown above, Adams '292 and Adams '452 disclose extending the interventional cardiology device through the proximal side opening. (*See* claim 9, above.)
advancing the interventional cardiology device through structure defining a full circumference portion; and	As shown above, Adams '452 discloses a proximal side opening with structure defining a full circumference portion. (*See* claim 9, above.)
advancing the interventional cardiology device through structure defining a partially	As shown above, Adams '452 discloses a proximal side opening with structure defining a partially cylindrical portion. (*See* claim 9, above.)

Claim Chart A-3: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Adams'452**
cylindrical portion.	

F. Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Mihara

Claims 1, 4, 9, 10, 13 of the '413 patent are obvious over Adams '292 in view of Mihara, neither of which was cited or considered, either alone or in combination, during prosecution of the '413 patent or the '032 patent, from which it claims priority. As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (Exh. 1003, ¶¶ 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Mihara. (*Id.* 109-110 and 119-121).

Mihara discloses a catheter "for penetrating a stenotic lesion" having a tubular catheter body with a skived proximal opening sized to receive a guidewire. (Exh. 1040, Figs. 1-3). This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires "selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof." (Exh. 1003 ¶ 120).

Dependent claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening" in the tubular structure while claim 10 (which depends from claim 9) requires "advancing" such device through

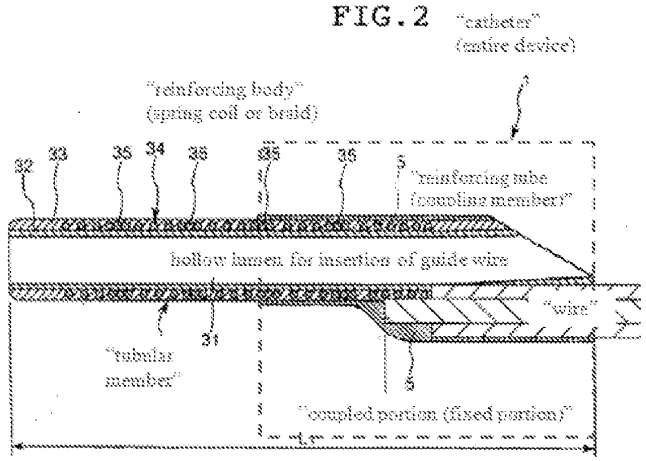
the "full circumference" and the "partially cylindrical" portions of such opening. Adams '292 discloses the functions of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003 ¶ 105). Mihara discloses the claimed structure of a proximal side opening extending for a distance along a proximal portion of the tubular structure, defining a full circumference portion and a partially cylindrical portion. (*Id.* ¶ 120). Extending the interventional cardiology device through the proximal side opening would therefore entails advancing the device through structures defining a full circumference portion and a partially cylindrical portion. (*Id.*)

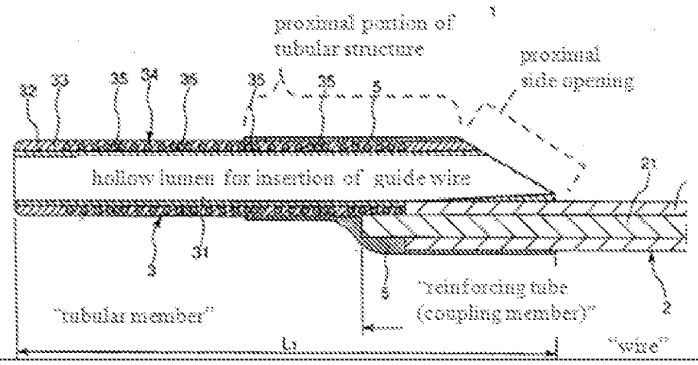
As confirmed by the Solar Declaration (Exh. 1003, ¶¶ 120-21), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Mihara to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams '292 and Mihara are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*Id.*, 71-74 and 80-81). Specifically, both Adams '452 and Mihara disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. (*Id.*, 78 and 80.)

Accordingly, a POSA would have been motivated to combine the guide catheter extension disclosed by Adams '292 with the skived proximal lumen opening of Mihara. (*Id*. 89-91 and 119-121). Indeed, Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1013, 6:24-34 (flared proximal end 38) *with id*., 11:65-12:12 (longitudinal slit 78)).

Thus, Adams '292 and Mihara show that using skived proximal openings for the delivery of interventional cardiology devices such as balloon catheters was well known by the time of the '413 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (Exh. 1003, ¶120).

Claim Chart A-4: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Mihara (Exh. 1040)**
4. The method as claimed in claim 1	Adams '292 discloses the method of claim 1 (*See* A-1, above).
further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.	Mihara discloses a substancially rigid portion comprising a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof: "The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion).

Claim Chart A-4: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Mihara (Exh. 1040)**
	Therefore high coupling strength can be obtained, and the enlargement of the distal end portion of the catheter 1 can be prevented." (Exh. 1040, ¶ [0061].) "Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5.... The overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process." Mihara, (Exh. 1040, ¶ [0062].) Annotated Fig. 2 (below) depicts that the proximal side opening (that includes a partially cylindrical portion) to the hollow device lumen (31) of the reinforcing tube (5) surrounding the overlapped portion of the wire (2) and tubular body (3) is skived or cut at an angle,forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis: FIG. 2  "the wire 2 is provided with appropriate rigidity

Claim Chart A-4: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Mihara (Exh. 1040)**
	(flexural rigidity and torsional rigidity), which enhances a push-in property and transmittance of a torque." (Exh. 1040, ¶ [0043].)
9. The method as claimed in claim 1	As shown above, Adams '292 discloses the method of claim 1.
further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." (Exh. 1013, 15:57- 16:13.) Mihara discloses "[t]he hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1040, ¶ [0049].) Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion: FIG. 2 
10. The method of claim 9,	Adams '292 and Mihara disclose the method of claim 9 (*See* discussion of claim 9, above).

Claim Chart A-4: Claims 4, 9, 10	
The '413 Patent	**Adams '292 in view of Mihara (Exh. 1040)**
further comprising extending the interventional cardiology device through the proximal side opening;	As shown above, Adams '292 and Adams '452 disclose extending the interventional cardiology device through the proximal side opening. (*See* discussion of claim 9.)
advancing the interventional cardiology device through structure defining a full circumference portion; and	As shown above, Adams '452 discloses a proximal side opening with structure defining a full circumference portion. (*See* discussion of claim 9.)
advancing the interventional cardiology device through structure defining a partially cylindrical portion.	As shown above, Adams '452 discloses a proximal side opening with structure defining a partially cylindrical portion. (*See* discussion of claim 9.)

G. Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Steinke

Claims 1, 4, 9, 10, 13 of the '414 patent are obvious over Adams '292 in view of Steinke, neither of which was cited or considered, either alone or in combination, during prosecution of the '413 patent or the '032 patent, from which it claims priority. As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (Exh. 1003, 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Steinke. (*Id.*, ¶ 122).

Steinke discloses "a catheter which allows rapid exchange" (Exh. 1016, 3:1-2) where the proximal end of the inner lumen tubing is skived at an angle, forming

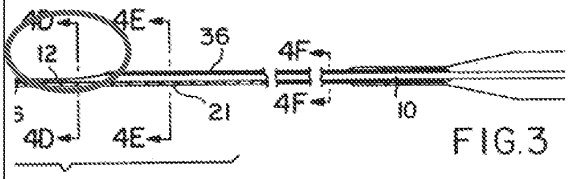
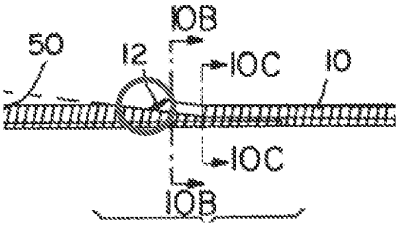
an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires "selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof." (Exh. 1003 ¶ 123).

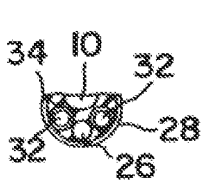
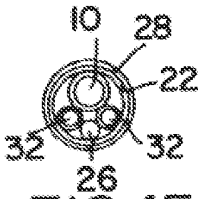
Dependent claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening" in the tubular structure while claim 10 (which depends from claim 9) requires "advancing" such device through the "full circumference" and the "partially cylindrical" portions of such opening. Adams '292 discloses the functions of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003 ¶ 105). Steinke discloses the claimed structure of a proximal side opening extending for a distance along a proximal portion of the tubular structure, defining a full circumference portion and a partially cylindrical portion. (*Id.* ¶ 123). Extending a the interventional cardiology device through the proximal side opening therefore entails advancing the interventional cardiology device through structure defining a full circumference portion and a partially cylindrical portion.

As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 123-125), a POSA would have found it obvious to modify the proximal opening of the Adams '292

device in view of Steinke to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams '292 and Steinke are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*Id.*, 71-74 and 82-83). Specifically, both Adams '452 and Steinke disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. Accordingly, a POSA would have been motivated to combine the guide catheter extension disclosed by Adams '292 with the skived entry port of Steinke. (*Id.*, ¶¶ 89-91). Indeed, Adams '292 highlights the advantages of varied designs for the proximal opening to the tube. (*Compare* Exh. 1013, 6:24-34 (flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)).

In sum, Adams '292 and Steinke show that using skived proximal openings with rapid exchange catheters was well known by the time of the '413 patent, and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (Exh. 1003, ¶¶ 122-125).

Claim Chart A-5: Cl. 4, 9 and 10	
The '413 Patent	**Adams '292 in view of Steinke**
4. The method as claimed in claim 1	Adams discloses the method of claim 1 (*See* A-1, above).
further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.	Steinke discloses "a catheter which allows rapid exchange" (Exh. 1016, 3:1-2.), where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  FIG.3 FIG.9  12 is "the guidewire entry 12 (also referred to as the distal entry or side port entry)." (Exh. 1016, 6:51-54.) Steinke further discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit…." (Exh. 1016, 9:66-10:1.) The skived side port entry of Steinke defines a full circumference portion and a partially cylindrical portion:

Claim Chart A-5: Cl. 4, 9 and 10	
The '413 Patent	**Adams '292 in view of Steinke**
	 FIG.4D  FIG.4E
9. The method as claimed in claim 1	As shown above, Adams '292 discloses the method of claim 1.
further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." (Exh. 1013, 15:57-16:13.)
10. The method of claim 9,	(*See* discussion of claim 9, above).
further comprising extending the interventional cardiology device through the proximal side opening;	As shown above, Adams '292 and Steinke disclose extending the interventional cardiology device through the proximal side opening. (*See* discussion of claim 9.)
advancing the interventional cardiology device through structure	As shown above, Steinke discloses a proximal side opening with structure defining a full circumference portion. (*See* discussion of claim 9.)

Claim Chart A-5: Cl. 4, 9 and 10	
The '413 Patent	**Adams '292 in view of Steinke**
defining a full circumference portion; and	
advancing the interventional cardiology device through structure defining a partially cylindrical portion.	As shown above, Steinke discloses a proximal side opening with structure defining a partially cylindrical portion. (*See* discussion of claim 9.)

H. Claim13 Is Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of The Knowledge Of One Of Ordinary Skill In The Art

Claim 13 is obvious over Adams '292 in view of the knowledge of one of ordinary skill in the art. (Exh. 1003, ¶¶ 126-127). As shown above, Claim 13 is anticipated by Adams '292, which discloses every limitation of that claim. (*Id.*, 106-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been known or obvious to a POSA or could be found by a POSA in one or more other references or analogous art. (*Id.*, 89-91).

Dependent claim 13 requires "selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter." The Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter (Exh. 1013, 5:64-67), defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner

diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. A POSA reading this disclosure of the Adams '292 patent at the time of the claimed invention would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner diameter of the outer guide catheter and, therefore, would have been motivated to practice the invention within the claimed range of not more than one French. (Exh. 1003 ¶ 127).

Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 418-20, 82 U.S.P.Q.2d 1385 (2007); In re Jones, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)*. In this case, the disclosed range for the difference in diameters between the outer guide catheter and the inner guide catheter of the device was already known in the field by the time of the '413 patent and, therefore, a POSA would have been motivated to conform to such teachings in practicing the Adams '292 invention with the predictable and expected results of allowing for the insertion of larger devices and avoiding the possibility of the

guidewire becoming disposed in the space between the inner and outer guide catheters. (*See* Exh. 1003 ¶ 127).

I. Claims 1 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Takahashi

Claims 1 and 13 are obvious over Adams '292 in view of Takahashi, which was cited during prosecution of the '413 Patent, but was not discussed in any Office Action or considered in combination with Adams '292. (Exh. 1003, ¶¶ 128-130). As shown above, Claim 1 is anticipated by Adams '292, which discloses every limitation of that claim. (*Id.*, 92-105). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Takahashi. (*Id.*, ¶ 128).

Claim 13 requires "selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter." (Exh. 1001, claim 13). Takahashi satisfies the limitations of claim 13 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter. (Exh. 1017, Fig. 5). The cross-sectional inner diameter of the 5 French catheter is not more than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and

the inner diameter of the outer guide catheter, and would recognize that this teaching of Takahashi's 5-in-6 system could be applied to any guide extension device for insertion through a standard guide catheter, such as the Adams '292, and would have been motivated to do so. (Ex. 1003 ¶¶ 129-30).

As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 129-30), a POSA would have found it obvious to modify the diameter of the Adams '292 device in view of Takahashi to meet the limitations of claim 13. Adams '292 and Takahashi are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*See id.* ¶¶ 71-74 and 84-86). As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Takahashi in addressing the problem addressed by the '413 patent.

In sum, Adams '292 and Takahashi show that selecting the cross-sectional inner diameter of the coaxial catheter to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter was well known by the time of the '413 patent, and would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*Id.*, ¶¶ 128-130).

Claim Chart A-6: Cl. 13

The '413 Patent	Adams '292 in view of Takahashi
13. The method of claim 1	Adams '292 discloses the method of claim 1 (*See* A-1, above).
further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	Takahashi discloses a method where the inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter: "The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A)." (Exh. 1017 at 452.) "The inner lumen of the 5 Fr Heartrail catheter is 0.059' in diameter…. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter…." (*Id.*) "In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter…." (*Id.*) "Only inserting the 5 Fr guiding catheter into the 6Fr catheter increased backup support…." (*Id.*) "A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter." (*Id.* at 454.)

VI. CONCLUSION

As shown herein, Adams '292 anticipates claims 1 and 13 of the '413 Patent, while claims 1, 4, 9, 10, and 13 of the '413 Patent are obvious in view of Adams '292 combined with the knowledge of a POSA and the teachings of the additional references cited above. The Examiner never considered Adams '292 and the prior

art combinations cited above; if he had, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '413 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

ARNOLD & PORTER LLP

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 15, 2014, to the USPTO correspondence address of record listed below:

Patterson, Thuente, Petersen, PA
4800 IDS Center
80 South 8th Street
Minneapolis, MN 55402-2100

Courtesy copies were also shipped to counsel for patent owner at the following address:

J. Thomas Vitt
Heather Redmond
Shannon Bjorklund
Forrest Tahdooahnippah
Dorsey & Whitney
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402
Telephone: (612) 340-2600

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

ATTACHMENT D

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,048,032

Attorney Docket No. 0025216-00057

PETITION FOR INTER PARTES REVIEW
UNDER 37 C.F.R. § 42.100

TABLE OF CONTENTS

Page

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)) 1
- A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) 1
- B. Related Matters (37 C.F.R. § 42.8(b)(2)) 1
- C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a)) 2
- D. Service Information (37 C.F.R. § 42.8(b)(4)) 2

II. PAYMENT OF FEES (37 C.F.R. § 42.103) 2

III. SUMMARY OF RELEVANT TECHNOLOGY AND '032 PATENT 3
- A. Overview Of Interventional Cardiology Procedures 3
- B. Description Of The Alleged Invention Of The '032 Patent 4
- C. Summary of the Prosecution History of the '032 Patent 6

IV. REQUIREMENTS FOR INTER PARTES REVIEW 9
- A. Grounds for Standing Under 37 C.F.R. § 42.104(a) 9
- B. Identification of Challenge and Relief Requested 10
- C. Claims for Which *Inter Partes* Review Is Requested 10
- D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2) 10
- E. Construction Of The Challenged Claims 11
  1. "rail structure without a lumen" 12
  2. "interventional cardiology device(s)" 13
  3. "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen" 14
  4. "adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery" 16
- F. Non-Redundancy of Proposed Alternative Grounds 17
- G. Level of Skill In the Art 20
- H. The Prior Art References 20

1. Adams '292 21
2. Klein 22
3. Adams '452 22
4. Steinke 23
5. Takahashi 23
I. How The Construed Claim(s) Are Unpatentable 24
V. SUPPORTING EVIDENCE UNDER 37 C.F.R. § 42.104(B)(5) 24
VI. ANTICIPATION OF THE CHALLENGED CLAIMS 24
A. Claims 1, 2, 8, 11, And 17 Are Anticipated Under 35 U.S.C. § 102(b) By Adams'292 25
1. Claim 1 25
2. Claim 2 27
3. Claim 11 27
4. Claims 8 and 17 27
VII. OBVIOUSNESS OF CHALLENGED CLAIMS 39
A. Claims 1-4, 8, 11, 13 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Klein 40
B. Claims 1-4, 8, 11, 13 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Adams '452 46
C. Claims 1-4, 8, 11, 13 and 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Steinke 51
D. Claims 8 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of The Knowledge of One Of Skill In The Art 57
E. Claims 1, 2. 8, 11 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams In View Of Takahashi 58
VIII. CONCLUSION 60

Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,048,032

Exhibit Description	Exhibit No.
U.S. Patent No. 8,048,032 to Root, et al.	1001
File History for U.S. Patent No. 8,048,032	1002
Declaration of Ronald Jay Solar, Ph.D., with attached Appendix1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,292,850 to Root, et al.	1004
U.S. Patent No. 8,142,413 to Root, et al.	1005
File History for U.S. Patent No. 8,292,850	1006
File History for U.S. Patent No. 8,142,413	1007
Copy of a Second Petition (excluding exhibits) for *Inter Partes* Review Filed Concurrently by Petitioner on the '032 Patent	1008
U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1009
Translation of Japanese Patent Application No. 2003-070808	1010
U.S. Patent No. 5,527,292 to Adams et al.	1011
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1012
U.S. Patent No. 6,638,268 to Niazi	1013
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1014
U.S. Publication No. 2004/0127927 to Adams	1015
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1016
U.S. Patent No. 5,776,141 to Klein et al.	1017
U.S. Patent No. 7,232,452 to Adams et al.	1018
U.S. Patent No. 5,328,472 to Steinke et al.	1019
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," *Catherization and Cardiovascular Interventions* 63:452-456 (2004)	1020
U.S. Patent No. 5,690,613 to Verbeek	1021
U.S. Patent No. 5,156,594 to Keith	1022
U.S. Patent No. 5,102,403 to Alt	1023
Kucklick, Theodore R., The Medical Device R&D Handbook (2006)	1024
Amended Complaint filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (May 28, 2013)	1025
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1026

Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1027
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (July 28, 2013)	1028
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (December 19, 2013)	1029
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed December 27, 2013	1030
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed January 3, 2014	1031
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir.) filed January 7, 2014	1032
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir.) filed January 29, 2014	1033
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir.) filed February 3, 2014	1034
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir.)	1035
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1036
Joint Claim Construction Statement filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (February 21, 2014)	1037
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1038
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1039
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1040
U.S. Patent No. 5,267,958 to Buchbinder et al.	1041

Inter partes review is respectfully requested for claims 1-4, 8, 11, 13, and 17 of U.S. Patent No. 8,048,032 ("the '032 Patent") (Exh. 1001).

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '032 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 1:13-cv-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of the '032 Patent on other grounds in another petition to be filed concurrently herewith. Further, Petitioner is filing two separate petitions on non-redundant grounds seeking *inter partes* review of U.S. Patent No. 8,292,850 (the "'850 patent") and one petition seeking review of U.S. Patent No. 8,142,413 (the "'413 patent" (Exh. 1005)) to be filed concurrently herewith. In all, five petitions will be filed. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and are directed generally to the same subject matter. Specifically, the '850 patent (Exh. 1004) is a

division of application No. 12/824,734, which issued as the '413 patent (Exh. 1005), and the '413 patent is a division of application No. 11/416,629, which issued as the '032 patent. The claims challenged therein are method ('413 patent) and system ('850 patent) versions of the apparatus claims of the '032 patent challenged herein.

C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

Lead Counsel	Back-Up Counsel
David R. Marsh (Reg. No. 41,408) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5068 Facsimile: 202.942.5999 Email: david.marsh@aporter.com	Kristan L. Lansbery (Reg. No. 53,183) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5186 Facsimile: 202.942.5999 Email: kristan.lansbery@aporter.com

D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to service by email to lead and backup counsel at xBSC_VSI_IPRService@aporter.com.

II. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 50-2387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for

any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF RELEVANT TECHNOLOGY AND '032 PATENT

A. Overview Of Interventional Cardiology Procedures

The claims of the '032 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (*See* Exh. 1001, 1:7-36.) During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.; see* Declaration of Ronald Jay Solar, Ph.D. ("Solar Declaration") (Exh. 1003, ¶ 8).) The physician introduces the treatment device into the patient's vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id.*) Often, to create a passage for such treatment devices, physicians insert a "guide catheter" earlier in the procedure. (*Id.*) In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id.*) The '032 patent is directed to an apparatus that is deliverable through a standard guide catheter for extension

beyond the ostium to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (*See, e.g.*, Exh. 1001, 2:45-49.)

B. Description Of The Alleged Invention Of The '032 Patent

The '032 Patent (Exh. 1001) contains 22 device claims, including two independent claims (claims 1 and 11). The specification of the '032 patent states that it relates "generally to catheters used in interventional cardiology procedures" and "[m]ore particularly ... apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." (Exh. 1001, 1:7-11.)

The challenged claims of the '032 patent are not straightforward. Unlike typical apparatus claims, the '032 patent claims are replete with functional language and ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Claim 1 of the '032 patent is representative of the independent claims:

> **1.** A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:
>
> a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure

having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

(*Id.*, claim 1.)

Dependent claim 2 of the '032 patent depends from independent claim 1 and requires "that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that

would otherwise tend to dislodge the guide catheter from the branch artery." (*Id.*, claim 2.)

Dependent claim 3 (depending from independent claim 1 and dependent claim 2), and dependent claim 13 (depending from independent claim 11), are directed to a "proximal side opening ... extending for a distance along the longitudinal axis" and "transverse [*i.e.*, at an angle] to the longitudinal axis." (*Id.*, claim 13.)

Dependent claim 4 depends from claim 3 and requires a "structure defining a full circumference portion and structure defining a partially cylindrical portion," as would result from a tube being skived at an angle for part of its length. These 'side opening claims' are directed to that which was well known in the art when the '032 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle. (*Id.*, claim 4.)

Dependent claims 8 (depending from independent claim 1) and 17 (depending from independent claim 11) require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." (*Id.*, claim 8.)

C. Summary of the Prosecution History of the '032 Patent

The '032 patent was filed as U.S. Application Serial No. 11/416,629 and issued on November 1, 2011. The original claims were restricted and the Applicant elected device claims. (Response to Restriction Requirement dated October 1, 2008, at 11 (Exh. 1002, at 378).)

Claims 1 and 12-15 were rejected as obvious over U.S. Patent 6,638,268 ("Niazi") (Exh. 1013) in view of U.S. Patent Application Publication No. 2003/0195546 to Solar ("Solar") (Exh. 1012). According to the Examiner, Niazi disclosed all but "the elongate structure with a substantially rigid portion proximal to the reinforced portion, including a cylindrical portion defining an opening along a side thereof, the opening extending at least a portion of the length of the rigid portion." (Exh. 1002, at 351.) That which was missing from Niazi was present in Solar, which disclosed "an elongate device comprising a pushing member 5 and tracking member 7 …." (*Id.*) While the rejection refers to claims 9 and 12-15, claim 8 is specifically discussed and treated as rejected. (Exh. 1002, at 350.)

Moreover, claims 9-11, 16, and 21 were rejected over the same combination and further in view of U.S. Patent Application Publication No. 2004/0127927 to Adams, *et al.*, ("Adams '927") (Exh. 1015) and U.S. Patent 6,338,725 to Hermann, *et al.*, ("Hermann") (Exh. 1016). Specifically, the Examiner observed that "Solar discloses a decreasing rigidity along the device as one travels distally. Adams discloses relief cuts as a method of forming a non-rigid bendable section in an

otherwise straight member...." (Exh. 1002, at 353.) The Examiner further noted that "Hermann discloses a metal coil imbedded in a flexible sheath to avoid kinking and collapse during use," and "Solar discloses using a guidewire 9 to allow the system to advance easily to a desired location within a patient's body." (Exh. 1002, 353-354).)

In an Office Action dated November 19, 2009, the Examiner maintained the rejection of then-claims 66, 69, and 74 (corresponding to claims 3 and 4 of the '032 patent) and also cited U.S. Patent No. 5,776,141 to Klein, *et al.*, ("Klein") (Exh. 1017.) Specifically, the Examiner observed that

> Klein discloses a … tracking member/sheath … that covers a delivery catheter …. ***The sheath of Klein has a slant that gives it both fully cylindrical and partial cylindrical portions***. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a … tracking member (including the cylindrical shape) as taught by Klein….(Exh. 1002, at 271) (emphasis added).)

Despite six attempts, multiple amendments, and an interview where the Applicant's representative brought "a device," the revised claims remained rejected over Niazi in view of Solar until the final Examiner amendment. In addition, the claim amendments had resulted in additional rejections as the claims lacked written description for multiple negative limitations, including the genus "non-tubular." (Exh. 1002 at 185) and (Exh. 1002, at 142). Patentee attempted to

overcome the written description rejection by stating, without specific citation to the specification, that "[t]he application as filed clearly describes and differentiates circular, cylindrical tubular shapes from those that are partially circumferential, non-circular or non-tubular." (Exh. 1002 at 125.) The application was allowed, however, only after an Examiner's amendment in which the Examiner deleted "non-tubular" and substituted with "rail structure without a lumen." (Exh. 1002 at 94.) Only after the Patent Owner accepted the Examiner's amendment, adding "rail structure without a lumen" to ***each independent*** claim, were any of the claims allowed. Thus, the Examiner never considered the side opening limitations of dependent claims 3, 4, and 13 to be inventive features standing alone. Neither the Patentee nor the Examiner cited any support for the substitution. A Notice of Allowance was mailed August 3, 2011, and the '032 Patent issued on November 1, 2011. (Exh. 1002 at 89-95.)

IV. REQUIREMENTS FOR INTER PARTES REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '032 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certify that the '032 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

B. Identification of Challenge and Relief Requested

Pursuant to 37 C.F.R. § 42.104(b), the precise relief requested by Petitioner is that claims 1-4, 8, 11, 13, and 17 of the '032 Patent be found unpatentable.

C. Claims for Which *Inter Partes* Review Is Requested

Pursuant to 37 CFR § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1-4, 8, 11, 13, and 17 of the '032 Patent.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

This Petition, supported by the grounds set forth below and the Solar Declaration, demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C. § 314(a). Dr. Solar, an expert with thirty-seven years of academic and industry experience in the field of interventional cardiology devices has reviewed the claim charts submitted in the '032 Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein. (*See* Exh. 1003 ¶ 81.) *Inter partes* review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103.

No.	Grounds
1	Claims 1-2, 8, 11, 17 are anticipated by US 5,527,292 ("Adams '292")
2	Claims 1-4, 8, 11, 13 and 17 are obvious over Adams '292 in view of US 5,776,141 ("Klein")
3	Claims 1-4, 8, 11, 13 and 17 are obvious over Adams '292 in view of US

	7,232,452 ("Adams '452'")
4	Claims 1-4, 8, 11,13, and 17 are obvious over Adams '292 in view of US 5,328,472 ("Steinke")
5	Claims 1, 2,8, 11, and 17 are obvious over Adams '292 in view of Knowledge of One of Skill in the Art
6	Claims 1, 2, 8, 11, and 17 are obvious over Adams '292 in view of "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," 2004, Takahashi Online Article ("Takahashi")

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

E. Construction Of The Challenged Claims

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]."*See* 37 C.F.R. § 42.100 (b); *see also, In re Swanson,* 540 F.3d 1368, 1377-78 (Fed. Cir. 2008)*; In re Trans Texas Holding Corp.,* 498 F.3d 1290, 1298 (Fed. Cir. 2007) (citing *In re Yamamoto,* 740 F.2d 1569, 1571 (Fed. Cir. 1984). Because the standards of claim interpretation used by the Courts in patent litigation differ from those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation and may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation ("BRI") in light of the

patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.[1]

1. "rail structure without a lumen"

Because the '032 patent does not disclose any structure for the "rail structure without a lumen" limitation of independent claims 1 and 11, it is invalid under 35 U.S.C. §112, ¶2. The word "rail" appears in the specification of the '032 patent only twice. *First*, the Summary of the Invention refers to a "guidewire rail segment," defined as "permit[ing] delivery without blocking the use of the guide catheter." (Exh. 1001, 2:55-56.) *Second*, Fig. 17 is described as "a plan view of a coaxial guide catheter having a longer rail segment," without any guidance as to which portion(s) of Figure 17 constitute the "rail segment." (*Id.*, 5:57-59.) Neither of these references discloses any meaning for "rail" in the claim term "rail structure without a lumen." (Exh. 1003 ¶ 63.) Moreover, nothing in the specification suggests that the rail structure consists of the "tapered inner catheter," "full circumference portion," "cutout portion," "reinforced portion," "hemicylindrical portion," "second full circumference portion," "arcuate portion," "braid or coil reinforcement," "most proximal portion of braid or coil

[1] Petitioner reserves the right to challenge the validity of the '032 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

reinforcement," "relief cut," "hemi-tube portion," "single cuts," "double cuts," "connector hub," "funnel portion," "grip portion," to name a few, nor would be so read by a POSA. (*Id.*)

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent apparatus claims 1 and 11 under 35 U.S.C. §§ 102 and 103, and claims 2, 3, 4, 8, 13, and 17 depending therefrom, Petitioner submits that a POSA would understand "rail structure" to refer to a pushing or advancement structure. "Monorail" or rapid exchange catheters are characterized by a relatively short guide wire lumen at the distal end; this cannot be the "rail structure" for purposes of the claim, however, because the claimed structure must be "without a lumen." (Exh. 1003 ¶¶ 63-65.) A POSA would therefore understand the "rail structure" to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id.*, ¶¶ 63-65) Accordingly, the term "rail structure without a lumen" can be construed for purposes of this Petition to mean a "pushing or advancement structure without a lumen."

2. "interventional cardiology device(s)"

Interventional cardiology devices are thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.* ¶ 66) The specification of the '032 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001, 1:19-21 ("For the purposes of this application, the term 'interventional cardiology devices is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters").)

3. "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen"

Dependent claim 3 recites that the structure of the proximal side opening is "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." Dependent claim 13 similarly recites an opening "adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen." (Exh. 1001, claim 3). This language merely indicates the intended use of the claimed proximal opening (to receive an interventional cardiology device), and the device itself (for use within a guide catheter) as well as the order in which such intended uses may

occur (receiving the device "into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter"). (*Id.*, 11:1-3.) Accordingly, such language should not be read as positive limitations on apparatus claims 3 or 13 of the '032 patent. To the extent that there is any question as to whether such language constitutes statements of intended use, the question should be resolved in favor of the BRI of the claims such that only the structural limitation(s) of claims 3 and 13 (namely, a skived proximal opening) are accorded patentable weight. The Federal Circuit has made clear that the validity of an apparatus claim depends ***solely*** "on the claimed structure [and] not on the use or purpose of that structure. *Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

Because the '032 patent claims are apparatus claims, the requisite invalidity analysis turns on a direct comparison of the claimed ***structures*** to prior art ***structures***. *See Carolina Mktg. Int'l, 289 F.3d at 810* ("To hold otherwise would effectively impose a method limitation on an apparatus claim without justification"); *In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). The functional statements in claims 3 and 13 are not structural because the entire structure of the proximal side opening is described elsewhere in the claim; deletion of the functional phrases from claims 3 and 13 would not affect the structure of the claimed proximal opening. At most, the language requires a

proximal opening large enough to allow passage of an interventional cardiology device.

Petitioner has, nevertheless, included sufficient evidence such that, even if the Board were to construe these functional statements of intended use as positive limitations of claims 3 and 13, the grounds for unpatentability set forth below still render the challenged claims invalid in view of the cited art.

4. "adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery"

Dependent claim 2 recites: "[t]he device of claim 1 wherein the tubular structure includes a distal portion ***adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.***" (Exh. 1001, 10:55-62.) These are statements of intended use, not structural language. The relevant structural limitations—a tubular structure having distal and proximal portions—is included elsewhere in the claim. As discussed above, to patentably distinguish the claimed invention from the prior art, a

recitation of intended use must result in a structural difference between the claimed invention and the prior art. *See, e.g.,* 1 Practitioner's Manual of Patent Examining Proc. § 707 (paragraph 7.37.09). As long as a prior art structure would be ***capable of*** performing the intended use, then it meets the claim. *Id.* In any event, even if this functional language in dependent claim 2 were accorded patentable weight, the prior art expressly discloses this function, as set forth below.

F. Non-Redundancy of Proposed Alternative Grounds

Petitioner urges the Board to adopt each ground of unpatentability raised with respect to claims 1-4, 8, 11, 13, and 17 of the '032 patent for at least the following reasons. The proposed grounds for institution presented in the present Petition ("Petition A") are not redundant over each other, or over the grounds of rejection presented in the concurrently filed parallel Petition for *inter partes* review of the challenged claims of the '032 patent, ("Petition B" (Exh. 1008)), because several differences exist between the applied prior art and their respective grounds for unpatentability. For example, the primary prior art reference U.S. Pub. No. 2004/0236215 ("Mihara") (Exh. 1009) in parallel Petition B differs from the primary prior art reference U.S. Patent No. 5,527,292 to Adams, *et al.* ("Adams '292") (Exh. 1011) raised herein. Mihara anticipates a different set of dependent claims (claims 3, 4, and 13) through its disclosure of a skived proximal side opening in Figures 1-3. Adams '292 anticipates the claimed difference in diameter

between the inner diameter of the device and the inner diameter of the standard guide catheter of "not more than one French" (claims 8 and 17). As a result, during the course of this proceeding, if instituted, Patent Owner could amend the claims to be limited to just one of these claimed embodiments that is not anticipated by Adams '292 (Petition A) or Mihara (Petition B) alone. Accordingly, all grounds based on both Adams '292 and Mihara are needed to cover all of the embodiments encompassed by claims 1, 2, and 11, and, as such, are not redundant. Indeed, because of the Patent Owner's unreasonably functional and broad claims, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structures of the systems in the cited references, and so that Petitioner may address any arguments by the Patent Owner regarding the ability of structures in the prior art to perform the various functions recited in each of the challenged claims.

For similar reasons, the grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 3, 4, and 13 are not redundant given the far reaching functional language of such claims. Although the alternative combinatory references of Adams '292 in view of either U.S. Patent No. 5,776,141 to Klein ("Klein") (Exh. 1017), U.S. Patent No. 7,232,452 to Adams ("Adams '452") (Exh. 1018), or U.S. Patent No. 5,328,472 ("Steinke") (Exh. 1019) encompass the functionality of each of the disclosed

systems, (each of these references discloses systems for receiving an interventional cardiology device through a lumen having a skived proximal opening), they are structurally different from each other in numerous other respects. Adams '452 explicitly discloses the insertion of devices through the skived proximal opening of its claimed device when a distal portion of the device is extended beyond the end of a guide catheter, and while the proximal portion is within the guide catheter lumen. Klein discloses the insertion of larger devices such as balloon catheters (in addition to guidewires), through its skived proximal opening, as was found by the Examiner during the prosecution of the '032 patent. Finally, Steinke discloses a proximal side "entry port" through which a guidewire is received, wherein the shape of the port clearly defines both full circumference and hemicylindrical portions.

If the PTAB disagrees and determines that the grounds raised herein are redundant of those raised in Petition B, and will institute only on the grounds of one Petition, Petitioner respectfully requests institution on the basis of this Petition. Moreover, if the PTAB determines that there is redundancy with respect to the grounds raised herein regarding obviousness of claims 3, 4, and 13 over Adams '292 in combination with either the knowledge of one of skill in the art, Klein, Adams '452, or Steinke, Petitioner suggests institution on the grounds of Adams '292 in combination with either Klein or Adams '452. Finally, to the extent that the

Board finds redundant Petitioner's proposed grounds of unpatentability for the claimed range of "not more than one French" in claims 8 and 17 based on anticipation in view of substantial disclosure by Adams '292, obviousness over Adams '292 in view of the knowledge of one of skill in the art, and Adams '292 in combination with the specific disclosure of the claimed range in the analogous art of Takahashi, Petitioner suggests institution by the Board on the basis of Adams '292 in combination with Takahashi.

G. Level of Skill In the Art

A person of ordinary skill in the art ("POSA") at the time of the alleged invention of the '032 patent would have been someone with at least the equivalent of a medical degree from an accredited institution (usually denoted in this country as a M.D. degree) or someone with the equivalent of a masters degree from an accredited institution (usually denoted in this country as an M.S. degree) in biomedical engineering. (Exh. 1003 ¶ 28.) The person must have at least three years of experience working as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer. (*Id.*) Extensive experience and technical training might substitute for educational requirements, while advanced degrees might substitute for experience. (*Id.*)

H. The Prior Art References

As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under at least §102(b).[2]

1. Adams '292

U.S. Patent No. 5,527,292 to Adams, *et al.* ("Adams '292") (Ex. 1011) matured from an application filed on September 9, 1994, prior to the earliest filing date the benefit of which is claimed by the '032 patent and is therefore available as prior art to the '032 patent under at least 35 U.S.C. § 102(b). Adams '292 describes a guide catheter extension: "The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter" (Exh. 1011, 4:35-38; Exh., 1003 ¶ 32), and discloses, *inter alia*:

> An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery. The device also including a push rod attached to a proximal end of the flexible tube to facilitate placement of the flexible tube within the coronary artery requiring treatment.

(Exh. 1011 at Abstract.) A benefit of the device disclosed in Adams '292 is the ability to extend the flexible tube beyond the distal tip of the guide catheter so that

[2] All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

it is sufficiently deep-seated beyond the ostium to anchor the position of the guide catheter during treatment:

> A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond....

(Exh. 1011, 9:19-24; Exh. 1003 ¶ 32, 68.)

2. Klein

U.S. Patent No. 5,776,141 to Klein ("Klein") (Exh. 1017) matured from an application filed on August 26, 1996, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under at least § 102(b). Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter and a proximal shaft attached to the proximal end of the tubular catheter body. (Exh. 1003 ¶ 34, 71.)

3. Adams '452

U.S. Patent No. 7,232,452 to Adams ("Adams '452") (Exh. 1018) matured from an application filed on July 12, 2002, prior to the earliest filing date the benefit of which is claimed by the '032 patent, and thus qualifies as prior art under at least § 102(b). The Adams '452 patent discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or

balloon." (Exh. 1018, 8:47-50; Exh. 1003 ¶ 35.) Adams '452 further discloses "[a] proximal wire or other control means...." (*Id.*, 8:27-30.) The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1003 ¶ 35, 74.) The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*Id.* ¶ 74.)

4. Steinke

U.S. Patent No. 5,328,472 to Steinke ("Steinke") (Ex. 1019) matured from an application filed on July 27, 1992, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under at least § 102(b). Steinke discloses "a catheter which allows rapid exchange" where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh.1019, 3:1-2; Exh. 1003 ¶¶ 36, 76.)

5. Takahashi

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions, 63:452-456 ("Takahashi") (Exh. 1020) is an article that was published in 2004 and, thus, qualifies as prior art under at least § 102(b). Takahashi describes method for deep-

seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶¶ 37, 78.) The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is less one French or less. (*Id.*)

I. How The Construed Claim(s) Are Unpatentable

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1-4, 8, 11, 13, and 17 of the '032 Patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration.

V. SUPPORTING EVIDENCE UNDER 37 C.F.R. § 42.104(B)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below and in the corresponding claim charts.

VI. ANTICIPATION OF THE CHALLENGED CLAIMS

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to achieve predictable results, all of which were well known to persons of ordinary

skill in the art in the field of interventional cardiology procedures at the time to which the '032 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

A. Claims 1, 2, 8, 11, And 17 Are Anticipated Under 35 U.S.C. § 102(b) By Adams'292

As shown below, each element recited in claims 1, 2, 8, 11, and 17 is anticipated by Adams '292, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '032 patent. (An unrelated patent by a different inventor with the last name "Adams" was disclosed.) "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See, e.g.*, *In re Schreiber*, 128 F.3d, at 1477.

1. Claim 1

Claim 1 of the '032 patent discloses: "A device for use with a standard guide catheter…" (Exh. 1001, 10:21); Adams '292 similarly, teaches: "For use in combination with a guide catheter …, an intravascular device…." (Exh. 1011, 23:33-35.) Claim 1 of the '032 patent further discloses a "device comprising: a flexible tip portion defining a tubular structure having a circular cross-section ..." with a shorter length and smaller diameter than the continuous lumen of the guide catheter (Exh. 1001, 10:28-32); Adams '292 similarly discloses "a relatively flexible tube having … the outer diameter … wherein the outer diameter is sized for insertion through the central lumen of the guide catheter …" (Exh. 1011, 23:37-

40) and "[t]he length of the flexible tube 32 is preferably approximately 6 to 10 inches" (*id.*, 5:61-63), which is shorter than the length of a standard guide catheter—approximately 40 inches. (*See* Exh. 1003 ¶ 97.) Claim 1 of the '032 patent recites an arrangement of the flexible tip and the guide catheter "defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable …" (Exh. 1001, 10:29-37); Adams '292 similarly discloses that "the guide catheter extension tube 70 is coaxially disposed within the guide catheter" (Exh. 1011, 11:58-60) and "[t]he inner diameter of the flexible tube is larger than the outer diameter of a typical angioplasty balloon catheter or other coronary treatment device." (*Id.*, 2:62-64.) Claim 1 of the '032 patent also discloses: "a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen …" (Exh. 1001, 10:38-41); Adams '292 similarly teaches that a "shaft 19 or push rod is attached to a proximal end of the elongated flexible tube 32" (Exh. 1011, 6:1-2) and that "[o]ne embodiment is shown in FIG. 2 and the shaft 19 or push rod is defined by an elongated wire." (*Id.*, 6:13-15.) Finally, claim 1 of the '032 patent provides that, "when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology

devices that are insertable into the guide catheter" (Exh. 1001, 10:48-54); likewise, Figure 1 of Adams '292 shows the flexible tube 32 extending beyond the distal tip of the guide catheter 12, while the push rod 19 extends proximally through the channel leg of the manifold 17 (where the hemostatic valve is located) in common with the balloon catheter shaft 26. (*See* Exh. 1011, FIG. 1.) Thus, the Adams '292 discloses every element of claim 1 of the '032 patent.

2. Claim 2

Both the '032 patent and Adams '292 are directed to the deep seating of a guide extension within a branch artery in order to secure the position of the guide catheter and facilitate the delivery of intravascular devices. (*Compare* Exh. 1001, 10:55-62 *with* Ex. 1011, 16:49-58.)

3. Claim 11

As discussed above, claim 11 of the '032 patent includes the same limitations as claim 1, plus one additional element, a "reinforced portion" proximal to the substantially rigid portion. Accordingly, Petitioner references its analysis of all elements of claim 1 set forth above and in the claim chart below, which shows, *inter alia*, that Adams '292 also disclosed the "reinforced portion" of claim 11.

4. Claims 8 and 17

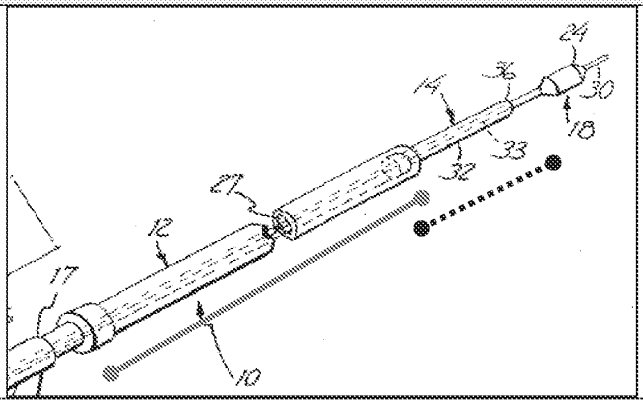
Dependent claims 8 (depending from claim 1) and 17 (depending from claim 11) require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner

diameter of the guide catheter." (Exh. 1001, 11:17-20, 12:35-38.) The Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which includes tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1011, 5:64-67; Exh. 1003, ¶ 121.) In disclosing a range overlapping or touching the claimed range, the Adams '292 anticipates the claimed range with sufficient specificity. *See ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

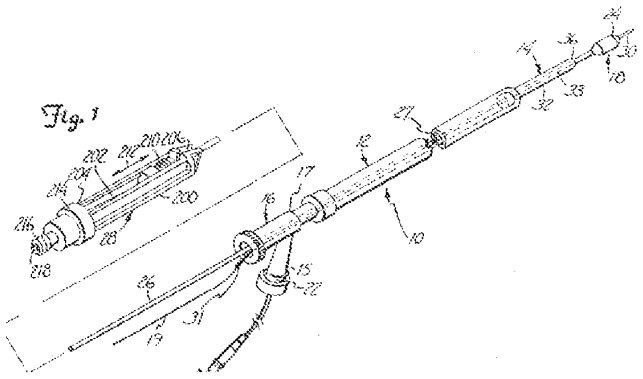
The '032 Patent	**Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)**
1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	**[1]** To the extent that the preamble is a limitation, Adams '292 discloses a device for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract ("An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery"); 4:36-37 ("The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter.") **[2]** The guide catheter used with the Adams device has a continuous central lumen and a proximal end with a mounted manifold having a primary channel that contains a hemostatic valve. 5:16-29 ("The guide catheter manifold 16 is mounted at the

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	proximal end of the guide catheter 12. Preferably, the guide catheter manifold 16 comprises a Y-shaped structure having a primary channel leg 17 and an extension leg 15 with a guide catheter port 22 on the extension leg 15…. A hemostatic valve (not shown) on channel leg 17 provides hemostatic control for the guide catheter system 10 of the present invention"); 11:17-30 ("Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or other angioplasty device is disposed and guided to a stenosis or obstruction. The guide catheter manifold 54 is mounted at a proximal end of the guide catheter 52, and preferably comprises a Y-shaped structure having a primary channel leg 51 and an extension leg 55 with a guide catheter port 58. The guide catheter port 58 provides an inlet injection port for dye to travel through the guide catheter system 50 to the arterial system or alternatively for the introduction of drugs into the patient to a treatment site. A hemostatic valve (not shown) on the primary channel leg 51 provides hemostatic control for the guide catheter.") **[3]** The lumen of the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. 6:24-32 ("In the embodiment shown in FIG. 2, the elongated tube 32 has a radially flared proximal end 38. The flared proximal end 38 of the elongated flexible tube 32 is configured to coincide with the inner diameter of the guide catheter 12 so that a catheter advanced, or other angioplasty device such as a guide wire, into and through the first guide catheter lumen 27 is piloted into the flared tip 38 and second guide catheter lumen 33"); 8:40-45 ("The diameter of the first guide catheter lumen 27

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	in the guide catheter 12 and the second guide catheter lumen 33 in the guide catheter extension 32 are larger than the outer diameters of the hollow balloon catheter shaft 26 and balloon 24 (deflated) which are advanced therethrough"); 16:36-44 ("a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment.")
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	**[1]** Adams '292 discloses a flexible tip portion defining a tubular structure in the form of a "relatively flexible tube." 2:44-51 ("The intravascular device includes a relatively flexible tube 45…"). **[2]** having an inner and outer diameter. 2:50-51 ("The flexible tube has an inner diameter sized for insertion over an angioplasty device"); 23:36-37 ("a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen …"). **[3]** Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). Fig. 12 also shows that flexible tube 255 is shorter than guide catheter 287.

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	
the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	**[1]** Adams '292 discloses that the outer diameter of the flexible tube is smaller than and sized for insertion through the guide catheter lumen. 5:64-67 ("The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the guide catheter 12 so that it may be slidably disposed therethrough and to permit insertion of the tube 32 …"); 23:37-40. **[2]** The flexible tube is placed coaxially relative to the guide catheter. 8:58-61 ("the angioplasty balloon catheter 18 and guide catheter extension 14 are coaxially positioned within the guide catheter 12 ..."); 11:58-60 ("During use, the guide catheter extension tube 70 is coaxially disposed within the guide catheter 52"); 15:65-66 ("The flexible tube 255 of the intravascular device 250 is 65 designed for coaxial placement relative to the guide catheter …"). **[3]** When used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen for the insertion and advancement of coronary treatment devices. 22:35-43 ("For use in combination with a guide catheter for insertion and advancement of a coronary treatment device through a coronary vessel having an ostium to a treatment site, the guide catheter having a central lumen, a distal end and a distal opening, an

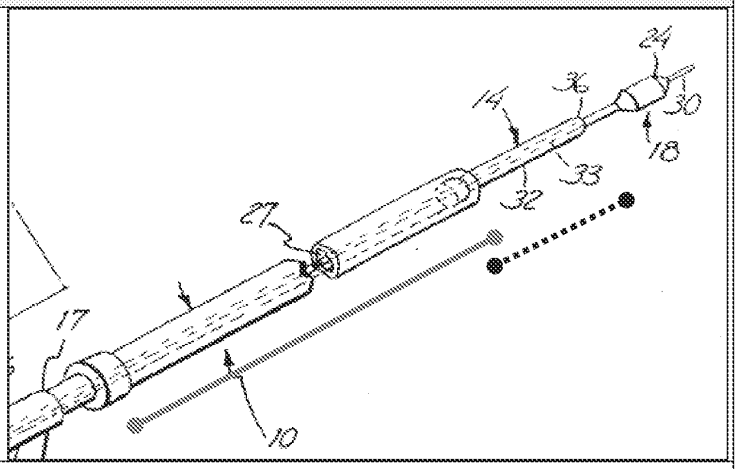
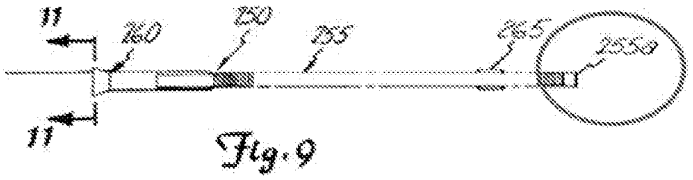
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	anchoring device comprising: a relatively flexible tube sized for insertion through the central lumen of the guide catheter into the coronary vessel, the flexible tube being concentrically aligned with the guide catheter …"); 16:38-44 ("the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment").
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Adams '292 discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." (7:22-26; *see* Abstract; 2:47-48; 6:1-2; 6:11-15; 15:8-12; 22:51-52; 23:44-45.)
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion	Adams '292 discloses that the diameter of the wire or stainless steel hypotube of the substantially rigid push rod is smaller (0.016 inch) than that of the flexible tube (0.065 inch). 6:14-17 ("the shaft 19 or push rod is defined by an elongated wire 34. The elongated wire 34 is of small diameter, preferably 0.010 to 0.016 of an inch in diameter"); 6:56-62 ("The rather thin dimension of the wire 34 eliminates or substantially reduces surface friction introduced by the longitudinal movement of an element within the guide catheter 12"); 7:18-21 ("The tubular shaft member 172 is preferably formed from stainless steel hypotube with an inside diameter of 0.010 inch and an outside diameter of 0.016 inch"); 8:24-25 ("For example, the outer diameter of the elongated tube 32A at its proximal end would.be approximately 0.065 inch and the outer diameter at its distal end would be approximately 0.053 inch (with a 0.045

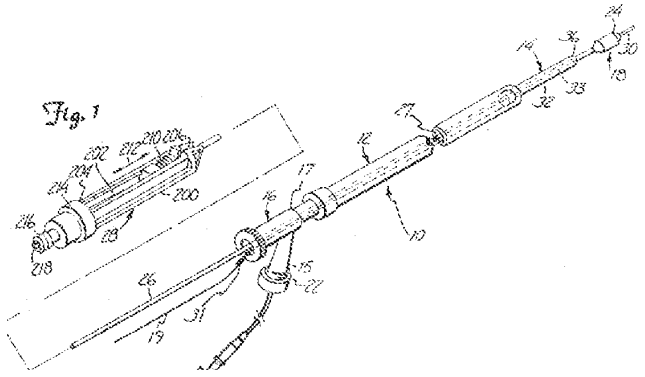
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	inch distal tubular opening …").
and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	**[1]** Adams '292 discloses that the combined length of the flexible tube and the push rod (50.5 to 51.5 inches) is longer than the guide catheter lumen (about 40 inches). 15:49-53 ("The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length. The push rod is:approximately 40.0 to 45.0 inches in length. The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches"). **[2]** When the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon catheter shaft:  "As seen in FIG. 1, shaft 19 or push rod … extends proximally … outside the guide catheter 12 so that it is accessible to the user…. The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12…." 6:1-10. 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. 5:17-29. 26 is a balloon catheter shaft. 8:40. The shaft 19 or push rod extends

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	from the manifold 17 at the same point as the balloon catheter shaft 26. 17:3-7 ("The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient").
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,	Adams '292 discloses that the proximal end of the flexible tube remains within a guide catheter while a distal portion of the flexible tube extends beyond the distal end of the guide catheter: "In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery." (Abstract); 9:19-22 ("A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends … beyond the distal end of the guide catheter 12…."); 15:57-60 ("The length of the tube is sized so that the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube 255 reaches a treatment site"); 16:60-64 ("A distal portion of the flexible tube 255 is advanced past the distal opening 288 of the guide catheter 287 … while a proximal portion thereof and the push rod 262 remain within the guide catheter 287").
such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	4:61-67 ("the distal extension may be advanced into and through the coronary arteries to the lesion or obstruction to facilitate original placement of angioplasty devices by serving to anchor the guide catheter at the coronary ostium of the vessel requiring treatment…"); 9:12-24 ("The extension of the elongated flexible tube 32 into the smaller dimension arteries also serves to maintain the position of the guide catheter 12 at the coronary ostium during operation…. [T]he flexible tube 32 defines an anchoring device for securing the guide catheter 12 for operation…. [A] significant portion

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond…."); 16:49-58 ("as a coronary device is advanced, the position of the distal opening 288 of the guide catheter 287 may shift out of alignment with the coronary ostium making placement of the coronary treatment device into the coronary artery requiring treatment more difficult. As previously explained, the present invention discloses an anchoring device for securing the guide catheter 287 relative to the coronary ostium of a patient to facilitate original insertion and subsequent insertion of a coronary treatment device"); 22:53-56 ("the flexible tube anchors the distal opening of the guide catheter relative to the ostium of the coronary vessel to secure the guide catheter and facilitate insertion of the coronary treatment device therethrough").
8. The device of claim 1	Adams '292 discloses the device of claim 1 (see above).
wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	Adams '292 discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter:"The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the guide catheter 12 so that it may be slidably disposed therethrough…." 5:64-67.
11. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined	**[1]** To the extent that the preamble is a limitation, Adams discloses a device for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract and 4:36-37.

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	**[2]** The guide catheter used with the Adams device has a continuous central lumen and a proximal end with a mounted manifold having a primary channel that contains a hemostasic valve. 5:16-29 and 11:20-30. **[3]** The lumen of the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. 8:40-45 and 16:39-44.
an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,	Adams discloses that the combined length of the flexible tube and the push rod (50.5 to 51.5 inches) is longer than the guide catheter lumen (about 40 inches). 15:49-53.
the elongate structure including: a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	**[1]** Adams '292 discloses a flexible tip portion defining a tubular structure in the form of a "relatively flexible tube." (*See e.g.*, 2:44; 2:54-55; 4:49-50; 14:3.) **[2]** having an inner and outer diameter. 2:44-50 and 23:36-37. **[3]** Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). This is also depicted in Fig. 12 which shows flexible tube 255 is shorter than guide catheter 287.

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	
the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;	**[1]** Adams '292 discloses that the outer diameter of the flexible tube is smaller than and sized for insertion through the guide catheter lumen. 5:64-67 and 23:37-40. **[2]** The flexible tube is placed coaxially relative to the guide catheter. 2:62-64; 11:58-60 and 15:65-66. **[3]** When used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen for the insertion and advancement of coronary treatment devices. 22:35-43.
a reinforced portion proximal to the flexible tip portion; and	"the relatively flexible tube of the intravascular device includes a coil spring extending along and defining at least a portion of the flexible tube." 20:3-6. "The guide catheter extension 14A … has a longitudinal guide catheter extension lumen,…a rounded distal tip 36A and may be reinforced by a coil 40A." 7:4-7.  Fig. 9

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Adams '292discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." 7:13-26; *see also* Abstract; 2:47-48; 6:1-2; 6:13-15; 15:8-12; 22:51-52; 23:44-45.
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,	Adams '292 discloses that the diameter of the wire or stainless steel hypotube of the substantially rigid push rod is smaller (0.016 inch) than that of the flexible tube (0.065 inch). 6:15-17; 6:56-62; 7:18-21 and 8:24-25.
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	Adams '292 discloses that when the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon catheter shaft:  "As seen in FIG. 1, shaft 19 or push rod … extends proximally … outside the guide catheter 12 so that it is accessible to the user…. The elongated flexible

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 8, 11, 17 in view of Adams '292 (Exh. 1011)
	tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12…." 6:1-10. 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. 5:17-29. 26 is a balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. "The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of the guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient." 17:3-7.
17. The device of claim 11	Adams '292 discloses the device of claim 11 (*See* A-1, above).
wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	*See* Adams '292 disclosures set forth in claim 8 (above).

VII. OBVIOUSNESS OF CHALLENGED CLAIMS

The below challenged claims of the '032 patent are rendered obvious under §103(a) in view of the prior art references set forth below,[3] either in view of the knowledge of one of ordinary skill in the art, or in the combinations expressly

[3] All references cited herein are patents and printed publications constituting prior art under § 102(b).

described herein. Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 418-20, 82 U.S.P.Q.2d 1385 (2007); In re Jones, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Claims 1, 2, 8, 11, and 17 are anticipated by Adams '292 for the reasons set forth above. To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292. (*See* Exh. 1003 ¶¶ 41-43, 111-114.)

A. Claims 1-4, 8, 11, 13 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Klein

Klein was cited during prosecution of the '032 Patent but was not considered in combination with Adams '292. As shown below, each element recited in claims 1-4, 8, 11, 13 and 17 is obvious over Adams '292 in view of Klein.

Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter. As set forth in the chart below, this disclosure satisfies the structural limitations of claim 3, requiring

that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," (Exh. 1017, 10:63-67), the requirement of claim 4 that "the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion," (*id.*, 11:4-6) and the limitation of claim 13 that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis." (*Id.*, 12:12-15.)

Even if the functional language of claims 3 and 13 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.*, Exh. 100_, 15:58-16:15) ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube 255 reaches a treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ..."). (*See* Exh. 1003 ¶ 104.)

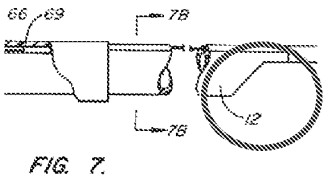
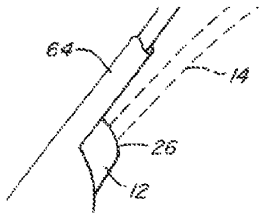
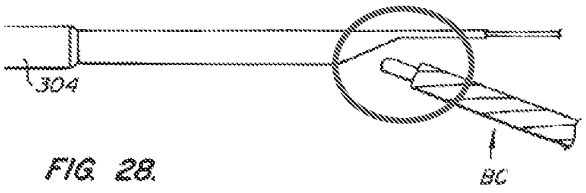
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 41-43, 107-110), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Klein to meet the limitations of the challenged claims. Adams '292 and Klein are both analogous to the '032 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably

pertinent to the problem faced by the inventor of the '032 patent. (Exh. 1003 ¶¶ 71-73.) As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Klein in addressing the problem addressed by the '032 patent.

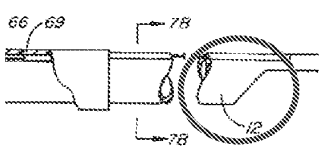
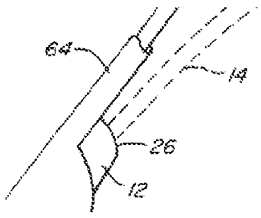
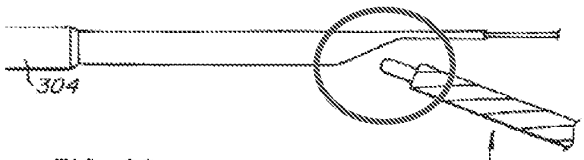
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78).) Accordingly, a POSA would be motivated to combine the device disclosed by Adams '292 with the teaching in Klein of the delivery of larger interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening of cardiovascular treatment catheter. This is particularly true given that Klein and Adams '292 both disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters.

Accordingly, Klein shows that using skived proximal openings for the delivery of interventional cardiology devices such as balloon catheters was well known by the time of the '032 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have

amounted to a simple substitution of a known element to obtain predictable results. (*See* Exh. 1003 ¶¶ 107-110.)

Claim Chart A-2: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (1011) in view of Klein (Exh. 1017)**
3. The device of claim 2	Adams '292 discloses the device of claim 2 (*See* A-1, above).
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	Klein discloses that "[t]ubular catheter body 16 includes an internal lumen 24 which extends from proximal port 26 to a distal port 28 to receive the balloon catheter 14. In particular, the lumen 24 will be sized sufficiently large to receive the balloon 30 of balloon catheter 14." 9:19-23. The length of "the tubular body 12" is "sufficient to extend from a treatment site within the coronary arteries back into a guiding catheter…. In this way, the entry port 26 will remain within the guiding catheter at all times." 10:16-22. Annotated Fig. 7 (below) depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  FIG. 7.  (Fig. 6.) 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.  FIG. 28. In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (*See also* Figs. 1, 8, 9, 9A, 10-15, 20-27.)

Claim Chart A-2: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (1011) in view of Klein (Exh. 1017)**
to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches a treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...." 15:57-16:13.
4. The device of claim 3 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	As shown above, Klein discloses a proximal opening of a lumen in a catheter skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion.
13. The device of claim 11	Adams '292 discloses the device of claim 11 (*See* A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	Klein discloses "[t]ubular catheter body 16 includes an internal lumen 24 which extends from proximal port 26 to a distal port 28 to receive the balloon catheter 14. In particular, the lumen 24 will be sized sufficiently large to receive the balloon 30 of balloon catheter 14." 9:19-23. The length of "the tubular body 12" is "sufficient to extend from a treatment site within the coronary arteries back into a guiding catheter…. In this way, the entry port 26 will remain within the guiding catheter at all times." 10:16-22. Annotated Fig. 7 (below) depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:

Claim Chart A-2: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (1011) in view of Klein (Exh. 1017)**
	 FIG. 7.  (Fig. 6.) 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.  FIG. 28. In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (*See also* Figs. 1, 8, 9, 9A, 10-15, 20-27.)
that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	Adams '292 is "directed to the structure and use of a distal extension … for a guide catheter," Adams '292, 4:36-37, wherein "[g]uide catheter 52 is an elongated, flexible tubular member defining a first guide cathter lumen 53 through which an angioplasty balloon catheter 60 or other angioplasty device is disposed and guided to a stenosis or obstruction," 11:17-20, and "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches a treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...." 15:57-16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion	As shown above, Klein discloses a proximal opening extending substantially along at least a portion of a length of the substantially rigid portion.

B. Claims 1-4, 8, 11, 13 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Adams '452

As shown below, each element recited in claims 1-4, 8, 11, 13 and 17 is obvious over Adams '292 in view of Adams '452, which was not cited or considered either alone or in combination with Adams '292 during prosecution of the '032 Patent. (*See* Exh. 1003 ¶¶ 41-43, 111-114.)

The Adams '452 patent discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." (Exh. 1018, 8:47-50.) The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*id.*)

The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (*See* Exh. 1003 ¶¶ 35, 74.) This disclosure satisfies the structural limitations of claim 3 requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of claim 4 that "the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical

portion," and the limitation of claim 13 that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis." (*See* Exh. 1001, claims 4, 13; 1003 ¶¶ 111-114.)

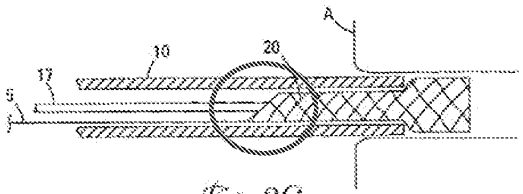
Even if the functional language of claims 3 and 13 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.,* Exh. 1003 ¶¶ 98-104; Exh. 1011, 15:57-16:13 ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube 255 reaches a treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...").)

As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 41-43, 111-114), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims. Adams '292 and Adams '452 are both analogous to the '032 patent as they are directed to the same type of device, are in the same field of endeavor and are reasonably pertinent to the problem faced by the inventor of the '032 patent. (*See* Exh. 1003 ¶¶ 74-75.) As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Adams '452 in addressing the problem addressed by the '032 patent. (*See id.* ¶¶ 41-43, 111-114.)

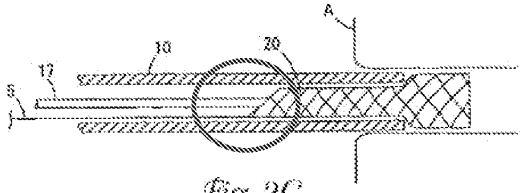
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 100_, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78).) Accordingly, a POSA would be motivated to combine the disclosure of Adams '292 with the teaching in Adams '452 of the advantages of a skived proximal opening to the lumen of a cardiovascular treatment device. (Exh. 1003 ¶¶ 83-85, 111-114.) This is particularly true given that the devices of Adams '452 and Adams '292 are both directed to the receipt of interventional cardiology devices through a proximal opening of the device while a proximal portion of the device is within the standard guide catheter. (*See* Exh. 1003 ¶¶ 74.) Moreover, Adams '292 and Adams '452 were both issued to the same named inventor, Daniel O. Adams; the fact that the inventor of the Adams '292 device in 1992 included a skived proximal side opening when designing a similar device (Adams '292 is cited as prior art on the face of the Adams '452 patent) ten years later is further evidence that, by 2006, a POSA would routinely include a skived or angular side opening in such rapid exchange devices.

In sum, Adams '452 shows that using skived proximal lumen openings for the delivery of devices while the proximal opening is within the lumen of a guide catheter was well known by the time of the '032 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292

device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*See* Exh. 1003 ¶¶ 35, 111-114.)

Claim Chart A-3: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Adams'452 (Exh. 1018)**
3. The device of claim 2	Adams '292 discloses the device of claim 2 (*See* A-1, above).
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	Adams '452 discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." 8:27-30. "A proximal wire … extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter." 8:27-30. The guide seal has a Adams '452 discloses a "portion which remains in the lumen of the guide catheter when the guide seal is deployed." 8:55-56. The guide seal may be formed of braided wires with a polymer covering or membrane attached. 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  *Fig. 2C* The proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery

Claim Chart A-3: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Adams'452 (Exh. 1018)**
	catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches a treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...." 15:57-16:13.
4. The device of claim 3	As shown above, Adams '292 in combination with Adams '452 discloses the device of claim 3.
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	As shown above, the Adams '452 patent discloses a proximal opening of a lumen in a catheter skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion.
13. The device of claim 11	Adams '292 discloses the device of claim 11 (*See* A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	Adams '452 discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." 8:47-50. "A proximal wire … extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter." 8:27-30. The guide seal has a "portion which remains in the lumen of the guide catheter when the guide seal is deployed." 8:55-56. The guide seal may be formed of braided wires with a polymer covering or membrane attached. 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the

Claim Chart A-3: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Adams'452 (Exh. 1018)**
	longitudinal axis:  *Fig. 2C* The proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches a treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...." 15:57- 16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion	As shown above, Adams '452 discloses a proximal opening extending substantially along at least a portion of a length of the substantially rigid portion.

C. Claims 1-4, 8, 11, 13 and 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Steinke

As shown below, each element recited in claims 1-4, 8, 11, 13 and 17 is obvious over Adams '292 in view of Steinke, which was not cited or considered

either alone or in combination with Adams '292 during prosecution of the '032 Patent. (Exh. 1003 ¶¶ 115-118.)

Steinke discloses "a catheter which allows rapid exchange" (Exh. 1019, 3:1-2) where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. This disclosure satisfies the structural limitations of claim 3 requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of claim 4 that "the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion," and the limitation of claim 13 that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis." A POSA would understand that the skived proximal "entry port" of Steinke functions as both an entryway and exit for an interventional cardiology device as a guidewire is passed or "received" therethrough upon delivering and removing the Steinke balloon catheter during treatment. (Exh. 1003, ¶ 117.)

Even if the functional language of claims 3 and 13 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.,* Exh. 1019, 15:57-16:13 ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches a treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...").) (Exh. 1003 ¶¶ 98, 104).

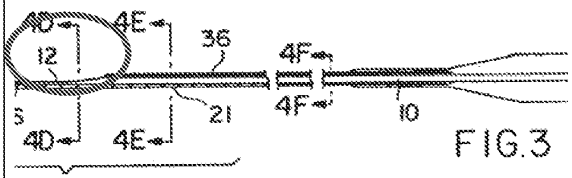
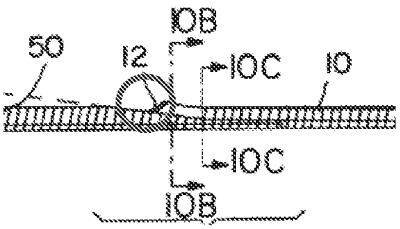
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 115-118), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Steinke to meet the limitations of the challenged claims. Adams '292 and Steinke are both in the same field of endeavor as the '032 patent and are pertinent to the problem faced by the inventor of the '032 patent. (*Id.* ¶¶ 76-77.) As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Steinke in addressing the problem addressed by the '032 patent.

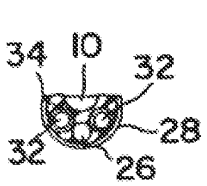
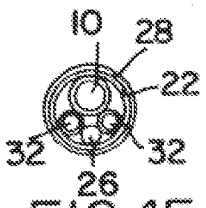
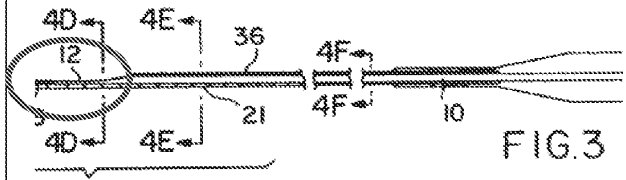
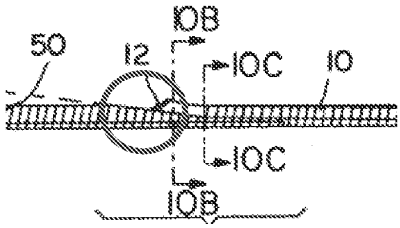
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78).) Accordingly, a POSA would be motivated to combine the Adams '292 disclosure with the teaching in Steinke of the advantages of a skived proximal opening to the device lumen of a cardiovascular treatment catheter for "varying flexibility along the

length of the catheter, without abrupt changes in stiffness, or an undesirably stiff transition region." (Exh. 1019, 3:1-7.) This is particularly true given that both Steinke and Adams '292 disclose rapid exchange devices, for use within a standard guide catheter, and are directed to extension beyond the distal end of the guide catheter to the treatment site.

In sum, Steinke shows that using skived proximal openings with rapid exchange catheters was well known by the time of the '032 patent, and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*See* Exh. 1003 ¶¶ 115-118.)

Claim Chart A-4: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Steinke (Exh. 1019)**
3. The device of claim 2	Adams discloses the device of claim 2 (*See* A-1, above).

Claim Chart A-4: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Steinke (Exh. 1019)**
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	Steinke discloses "a catheter which allows rapid exchange," 3:1-2, where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  FIG.3 FIG.9  12 is "the guidewire entry 12 (also referred to as the distal entry or side port entry)." 6:51-54. Steinke further discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit…." 9:66-10:1.
to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site….[T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57-16:13.
4. The device of claim 3	As shown above, Adams '292 in combination with Steinke discloses the device of claim 3.
wherein the proximal side opening includes	The skived side port entry of Steinke defines a full circumference portion and a partially cylindrical portion:

Claim Chart A-4: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Steinke (Exh. 1019)**
structure defining a full circumference portion and structure defining a partially cylindrical portion.	 FIG.4D  FIG.4E
13. The device of claim 11	Adams discloses the device of claim 11 (*See* A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	Steinke discloses "a catheter which allows rapid exchange" (col. 3, ll. 1-2) where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  FIG.3 FIG.9  12 is "the guidewire entry 12 (also referred to as the distal entry or side port entry)." 6:51-53. Steinke further discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit…." 9:66-10:1.
that is adapted to receive an interventional cardiology device passed through	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches a treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into the lumen 269 of extension 250 ...." 15:57-

Claim Chart A-4: Cl. 3-4, 13	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Steinke (Exh. 1019)**
continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion	As shown above, Steinke discloses a proximal opening extending substantially along at least a portion of a length of the substantially rigid portion.

D. Claims 8 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of The Knowledge of One Of Skill In The Art

Dependent claims 8 (depending from claim 1) and 17 (depending from claim 11) require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." (Exh. 1001, 11:17-20.) The Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1011, 5:64-67.) A POSA reading this disclosure of the Adams '292 patent at the time of the claimed invention would have understood the advantages of minimizing the difference in diameter between the inner guide catheter and the

outer guide catheter and, therefore, would have been motivated to practice the invention within the claimed range of not more than one French. (Exh. 1003 ¶ 125.)

In this case, the disclosed range for the difference in diameters between the outer guide catheter and the inner guide catheter of the device was already known in the field by the time of the '032 patent and, therefore, a POSA would have been motivated to conform to such teachings in practicing the Adams '292 invention with the predictable and expected results of allowing for the insertion of larger devices and avoiding the possibility of the guidewire becoming disposed in the space between the inner and outer guide catheters. (Exh. 1003 ¶ 121.)

E. Claims 1, 2. 8, 11 And 17 Are Obvious Under 35 U.S.C. § 103 Over Adams In View Of Takahashi

As shown below, each element recited in dependent claims 8 and 17 is obvious over Adams '292 in view of Takahashi, which was cited during prosecution of the '032 Patent but was not discussed in any Office Action or considered in combination with Adams '292. Claims 8 and 17 require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." Takahashi satisfies the limitations of claims 8 and 17 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter such that the cross-sectional inner diameter of the 5 French catheter is not more

than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of minimizing the difference in diameter between the inner guide catheter and the outer guide catheter, and would recognize that this teaching of Takahashi's 5-in-6 system could be applied to any guide extension device for insertion through a standard guide catheter, such as the Adams '292, and would have been motivated to do so. (Ex. 1003 ¶¶ 78-80, 126-128.)

Claim Chart A-5: Cl. 8, 17	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1020)**
8. The device of claim 1	Adams '292 discloses the device of claim 1 (*See* A-1, above).
wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	Takahshi discloses "[t]he five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A)." (Exh. 1020 at 452.) "The inner lumen of the 5 Fr Heartrail catheter is 0.059' in diameter…. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter…." (*Id*. at 453.) "In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter…." (*Id*. at 453.) "Only inserting the 5 Fr guiding catheter into the 6 Fr catheter increased the backup support…." (*Id*. at Fig. 3.) "A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter." (*Id*. at 454.)

Claim Chart A-5: Cl. 8, 17	
The '032 Patent	**Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1020)**
17. The device of claim 11	Adams discloses the device of claim 11 (*See* A-1, above).
wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	*See* Takahashi disclosures set forth in claim 8 (above).

VIII. CONCLUSION

Based on the foregoing, it is clear that claims 1, 2, 8, 11, and 17 of the '032 patent define subject matter that is anticipated in view of Adams '292 and that claims 1-4, 8, 11, 13, and 17 of the '032 patent define subject matter that is

obvious in view of the knowledge of a POSA combined with Adams '292 and the teachings of the additional references cited above. Adams '292 and the prior art combinations cited above were never considered by the Examiner; if they had been, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '032 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

ARNOLD & PORTER LLP

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 16, 2014, to the USPTO correspondence address of record listed below:

Patterson, Thuente, Petersen, PA
4800 IDS Center
80 South 8th Street
Minneapolis, MN 55402-2100

Courtesy copies were also shipped to counsel for patent owner at the following address:

J. Thomas Vitt
Heather Redmond
Shannon Bjorklund
Forrest Tahdooahnippah
Dorsey & Whitney
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402
Telephone: (612) 340-2600

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

ATTACHMENT E

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,048,032

Attorney Docket No. 0025216-00057

PETITION FOR INTER PARTES REVIEW
UNDER 37 C.F.R. § 42.100

TABLE OF CONTENTS

Page

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)) 1
- A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) 1
- B. Related Matters (37 C.F.R. § 42.8(b)(2)) 1
- C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a)) 2
- D. Service Information (37 C.F.R. § 42.8(b)(4)) 2

II. PAYMENT OF FEES (37 C.F.R. § 42.103) 2

III. SUMMARY OF RELEVANT TECHNOLOGY AND '032 PATENT 3
- A. Overview Of Interventional Cardiology Procedures 3
- B. Description Of The Alleged Invention Of The '032 Patent 4
- C. Summary of the Prosecution History of the '032 Patent 6

IV. REQUIREMENTS FOR INTER PARTES REVIEW 9
- A. Grounds for Standing Under 37 C.F.R. § 42.104(a) 10
- B. Identification of Challenge and Relief Requested 10
- C. Claims for Which *Inter Partes* Review Is Requested 10
- D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2) 10
- A. Construction Of The Challenged Claims 14
  - 1. "rail structure without a lumen" 15
  - 2. "interventional cardiology device(s)" 16
  - 3. "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen" 17
  - 4. "adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery" 19
- B. The Prior Art References 20
  - 1. Mihara 21
  - 2. Takahashi 22

C. How The Construed Claim(s) Are Unpatentable 23
D. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5) 23
VII. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b) (4) 23
A. Claims 1, 2, 3, 4, 11, and 13 Are Anticipated Under 35 U.S.C. §102(b) By Mihara 24
1. Claim 2 31
2. Claims 3, 4, and 13 32
3. Claim 11 34
B. Claims 1, 2, 3, 4, 11 And 13 Are Obvious Under 35 U.S.C. §103 Over Mihara In View of the Knowledge of a Person of Ordinary Skill in the Art 50
C. Claims 1-4, 8, 11, 13 and 17 Are Obvious Under 35 U.S.C. §103(a) Over Mihara In View Of Takahashi 51
VIII. CONCLUSION 54

Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,048,032

Exhibit Description	Exhibit No.
U.S. Patent No. 8,048,032 to Root, et al.	1001
File History for U.S. Patent No. 8,048,032	1002
Declaration of Ronald Jay Solar, Ph.D., with attached Appendix1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,292,850 to Root, et al.	1004
U.S. Patent No. 8,142,413 to Root, et al.	1005
File History for U.S. Patent No. 8,292,850	1006
File History for U.S. Patent No. 8,142,413	1007
Copy of a Second Petition (excluding exhibits) for *Inter Partes* Review Filed Concurrently by Petitioner on the '032 Patent	1008
U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1009
Translation of Japanese Patent Application No. 2003-070808	1010
U.S. Patent No. 5,527,292 to Adams et al.	1011
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1012
U.S. Patent No. 6,638,268 to Niazi	1013
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1014
U.S. Publication No. 2004/0127927 to Adams	1015
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1016
U.S. Patent No. 5,776,141 to Klein et al.	1017
U.S. Patent No. 7,232,452 to Adams et al.	1018
U.S. Patent No. 5,328,472 to Steinke et al.	1019
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," *Catherization and Cardiovascular Interventions* 63:452-456 (2004)	1020
U.S. Patent No. 5,690,613 to Verbeek	1021
U.S. Patent No. 5,156,594 to Keith	1022
U.S. Patent No. 5,102,403 to Alt	1023
Kucklick, Theodore R., The Medical Device R&D Handbook (2006)	1024
Amended Complaint filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (May 28, 2013)	1025
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1026

Exhibit Description	Exhibit No.
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1027
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (July 28, 2013)	1028
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (December 19, 2013)	1029
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed December 27, 2013	1030
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed January 3, 2014	1031
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir.) filed January 7, 2014	1032
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir.) filed January 29, 2014	1033
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir.) filed February 3, 2014	1034
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir.)	1035
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1036
Joint Claim Construction Statement filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn.) (February 21, 2014)	1037
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1038
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1039
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1040
U.S. Patent No. 5,267,958 to Buchbinder et al.	1041

Inter partes review is respectfully requested for claims 1-4, 8, 11, 13, 17 of U.S. Patent No. 8,048,032 ("the '032 Patent") (Exh. 1001).

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '032 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of the '032 Patent on other grounds in another petition to be filed concurrently herewith. Further, Petitioner is filing two separate petitions on non-redundant grounds seeking *inter partes* review of U.S. Patent No. 8,292,850 (the "'850 patent") and one petition seeking review of U.S. Patent No. 8,142,413 (the "'413 patent") to be filed concurrently herewith. In all, five petitions will be filed. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and are directed generally to the same subject matter. Specifically, the '850 patent is a division of application No.

12/824,734, which issued as the '413 patent, and the '413 patent is a division of application No. 11/416,629, which issued as the '032 patent. The claims challenged therein are method ('413 patent) and system ('850 patent) versions of the apparatus claims of the '032 patent challenged herein.

C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

Lead Counsel	Back-Up Counsel
David R. Marsh (Reg. No. 41,408) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5068 Facsimile: 202.942.5999 Email: david.marsh@aporter.com	Kristan L. Lansbery (Reg. No. 53,183) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5186 Facsimile: 202.942.5999 Email: kristan.lansbery@aporter.com

D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to service by email to lead and backup counsel at xBSC_VSI_IPRService@aporter.com.

II. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 50-2387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for

any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF RELEVANT TECHNOLOGY AND '032 PATENT

A. Overview Of Interventional Cardiology Procedures

The claims of the '032 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (*See* Exh. 1001, 1:7-36.) During such procedures, physicians deploy thin, flexible treatment devices, such as guide wires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.; see* Declaration of Ronald Jay Solar, Ph.D. ("Solar Declaration") (Exh. 1003, ¶ 8).) The physician introduces the treatment device into the patient's vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id.*). Often, to create a passage for such treatment devices, physicians insert a "guide catheter" earlier in the procedure. *Id.* In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. *Id.* The '032 patent is directed to an apparatus that is deliverable through a standard guide catheter for extension

beyond the ostium to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. *See, e.g.*, (Exh. 1001, 2:45-49.)

B. Description Of The Alleged Invention Of The '032 Patent

The '032 Patent (Exh. 1001) contains 22 device claims, including two independent claims (claims 1 and 11). The specification of the '032 patent states that it relates "generally to catheters used in interventional cardiology procedures," and "[m]ore particularly ... apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." (Exh. 1001, 1:7-11.)

The challenged claims of the '032 patent are not straightforward. Unlike typical apparatus claims, the '032 patent claims are replete with functional language and ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Claim 1 of the '032 patent is representative of the independent claims:

> **1.** A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:
>
> a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure

having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

Dependent claim 2 of the '032 patent depends from independent claim 1 and requires "that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery." (*Id.*, claim 2.)

Dependent claim 3 (depending from independent claim 1 and dependent claim 2), and dependent claim 13 (depending from independent claim 11), are directed to a "proximal side opening...extending for a distance along the longitudinal axis" and "transverse [*i.e.*, at an angle] to the longitudinal axis."

Dependent claim 4 depends from claim 3 and requires a "structure defining a full circumference portion and structure defining a partially cylindrical portion," as would result from a tube being skived at an angle for part of its length. These 'side opening claims' are directed to that which was well known in the art when the '032 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle. (*Id.*, claim 4.)

Dependent claims 8 (depending from independent claim 1) and 17 (depending from independent claim 11) require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." (*Id.*, claim 8.)

C. Summary of the Prosecution History of the '032 Patent

The '032 patent was filed as U.S. Application Serial No. 11/416,629 and issued on November 1, 2011. The original claims were restricted and the Applicant elected device claims. (Response to Restriction Requirement dated October 1, 2008) at 11 (Exh. 1002, at 378).)

Claims 9 and 12-15 (corresponding generally to claims 1 and 11 of the '032 patent) were rejected as obvious over U.S. Patent 6,638,268 ("Niazi") (Exh. 1013) in view of U.S. Patent Application Publication No. 2003/0195546 to Solar *et al.*, ("Solar") (Exh. 1012). The Examiner found that Niazi disclosed all but "the elongate structure with a substantially rigid portion proximal to the reinforced portion, including a cylindrical portion defining an opening along a side thereof, the length of the rigid portion." (Non Final Office Action ("NFOA") (Dec. 5, 2008) at 3 (Exh. 1002 at 351).) The element missing from Niazi was, however, disclosed in Solar: "an elongate device comprising a pushing member 5 and tracking member 7 ...." (*Id.*) While the rejection refers to claims 9 and 12-15, claim 8 is specifically discussed and treated as rejected. (*Id.* at 2 (Exh. 1002 at 350).)

Claims 9-11, 16, and 21 (corresponding generally to claims 1, 8, 11, and 17 of the '032 patent) were rejected over the same combination and additionally in view of U.S. Patent Application Publication No. 2004/0127927 to Adams, *et al.* ("Adams '927") (Exh. 1015) and U.S. Patent No 6,338,725 to Hermann, *et al.*, ("Hermann") (Exh. 1016). The Examiner found that "Solar discloses a decreasing rigidity along the device as one travels distally. Adams '927 discloses relief cuts as a method of forming a non-rigid bendable section in an otherwise straight member...." (*Id.* at 5 (Exh. 1002 at 353).) The Examiner also found that

"Hermann discloses a metal coil imbedded in a flexible sheath to avoid kinking and collapse during use" and "Solar discloses using a guidewire 9 to allow the system to advance easily to a desired location within a patient's body." (*Id.* At.5- 6 (Exh. 1002, 353-54).)

Further, in an Office Action dated November 19, 2009, the Examiner maintained the rejection of then-claims 66, 69, and 74 (corresponding generally to claims 3 and 4 of the '032 patent), citing U.S. Patent No. 5,776,141 to Klein, *et al.*, ("Klein") (Exh. 1017). Specifically, the Examiner found that:

> Klein discloses a ... tracking member/sheath ... that covers a delivery catheter .... ***The sheath of Klein has a slant that gives it both fully cylindrical and partial cylindrical portions***. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a ... tracking member (including the cylindrical shape) as taught by Klein....

(NFOA (Nov. 19, 2009) at 3 (Exh. 1002 at 271) (emphasis added).)

Despite six amendments, the revised claims remained rejected over Niazi in view of Solar. Moreover, the claim amendments resulted in additional rejections as the newly presented claims lacked a written description for multiple negative limitations, including the genus "non-tubular." (NFOA (July 30, 2010) at 2 (Exh. 1002 at 185); Final Action (Dec. 21, 2010) at 2 (Exh. 1002 at 142).) Applicants attempted to overcome the written description by asserting, without specific

citation to the specification, that "[t]he application as filed clearly describes and differentiates circular, cylindrical tubular shapes from those that are partially circumferential, non-circular or non-tubular." (Response to Final Action (Dec. 21, 2010) at 11 (Exh. 1002 at 125).)

None of the Applicants' arguments or amendments were sufficient; the claims were allowed only after an Examiner's amendment following an interview. "Non-tubular" was deleted from the description of the substantially rigid portion in the independent claims and the Examiner substituted "***rail structure without a lumen***." (Notice of Allowability (Nov. 3, 2011) (Exh. 1002 at 94).) Only after the Applicants accepted the addition of that limitation to ***each independent claim*** that any of the claims were allowed. (Neither the Applicants nor the Examiner cited any support for the substitution.)

Thus, the Examiner never considered the side opening limitations of dependent claims 3, 4, and 13 or the "one French" limitation of dependent claim 8 to be inventive features standing alone. A Notice of Allowance was mailed August 3, 2011, and the '032 Patent issued on November 1, 2011 (Exh. 1002)

IV. REQUIREMENTS FOR INTER PARTES REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '032 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '032 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

B. Identification of Challenge and Relief Requested

Pursuant to 37 C.F.R. § 42.104(b), the precise relief requested by Petitioner is that claims 1-4, 8, 11, 13, and 17 of the '032 Patent be found unpatentable.

C. Claims for Which *Inter Partes* Review Is Requested

Pursuant to 37 CFR § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1-4, 8, 11, 13, and 17 of the '032 Patent.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

This Petition, supported by the grounds set forth below and the Solar Declaration, demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C. § 314(a). Dr. Solar, an expert with thirty-seven years of academic and industry experience in the field of interventional cardiology devices has reviewed the claim charts submitted in the '032 Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein. (*See* Exh. 1003 ¶ 81.) *Inter partes* review is

requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103.

No.	Grounds
1	Claims 1-4, 11, and 13 are anticipated by U.S. Pub. No. 2004/0236215 to Mihara, *et. al*.
2	Claims 1-4, 11, and 13 are obvious over Mihara in view of the Knowledge of One of Skill in the Art
3	Claims 8 and 11 are obvious over Mihara in view of "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," *Catherization and Cardiovascular Interventions* 63:452-456 (2004), Takahashi Online Article ("Takahashi") (Exhibit 1020)

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

V. Non-Redundancy of Proposed Alternative Grounds

Petitioner urges the Board to adopt each ground of unpatentability raised with respect to claims 1-4, 8, 11, 13 and 17 of the '032 patent for at least the following reasons. The proposed grounds for institution presented in the present Petition ("Petition B") are not redundant over each other, or over the grounds of rejection presented in the concurrently filed parallel Petition for *inter partes* review of the challenged claims of the '032 patent, ("Petition A" (Exh. 1008)), because several differences exist between the applied prior art and their respective grounds for unpatentability. For example, the primary prior art reference ("Adams '292") (Exh. 1011) in parallel Petition A differs from the primary prior art reference raised herein ("Mihara") (Exh. 1009). Mihara anticipates a different set of

dependent claims (claims 3, 4, and 13) through its disclosure of a skived proximal side opening in Figures 1-3. Adams '292 anticipates the claimed difference in diameter between the inner diameter of the device and the inner diameter of the standard guide catheter of "not more than one French" (claims 8 and 17). As a result, during the course of this proceeding, if instituted, Patent Owner could amend the claims to be limited to just one of these claimed embodiments that is not covered by anticipation in view of Adams '292 (Petition A) or Mihara (Petition B) alone. Accordingly, all grounds based on both Adams '292 and Mihara are needed to cover all of the embodiments encompassed by claims 1, 2, and 12, and, as such, are not redundant. Indeed, because of the Patent Owner's unreasonably functional and broad claims, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structures of the systems in the cited references, and so that Petitioner may address any arguments by the Patent Owner regarding the ability of structures in the prior art to perform the various functions recited in each of the challenged claims.

For similar reasons, the grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 3, 4, and 14 are not redundant given that the far reaching functional language of such claims necessitate Petitioner's alternative proposed grounds of unpatentability on

the basis of both anticipation in view of Mihara and obviousness over Mihara in view of the knowledge of one of skill in the art.

If the PTAB disagrees and determines that the grounds raised herein are redundant of those raised in Petition A, and will institute only on the grounds of one Petition, Petitioner respectfully requests institution on the basis of Petition A. Moreover, if the PTAB determines that there is redundancy with respect to the grounds raised herein regarding anticipation in view of Mihara and obviousness of claims 3, 4, and 14 over Mihara in combination with the knowledge of one of skill in the art, Petitioner suggests institution on the grounds of Mihara in view of the knowledge of one of skill in the art.

VI. Level of Skill In the Art

A person of ordinary skill in the art ("POSA") at the time of the alleged invention of the '032 patent would have been someone with at least the equivalent of a medical degree from an accredited institution (usually denoted in this country as a M.D. degree) or someone with the equivalent of a masters degree from an accredited institution (usually denoted in this country as an M.S. degree) in biomedical engineering. The person must have at least three years of experience working as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer. Extensive experience and technical training might substitute

for educational requirements, while advanced degrees might substitute for experience. (Exh. 1003 ¶ 28.)

A. Construction Of The Challenged Claims

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]."*See* 37 C.F.R. § 42.100 (b); *see also, In re Swanson,* 540 F.3d 1368, 1377-78 (Fed. Cir. 2008)*; In re Trans Texas Holding Corp.,* 498 F.3d 1290, 1298 (Fed. Cir. 2007) (citing *In re Yamamoto,* 740 F.2d 1569, 1571 (Fed. Cir. 1984).

Because the standards of claim interpretation used by the Courts in patent litigation differ from those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation ("BRI") in light of the patent specification, including

their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.[1]

1. "rail structure without a lumen"

Because the '032 patent does not disclose any structure for the "rail structure without a lumen" limitation of independent claims 1 and 11, it is invalid under 35 U.S.C. §112, ¶2. The word "rail" appears in the specification of the '032 patent only twice. *First*, the Summary of the Invention refers to a "guidewire rail segment," defined as "permit[ing] delivery without blocking the use of the guide catheter." (Exh. 1001, 2:55-56.) *Second*, Fig. 17 is described as "a plan view of a coaxial guide catheter having a longer rail segment," without any guidance as to which portion(s) of Figure 17 constitute the "rail segment." (*Id.*, 5:57-59.) Neither of these references discloses any meaning for "rail" in the claim term "rail structure without a lumen." (Exh. 1003 ¶ 63.) Moreover, nothing in the specification suggests that the rail structure consists of the "tapered inner catheter," "full circumference portion," "cutout portion," "reinforced portion," "hemicylindrical portion," "second full circumference portion," "arcuate portion," "braid or coil reinforcement," "most proximal portion of braid or coil

[1] Petitioner reserves the right to challenge the validity of the '032 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

reinforcement," "relief cut," "hemi-tube portion," "single cuts," "double cuts," "connector hub," "funnel portion," "grip portion," to name a few, nor would be so read by a POSA. (*Id.*)

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent apparatus claims 1 and 11 under 35 U.S.C. §§ 102 and 103, and claims 2, 3, 4, 8, 13, and 17 depending therefrom, Petitioner submits that a POSA would understand "rail structure" to refer to a pushing or advancement structure. "Monorail" or rapid exchange catheters are characterized by a relatively short distal guide wire lumen; this cannot be the "rail structure" for purposes of the claim, however, because the claimed structure must be "without a lumen." (Exh. 1003 ¶¶ 63-65.) A POSA would therefore understand the "rail structure" to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id.*, ¶¶ 63-65) Accordingly, the term "rail structure without a lumen" can be construed for purposes of this Petition to mean a "pushing or advancement structure without a lumen."

2. "interventional cardiology device(s)"

Interventional cardiology devices are thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (Id. ¶ 66.) The specification of the '032 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001) ("For the purposes of this application, the term 'interventional cardiology devices is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters").) During the prosecution of the '032 patent, the Examiner stated his understanding that interventional cardiology devices include guide wires:

> Applicant argues that [the Solar Publication] teaches away from a lumen large enough to receive an interventional cardiology device. ***No inherent meaning is give[n] to this cardiology device that precludes structures such as guide wires and obturators***.

(Exh. 1002, July 30, 2010 Office Action at 9 (emphasis added).)

3. "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen"

Dependent claim 3 recites that the structure of the proximal side opening is "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." Dependent claim

13 similarly recites an opening "adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen." (Exh. 1001, claim 3 (emphasis added).) This language merely indicates the intended use of the claimed proximal opening (to receive an interventional cardiology device), and the device itself (for use within a guide catheter) as well as the order in which such intended uses may occur (receiving the device "into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter"). *Id.* Accordingly, such language should not be read as positive limitations on apparatus claims 3 or 13 of the '032 patent. To the extent that there is any question as to whether such language constitutes statements of intended use, the question should be resolved in favor of the BRI of the claims such that only the structural limitation(s) of claims 3 and 13 (namely, a skived proximal opening) are accorded patentable weight. The Federal Circuit has made clear that the validity of an apparatus claim depends ***solely*** on the claimed structure and not on the use or purpose of that structure. *Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

Because the '032 patent claims are apparatus claims, the requisite invalidity analysis turns on a direct comparison of the claimed ***structures*** to prior art ***structures***. *See Carolina Mktg. Int'l, 289 F.3d at 810* ("To hold

otherwise would effectively impose a method limitation on an apparatus claim without justification"); *In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). The functional statements in claims 3 and 13 are not structural because the entire structure of the proximal side opening is described elsewhere in the claim; deletion of the functional phrases from claims 3 and 13 would not affect the structure of the claimed proximal opening. At most, the language requires a proximal opening large enough to allow passage of an interventional cardiology device.

Petitioner has, nevertheless, included sufficient evidence such that, even if the Board were to construe these functional statements of intended use as positive limitations of claims 3 and 13, the grounds for unpatentability set forth below still render the challenged claims invalid in view of the cited art.

4. **"adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery"**

Dependent claim 2 recites: "the device of claim 1 wherein the tubular structure includes a distal portion ***adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces***

exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery." These are statements of intended use, not structural language. The relevant structural limitations—a tubular structure having distal and proximal portions—is included elsewhere in the claim. As discussed above, to patentably distinguish the claimed invention from the prior art, a recitation of intended use must result in a structural difference between the claimed invention and the prior art. *See, e.g.,* 1 Practitioner's Manual of Patent Examining Proc. § 707 (paragraph 7.37.09). As long as a prior art structure would be ***capable of*** performing the intended use, then it meets the claim. *Id.* Petitioner further notes that the clauses "wherein" and "adapted to" are particularly recognized as raising questions as to the limiting effect of the language in a claim. *See, e.g.,* MPEP § 2111.04. The prosecution history of the '032 patent further demonstrates that the Examiner did not view the non-structural language of dependent claim 2 to be limiting, and that this understanding was not disputed by the Patent Owner. (Exh. 1002).

In any event, even if the functional language in dependent claim 2 were accorded patentable weight, the prior art expressly discloses this function, as set forth below.

B. The Prior Art References

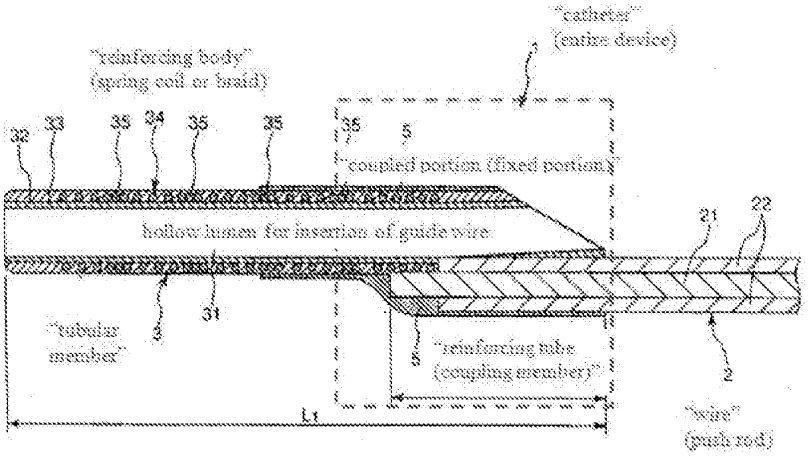
As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under at least §102(b).[2]

1. Mihara

U.S. Pub. No. 2004/0236215 ("Mihara") (Exh. 1009) is an application published on November 25, 2004, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under § 102(b). The Mihara publication discloses a "catheter for penetrating a stenotic lesion occurred in a lumen in a human body, including: a linear wire; and a tubular body placed on a distal end side of the wire and allowing a guide wire to be inserted through its hollow portion." (Exh. 1009, Abstract; Exh. 1003 ¶¶ 31 and 54-55.) An annotated version of Fig. 2 (below) provides a cross-sectional view of the Mihara catheter (the left side of Fig. 2 depicts a "distal end" of the device, and the right side depicts a "proximal end") (Exh. 1009, Fig. 2, [0028], [0031]):

[2] All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

FIG. 2



As shown in Fig. 2, "the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31." (Exh. 1009, [0033]).

2. Takahashi

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 ("Takahashi") is an article published in 2004 and, thus, qualifies as prior art under § 102(b). Takahashi describes a method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶ 32.) The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is less one French or less. (*Id.*)

C. How The Construed Claim(s) Are Unpatentable

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1-4, 8, 11, 13, and 17 of the '032 Patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section V below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration.

D. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below and the corresponding claim charts set forth therein. Dr. Solar, an expert with thirty-seven years of academic and industry experience in the field has reviewed the claim charts and evidentiary support submitted in this Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein.

VII. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b) (4)

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to achieve predictable results, all of which were well known to persons of ordinary

skill in the art in the field of interventional cardiology procedures at the time to which the '032 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

A. Claims 1, 2, 3, 4, 11, and 13 Are Anticipated Under 35 U.S.C. §102(b) By Mihara

As shown below, each element recited in claims 1, 2, 3, 4, 11 and 13 is anticipated by Mihara, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '032 patent. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See, e.g.*, *In re Schreiber*, 128 F.3d at 1477.

Claim 1 of the '032 patent discloses:

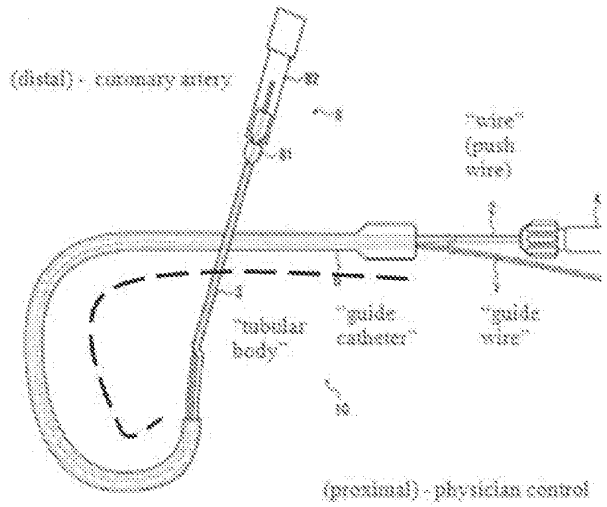
> ***A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:***

The preamble of a patent may not be limiting. *See, e.g., STX LLC. v. Brine, Inc.*, 211 F.3d 588, 591 (Fed. Cir. 2000); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). The prosecution history of the '032 patent demonstrates that the Examiner did not view the preamble language of independent claims 1or 11 to be

limiting, and that this understanding was not disputed by the Patent Owner. (Exh. 102). Nevertheless, all limitations recited in the preamble are disclosed by Mihara.

Specifically, Mihara discloses a device for use with a standard guide catheter. (Exh. 1009, [0092] ("First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery.").) In annotated Figure 3 below, the guide catheter 6 (dashed blue line) used with the Mihara catheter has a continuous central lumen and a proximal end which a POSA would understand is directed to insertion through a hemostatic valve. (Exh. 1009, Fig. 3.)

FIG. 3



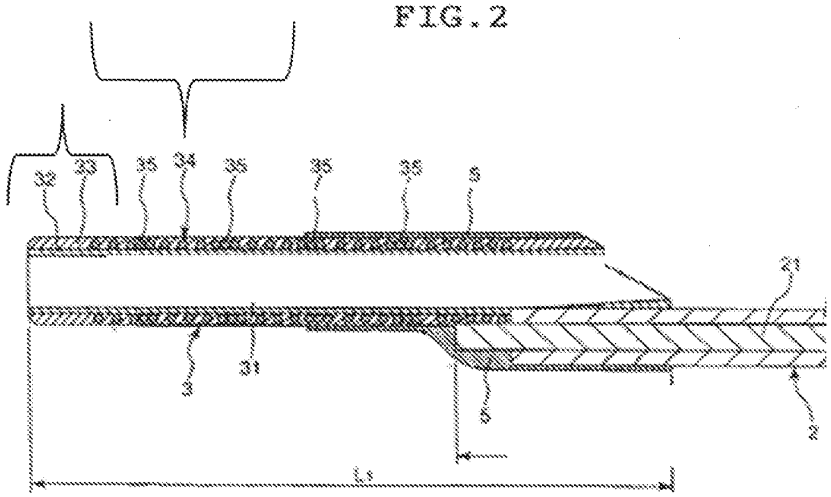
Mihara also discloses that the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough

and into a branch artery. (Exh. 1009, [0005] ("a long hollow tube called a guide catheter is inserted into a blood vessel, and placed at an entrance of a coronary artery. After that, the guide wire is pulled out, and another guide wire and a balloon catheter are inserted in a lumen of the guide catheter"); *see id.* Fig. 3; [0092]-[0093].)

a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,

Mihara discloses a flexible tip portion defining a tubular structure in the form of a "tubular body," having an inner and outer diameter. Specifically, annotated Fig. 2 of Mihara (below) discloses a catheter wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being "preferably formed of a flourine resin such as polytetrafluoroethylene (PTFE)." (Exh. 1009, [0051].) The outer layer 33 is also described as being preferably "composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof." (*Id.*, [0052].)

FIG. 2



The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm." (Exh. 1009, [0056].)

The tubular structure 3 is also shorter (10-40 cm) than the predefined length of the continuous lumen of the guide catheter 6 (100 cm). (Exh. 1009, [0057]) ("Although the length of the tubular body 3…is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm.") Annotated Figure 3 of Mihara above shows how the length of the flexible tubular member 3 (solid red line) is shorter than the length of the continuous lumen of the guide catheter 6 (dashed blue line).

the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm). (Exh. 1009, [0081]-[0092].) As shown in annotated Fig. 3 in the claim chart below, Mihara further discloses that the flexible tube ("tubular body 3") is placed coaxially relative to the guide catheter 6.

Mihara also discloses that, when used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen through which the interventional cardiology device of guide wire 7 is insertable. (Exh. 1009, [0033] ("As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end of the wire 2"); *id.*, [0049]) ("The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31").)

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen

Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: (Exh. 1009, [0036] ("As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed"); *id.*, [0037] ("The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2").)

As detailed above, the broadest reasonable construction of this limitation for purposes of these proceedings is "a pushing or advancement structure without a lumen." As such, the rigid push wire of Mihara meets the limitations of this claim element in that it constitutes a structure without a lumen that is substantially rigid relative to the flexible tube to which it is proximal and operably connected.

and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion

Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip. (Exh. 1009, [0048] ("The outer diameter of the wire 2 in the proximal portion is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm"); *id.*, [0055] ("[T]he outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm").)

and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

Mihara discloses that the combined length of the tubular member and the substantially rigid portion of the device is "preferably in the range of 1110-1500 mm" (110-150 cm), which is longer than the length of a standard guide catheter lumen (100 cm). (Exh. 1009, [0092]-[0034]; *see id.* [0073]-[0075].) Annotated

Figure 3 also shows how the combined length of the wire 2 and tubular body 3 is longer than the guide catheter lumen 6 (dashed blue line). (*Id.*, Fig. 3.)

Figure 3 further depicts how Mihara discloses to a POSA that when the tubular member 3 is extended beyond the distal end of the guide catheter 6, the push wire 2 extends proximally outside the guide catheter at the same point as the guidewire 7 (where, in practice, the hemostatic valve is located). (Exh. 1003, ¶ 77.)

1. Claim 2

Regarding dependent claim 2, both the '032 patent and Mihara are directed to a catheters that provide strong backup support or "pushabililty" for deep intubation beyond the ostium, providing a counter-force to the force/resistance created by the advancement of a guidewire into a tight or substantially occluded target vessel. (Exh. 1003, ¶ 94.) These are purely functional characteristics as claim 2 recites no additional structural features from those included in the limitations of claim 1. As noted above, claim scope is not limited by nonstructural language and statements of intended use for a claimed apparatus.

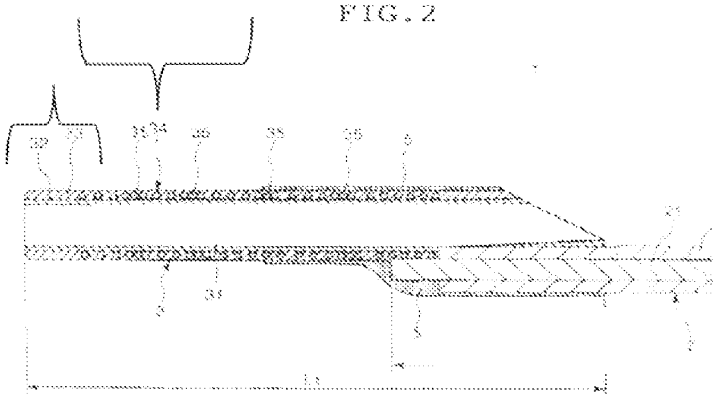
Even if the functional language in dependent claim 2 regarding the intended use of the device is found to limit the scope of claim 2, Mihara expressly discloses the function claimed therein as detailed in the claim charts below. Specifically, Mihara discloses that "the catheter of the present invention has an excellent push-in property. Therefore a push-in force applied from a proximal end side is

transmitted to a distal end portion exactly, and as a result, the catheter can penetrate a stenotic lesion occurred in a lumen in the human body easily and rapidly." (Exh. 1009 [0024].)

2. Claims 3, 4, and 13

Dependent claims 3, 4, and 13 are all directed to a skived proximal side opening to a lumen through which interventional cardiology devices are received. Mihara was neither cited nor considered during the prosecution of the '032 Patent. Figure 2 of Mihara depicts how the proximal opening of the tubular body 3 to the guide wire lumen 31 of the catheter 1 is skived or cut at an angle where the tubular body 3 overlaps with and is connected to the wire push rod 2.

FIG. 2



Specifically:

- "the wire 2 is provided with appropriate rigidity (flexural rigidity and torsional rigidity), which enhances a push-in property and transmittance of a torque." (Exh. 1009, [0043].)

- "The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion). Therefore high coupling strength can be obtained, and the enlargement of the distal end portion of the catheter 1 can be prevented." (Exh. 1009, [0061].)
- "Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5.... [t]he overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process." (Exh. 1009, [0062].)

The proximal opening in the tubular body 3—and in the reinforcing tube 5 surrounding the overlapped portion of the wire 2 and tubular body 3—thereby defines a side opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis such that "[t]he hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049].)

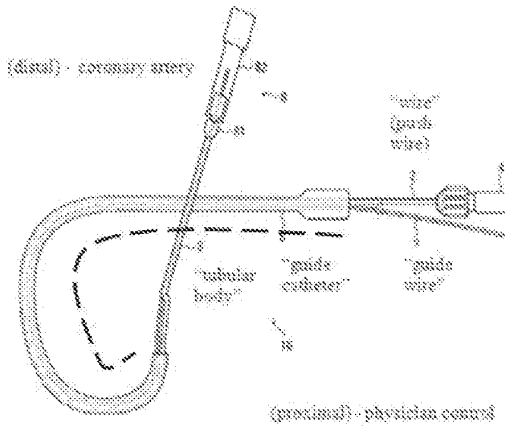
This disclosure satisfies the structural limitations of dependent claim 3 (which depends from claims 1 and 2) requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of dependent claim 4 (depending from claims 1, 2, and 3) that "the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion," and the limitation of claim 13 (depending from claim 11) that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis."

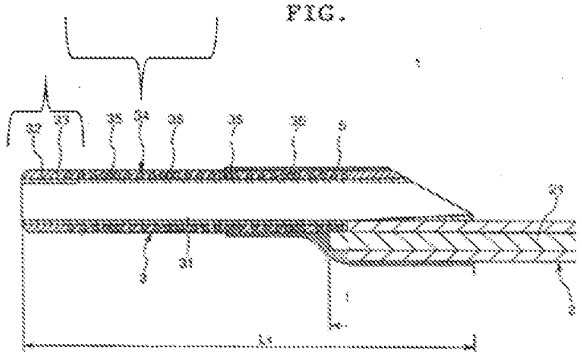
3. Claim 11

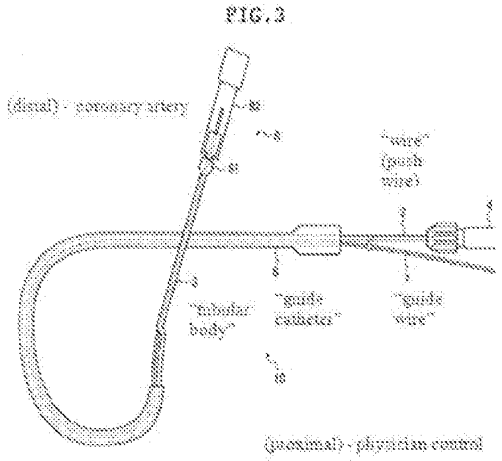
a reinforced portion proximal to the flexible tip portion;

As discussed above, claim 11 of the '032 patent includes the same limitations as claim 1, with the exception of one additional element, a "reinforced portion" proximal to the substantially rigid portion. Accordingly, Petitioner references and includes its analysis of all elements of claim 1 set forth above and in the chart below. Mihara also disclosed the "reinforced portion" of claim 11, as shown in the claim chart below.

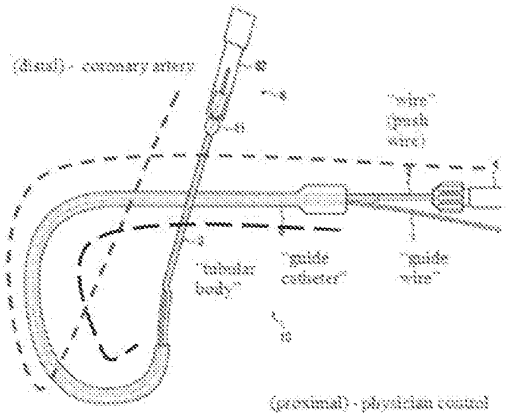
The '032 Patent	**Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)**

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	**[1]** To the extent that the preamble is a limitation, Mihara discloses a device for use with "guiding catheter 6" (*see* dashed blue line in annotated Fig. 3 below) having a continuous lumen extending for a predefined length from a proximal end to a distal end adapted to be placed in a branch artery: FIG. 3  "First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery." (Exh. 1009, [0092].) **[2]** As shown in annotated Fig. 3 above, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. "First the guiding catheter 6 … having an inner diameter of 1.8 mm … was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of

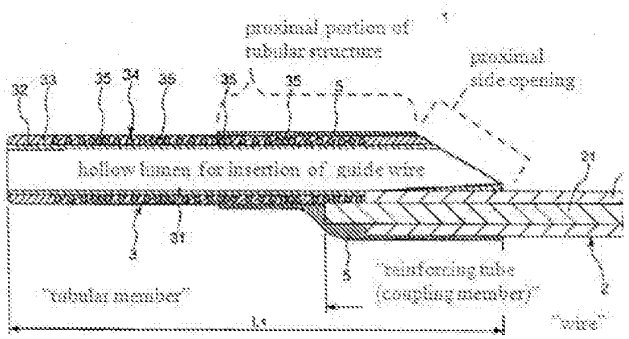
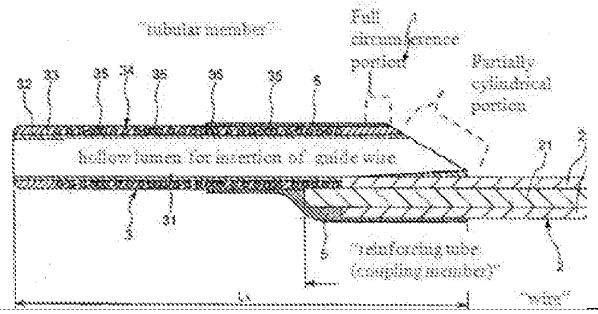
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	the coronary artery. Then, the guide wire 7…was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093].)
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	Annotated Fig. 2 of Mihara (below) discloses a catheter wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being "preferably formed of a flourine resin such as polytetrafluoroethylene (PTFE)." (Exh. 1009, [0051].) The outer layer 33 is further described as being preferably "composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof." (*Id.*, [0052].) FIG.  **[2]** The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm." (Exh. 1009, [0056].)

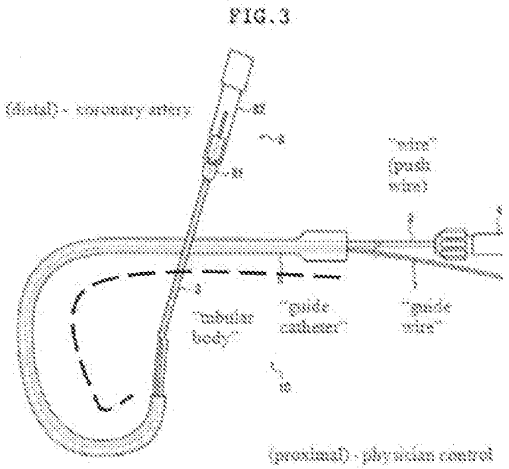
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	[3] "Although the length of the tubular body 3…is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm." (Exh. 1009, [0057].)
the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	**[1]** Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm): "Outer diameter of a portion between 0 and 90 mm from the proximal end side of the tubular body 3: 0.87 mm." (Exh. 1009, [0081].) "First, the guiding catheter 6…having an inner diameter of 1.8 mm…." (Exh. 1009, [0092].) **[2]** As shown in annotated Fig. 3 below, Mihara discloses that the flexible tube ("tubular body 3") is placed coaxially relative to the guide catheter 6: FIG. 3  **[3]** "As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion

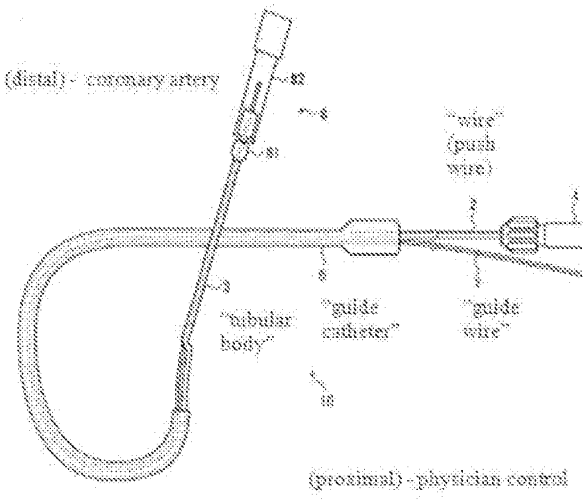
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	(holding portion) 4 placed on a proximal end of the wire 2" (Exh. 1009, [0033].) "The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049].)
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: "As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed." (Exh. 1009, [0036].) "The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2." (Exh. 1009, [0037])
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion	Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip: "The outer diameter of the wire 2 in the proximal portion is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm." (Exh. 1009, [0048].) "[T]he outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm." (Exh. 1009, [0055].)

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	As shown in annotated Fig. 3 below, Mihara discloses that the combined length of the wire 2 and tubular body 3 (dashed red line) is longer than the guide catheter lumen 6 (dashed blue line). (Exh. 1009, Fig. 3.) FIG. 3  *Compare* 1006, [0092]: ("the guiding catheter 6 (Heart Rail 6, produced by Terumo Corp.; having an inner diameter of 1.8 mm and a length of 100 cm)"), *with* [0034] ("The entire length of the catheter 1 is not particularly limited, but preferably in the range of 900 to 1700 mm, and more preferably in the range of 1100 to 11500 mm"); *see* [0073]-[0075] ("Length of the wire 2: 1060 mm[;] Length of L2: 10 mm[;] Length of L1: 250 mm")
2. The device of claim 1	Mihara discloses the device of claim 1 (*see above*)

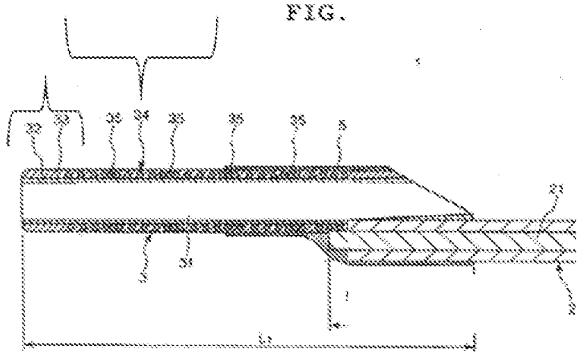
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	"As shown in Table 1, it was confirmed that the catheter of the present invention (Example 1) has a high striking resistance and an excellent push-in property, compared with the catheter with the guide wire lumen formed over the entire length of the catheter (Comparative Example)." (Exh. 1009, [0100].) "An object of the present invention is to provide a catheter excellent in push-in property, capable of easily and rapidly penetrating a stenotic lesion …." (Exh. 1009, [0010].) "As described below, the catheter of the present invention has an excellent push-in property. Therefore, a push-in force applied from a proximal end side is transmitted to a distal end portion exactly, and as a result, the catheter can penetrate a stenotic lesion occurred in a lumen in the human body easily and rapidly." (Exh. 1009, [0024].)
3. The device of claim 2	Mihara discloses the device of claim 2. (*see above*)
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a proximal side opening extending for a distance along the longitudinal axis and accessible from a longitudinal side defined transverse to the longitudinal axis. (Exh. 1009, Fig. 1.)

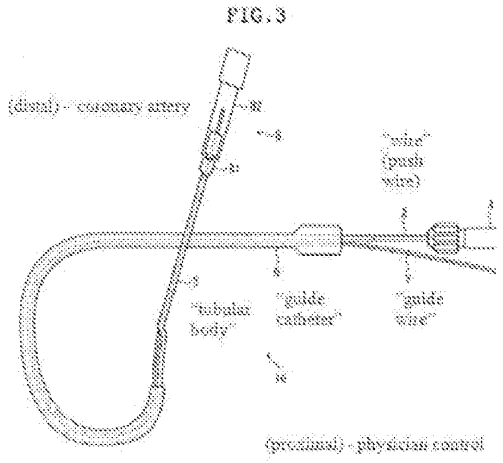
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	FIG. 2 
to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	"The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049].)
4. The device of claim 3	Mihara discloses the device of claim 3. (*see above*)
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion: FIG. 2 
11. A device for use with a standard guide catheter, the	**[1]** To the extent that the preamble is a limitation, Mihara discloses a device for use with "guiding

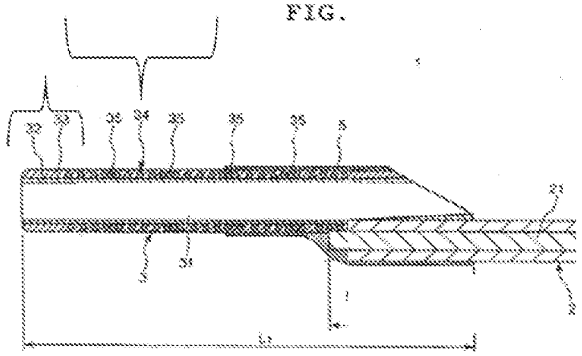
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	catheter 6" (*see* dashed blue line in annotated Fig. 3 below) having a continuous lumen extending for a predefined length from a proximal end to a distal end adapted to be placed in a branch artery:  "First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery." (Exh. 1009, [0092].) **[2]** As shown in annotated Fig. 3 above, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. "First the guiding catheter 6…having an inner diameter of 1.8 mm…was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7…was

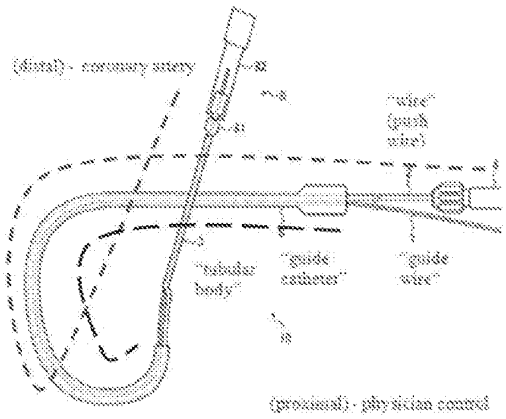
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093].) "First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery." (Exh. 1009, [0092].) **[2]** As shown in annotated Fig. 3 below, the guide catheter 6 used with the Mihara device has a continuous central lumen FIG. 3  **[4]** As shown in annotated Fig. 3 below, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. "First the guiding catheter 6 … having an inner

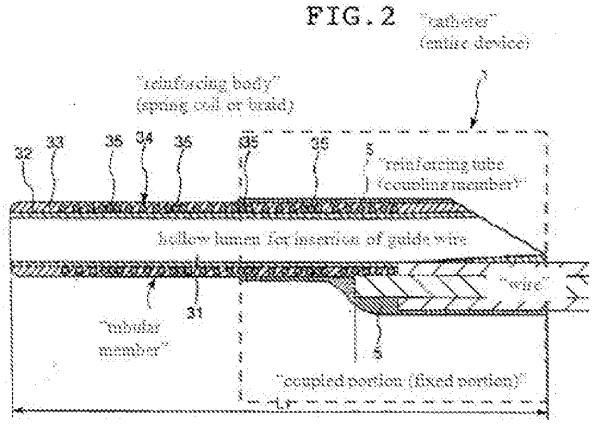
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	diameter of 1.8 mm…was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7…was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093.)
an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,	Mihara discloses that the combined length of the wire 2 and tubular body 3 is longer than the guide catheter lumen. (*See* Fig. 3 below.) As shown in Fig. 3, catheter is longer that the continuous lumen of the guide catheter 6 as the wire 2 extends beyond the proximal end of the catheter and tubular body 3 extends beyond the distal end of the guide catheter 6.
the elongate structure including: a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	Annotated Fig. 2 of Mihara (below) discloses an elongate structure 1 including a flexible tip portion defining a tubular body 3 wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being "preferably formed of a flourine resin such as polytetrafluoroethylene (PTFE)." (Exh. 1009, [0051].) The outer layer 33 is further described as being preferably "composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof." (*Id*., [0052].)

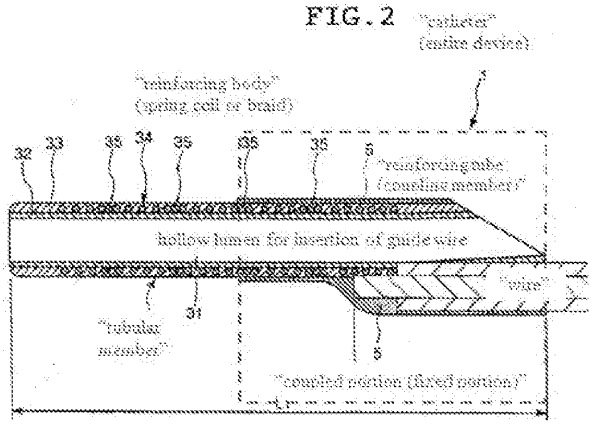
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	FIG.  **[2]** The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm." (Exh. 1009, [0056].) **[3]** "Although the length of the tubular body 3 … is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm." (Exh. 1009, [0057].) Annotated Fig. 3 below shows length of tubular body 3 (solid red line) is shorter than length of guide catheter 6 (dashed blue line):
the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner	**[1]** Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm): "Outer diameter of a portion between 0 and 90 mm from the proximal end side of the tubular body 3: 0.87 mm." (Exh. 1009, [0081].) "First, the guiding catheter 6 … having an inner diameter of 1.8 mm…." (Exh. 1009, [0092].) **[2]** As shown in annotated Fig. 3 below, Mihara

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
diameter through which interventional cardiology devices are insertable;	discloses that the flexible tube ("tubular body 3") is placed coaxially relative to the guide catheter 6:  FIG. 3 (distal) - coronary artery wire (push wire) tubular body guide catheter guide wire (proximal) - physician control **[3]** "As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end of the wire 2" (Exh. 1009, [0033].) "The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049].)
a reinforced portion proximal to the flexible tip portion; and	As shown in annotated Fig. 1 below: "The tubular body 3 has an inner layer 32 positioned on an inner circumferential side, an outer layer 33 formed on an outer circumferential side of the inner layer 32, and a reinforcing body (reinforcing member) 34 placed between the inner layer 32 and the outer layer 33." (Exh. 1009, [0050].)

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	FIG. 
a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: "As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed." (Exh. 1009, [0036].) "The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2." (Exh. 1009, [0037].)
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,	Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip: "The outer diameter of the wire 2 in the proximal portion is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm." (Exh. 1009, [0048].) "[T]he outer diameter of the tubular body 3 in a fixed

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm." (Exh. 1009, [0055].)
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	As shown in annotated Fig. 3 below, Mihara discloses that when at least a distal portion of the tubular body 3 is extended distally of the distal end of the guide catheter 6with at least proximal portion of the rigid push wire 2 remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally in common with a guide wire 7 that is insertable into the guide catheter. (Exh. 1009, Fig. 3.) FIG. 3 
13. The device of claim 11	Mihara discloses the system of claim 11 (*See* cl. 11 above.)
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	"The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion). Therefore high coupling strength can be obtained, and the

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	enlargement of the distal end portion of the catheter 1 can be prevented." (Exh. 1009, [0061].) "Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5. . . . [t]he overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process." (Exh. 1009, [0062]). Annotated Fig. 2 (below) depicts that the proximal side opening (that includes a partially cylindrical portion) to the hollow device lumen 31 of the reinforcing tube 5 surrounding the overlapped portion of the wire 2 and tubular body 3 is skived or cut at an angle,forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis: FIG. 2  "the wire 2 is provided with appropriate rigidity (flexural rigidity and torsional rigidity), which

The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	enhances a push-in property and transmittance of a torque." (Exh. 1009, [0043].)
that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	"The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049].)
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	Annotated Fig. 2 (below) of Mihara discloses a proximal opening extending substantially along at least a portion of a length of the substantially rigid portion. 

B. Claims 1, 2, 3, 4, 11 And 13 Are Obvious Under 35 U.S.C. §103 Over Mihara In View of the Knowledge of a Person of Ordinary Skill in the Art

To the extent that the Board concludes that the order and intended use limitations of claims 1, 2, 3, 4, 11, and 13 are not expressly or inherently disclosed

by Mihara, Petitioner asserts that those characteristics should be deemed obvious based on Mihara alone. All of the structural recitations of the claims are expressly disclosed by Mihara as discussed above, and therefore, Petitioner references the analysis and claim charts for those elements as part of its obviousness analysis here. As recognized in *Intellectual Ventures Mgmt., LLC v. Xilinx*, IPR2012-00020, 9 (Feb. 11, 2014):

> A reference need not teach every feature for it to render a claimed invention obvious....[A]n obviousness determination takes into account what a person of ordinary skill in the art would have known at the time of the invention and is not limited to what is contained within the four corners of a parent or printed publication.

See, e.g., Leapfrog Enters., Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1162 (Fed. Cir. 2007).

C. Claims 1-4, 8, 11, 13 and 17 Are Obvious Under 35 U.S.C. §103(a) Over Mihara In View Of Takahashi

As shown below, each element recited in claims 1-4, 8, 11, 13 and 17 is obvious over Mihara in view of Takahashi. To the extent any of the claim limitations are not explicitly disclosed in Mihara, such limitations could be found by one of ordinary skill in view of one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Mihara and Takahashi. (Exh. 1003 ¶ 95.)

Claims 8 and 17 require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter." Takahashi satisfies the limitations of claims 8 and 17 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter such that the cross-sectional inner diameter of the 5 French catheter is not more than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of minimizing the difference in diameter between the inner guide catheter and the outer guide catheter, and would recognize that this teaching of Takahashi's 5-in-6 system could be applied to any coaxial catheter directed to insertion through a standard guide catheter for purposes of providing backup support during interventional cardiology procedures, such as Mihara, and would have been motivated to do so. (Ex. 1003 ¶ 95.)

In 2004, the same year in which the Mihara publication was filed and published on behalf of assignee Terumo (and within which the Terumo Heartrail is expressly discussed as being used during testing of the Mihara support catheter), the Takahashi article disclosed use of Terumo's Heartrail guide catheter in teaching the advantages of minimizing differences in diameter for purposes of achieving the functionality of both a support catheter (enhanced pushability and

backup support) and a guide catheter (working channel between the site of vascular access and the target vessel).

A POSA reviewing the device disclosed by Mihara at the time of the claimed invention would, therefore, have been motivated by Takahashi to achieve the advantages of having minimal difference in diameter by practicing the invention of Mihara within the claimed range of not more than one French with the predictable and expected results of allowing for the insertion of larger devices through the creation of a larger working channel. (*See* Exh. 1003 ¶¶ 60-62 and 90-95.)

Claim Chart A-2: Cl. 8, 17	
The '032 Patent	**Mihara (Exh. 1009) in view of Takahashi (Exh. 1020)**
8. The device of claim 1	Mihara discloses the device of claim 1 (*See* A-1, above).
wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	"The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A)." (Exh. 1020 at 452.) "The inner lumen of the 5 Fr Heartrail catheter is 0.059' in diameter…. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter…." (*Id.*) "In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter…." (*Id.*) "Only inserting the 5 Fr guiding catheter into the 6Fr catheter increased

Claim Chart A-2: Cl. 8, 17	
The '032 Patent	**Mihara (Exh. 1009) in view of Takahashi (Exh. 1020)**
	backup support…." (*Id.*) "A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter." (*Id.* at 454.)
17. The device of claim 11	Mihara discloses the device of claim 11 (*See above*).
wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	*See* Takahashi disclosures set forth in claim 8 (*See above*).

VIII. CONCLUSION

Based on the foregoing, it is clear that claims 1-4, 11, and 13 of the '032 patent define subject matter that is anticipated by Mihara and that claims 1-4, 8, 11, 13 and 17 of the '032 patent define subject matter that is obvious in view of

Mihara combined with the teachings of Takahashi. Mihara and the prior art combination cited above were never considered by the Examiner; if they had been, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '032 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

ARNOLD & PORTER LLP

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 16, 2014, to the USPTO correspondence address of record listed below:

Patterson, Thuente, Petersen, PA
4800 IDS Center
80 South 8th Street
Minneapolis, MN 55402-2100

Courtesy copies were also shipped to counsel for patent owner at the following address:

J. Thomas Vitt
Heather Redmond
Shannon Bjorklund
Forrest Tahdooahnippah
Dorsey & Whitney
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402
Telephone: (612) 340-2600

/David R. Marsh/

David R. Marsh (Atty. Reg. No. 41,408)
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, D.C. 20004
Tel: (202) 942-5068
Fax: (202) 942-5999

Electronic Acknowledgement Receipt	
EFS ID:	19818264
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	08-AUG-2014
Filing Date:	01-NOV-2013
Time Stamp:	15:48:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of concurrent proceedings / decisions	2005_86USREI3_NotConcurrentProceeds2.pdf	4259377 f43f81a712aa33e8d6e90722cb781b9ad993a784	no	327
Warnings:					
Information:					

Total Files Size (in bytes):	4259377

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Bradley Osinski
Sheet	1	of	1	Attorney Docket Number	2005.86USREI3

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Judgment and Order Granting Termination of Proceedings, Paper 10, Entered August 11, 2014, in Case No. IPR2014-00759; Case No. IPR2014-00760; Case No. IPR2014-00761; Case No. IPR2014-00762; and Case No. IPR2014-00763.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00759.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00760.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00761.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00762.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00763.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00759.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00760.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00761.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00762.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00763.	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt	
EFS ID:	19845160
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	12-AUG-2014
Filing Date:	01-NOV-2013
Time Stamp:	16:15:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Supplemental_IDS.pdf	478066 01ca566e70824e5d2a953ddff04f916a9abc7aaa	yes	4

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	3	
	Information Disclosure Statement (IDS) Form (SB08)		4	4	
Warnings:					
Information:					
2	Non Patent Literature	NPL1_JudgmentGrantingTerminationFinalDec_Paper10.pdf	79546 684c8663c8c5994a57c1ee674afebf2cf8b36469	no	4
Warnings:					
Information:					
3	Non Patent Literature	NPL2_IPR2014_00759_JointMotionToTerminate.pdf	148395 70e4138d433b08a4c8a9a9830f55713f7896dd40	no	5
Warnings:					
Information:					
4	Non Patent Literature	NPL3_IPR2014_00760_JointMotionToTerminate.pdf	148386 d4a3139eee30e7b8998820b2e5a6e2d3e5efa23c	no	5
Warnings:					
Information:					
5	Non Patent Literature	NPL4_IPR2014_00761_JointMotionToTerminate3.pdf	148396 6ce072867d437ab4389331d4f47104152b4e744e	no	5
Warnings:					
Information:					
6	Non Patent Literature	NPL5_IPR2014_00762_JointMotionToTerminate4.pdf	148788 79460a4007835f32ec8632ae925796a3fcd25d21	no	5
Warnings:					
Information:					
7	Non Patent Literature	NPL6_IPR2014_00763_JointMotionToTerminate.pdf	148775 95c1b5eb2024f47b744304786e963634469cefae	no	5
Warnings:					
Information:					
8	Non Patent Literature	NPL7_IPR2014_00759_JointReqForConfidentiality.pdf	97846 9b6ca7f6a9b9c8e08a8ef968dd99675319bd0eb5	no	3
Warnings:					
Information:					

9	Non Patent Literature	NPL8_IPR2014_0760_JointReqForConfidentiality.pdf	97850 87747be9d8003d583e1fbf0da04711aa5325d767	no	3
Warnings:					
Information:					
10	Non Patent Literature	NPL9_IPR2014_00761_JointReqForConfidentiality.pdf	97849 0d1e7cc8691dbc531d7830e97861df2ac1c088d2	no	3
Warnings:					
Information:					
11	Non Patent Literature	NPL10_IPR2014_00762_JointReqForConfidentiality.pdf	97849 cd44df1322915469e4f96240711ac9740968e7d6	no	3
Warnings:					
Information:					
12	Non Patent Literature	NPL11_IPR2014_00763_JointReqForConfidentiality.pdf	97849 6007cdcb5a798128099cc771c0e6fecc2363237a	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	1789595		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root Et Al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: Bradley Osinski
Filed: November 1, 2013	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 CFR § 1.56, and in addition to information disclosed in any previously filed prior Information Disclosure Statements, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of the above-referenced application, and be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information may not be prior art, and/or prove that this information may not be enabling for any aspect of the information provided herewith.

This Information Disclosure Statement is being filed without a certification or fee because this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR § 1.97(b)(3).

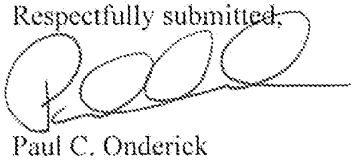
It will be noted that the Examiner may request access to the confidential Settlement Agreement pursuant to the requirements of 35 USC 317(b) ("shall be made available only to Federal Government agencies upon written request") and 37 CFR 42.74(c)(1) ("the settlement shall only be available: (1) To a Government agency on written request to the Board").

The Examiner's attention is directed to the applications or patents, if any, to which priority is claimed, as well as to any continuing applications which claim priority to the above-referenced application, and to applications, if any, that may be related by virtue of similar claimed subject matter as the above-referenced application (collectively, the "Related Case(s)"). The Examiner's attention is also directed to related Reissue applications identified in the Related U.S. Applications section of this reissue application as amended by Preliminary Amendment(s) during the prosecution hereof.

The Examiner is requested to consider the information which has been considered by the Office in the parent applications as well as information in and related to the related reissue applications pursuant to the requirements of MPEP 609.02 and MPEP 1406. Examiner Reip of the Central Reexamination Unit in one of the related reissue applications confirmed that information in the parent applications as well as the related reissue applications will be considered pursuant to the requirements of MPEP 609.02 and MPEP 1406 in a telephone call with the undersigned on August 12, 2014. Because the file histories of the related applications are all available to the Examiner electronically copies thereof are not submitted with this IDS.

The prosecution history for any and all of these Related Case(s) may include information material to patentability of the above-referenced application including Office Actions, Responses, Office Communications or Notices of Allowance, all of which are readily accessible to the Examiner via PAIR/PALM. To promote consistency and full disclosure during the prosecution of the above-referenced application together with the prosecution of any of the Related Case(s) and to assist the Examiner in complying with the obligations of MPEP 2001.06(b), the Examiner is respectfully requested to review the prosecution history of each of the Related Case(s). **This request for review should be considered ongoing throughout the prosecution of the above-referenced application with an updated review via PAIR/PALM of the prosecution histories of any Related Case(s) being made prior to issuance of any Notice of Allowance for the above-referenced application.** The identification of any of the Related Case(s) for purposes of this Information Disclosure Statement should not be construed as a waiver of secrecy, if applicable, as to such applications now or upon issuance of the above-referenced application as a patent. For purposes of the Related Case(s), it should be noted that all of the Related Case(s) are published or otherwise publicly available on PAIR.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5766

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

24113 7590 12/01/2014
PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/01/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/070,161	11/01/2013	Howard Root	2005.86USREI3	8790

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	03/02/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7590 12/01/2014
PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/070,161	11/01/2013	Howard Root	2005.86USREI3	8790

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	03/02/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
OSINSKI, BRADLEY JAMES	3763	604-527000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/070,161	11/01/2013	Howard Root	2005.86USREI3	8790

24113 7590 12/01/2014

PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/01/2014

Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/070,161	Applicant(s) ROOT ET AL.	
	Examiner BRADLEY OSINSKI	Art Unit 3763	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *preliminary amendment 6/11/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-4,6-33 and 45-53*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   Certified copies:
   a) ☐ All b) ☐ Some *c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date See Continuation Sheet
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Aarti Bhatia Berdichevsky/ Primary Examiner, Art Unit 3763	/BRADLEY OSINSKI/ Examiner, Art Unit 3763

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 1/21/2014, 6/12/2014,7/23/2014,8/12/2014.

The present application is being examined under the pre-AIA first to invent provisions.

Terminal Disclaimer

The terminal disclaimer filed on 3/25/2014 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 8,043,032, 8,142,413 and 8,292,850 and Reissue Applications 14/195,413, 14/195,435 and 14/195,385 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul Onderick on 7/3/2014.

The application has been amended as follows:

Claims 34-44 and 54 have been cancelled.

Claim 1

On line 16, after "defining a", "rail_structure" has been deleted and --rail structure-- has been inserted.

The following paragraph has been added to the end of claim 1:

--; wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.--

Such that claim 1 reads:

A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-

sectional inner diameter through which interventional cardiology devices are insertable; and

a substantially rigid portion proximal of and operably connected to, and more

rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.

Claim 5

Claim 5 has been cancelled

Claim 6

Claim 6 is amended to depend from claim 1. Such that it now reads:

The system of claim [[5]] 1, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

Claim 12

The “and” on line 16 of page 17 of the claim set has been deleted.

The following paragraph has been added to the end of claim 12:

--; and wherein the flexible tip portion is more flexible than the reinforced portion--

Such that claim 12 now reads:

A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

a flexible tip portion defining a tubular structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;

a reinforced portion proximal to the flexible tip portion; [[and]]

a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter; and

wherein the flexible tip portion is more flexible than the reinforced portion.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhisma Mehta can be reached on (571)272-3383. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRADLEY OSINSKI/
Examiner, Art Unit 3763

/Aarti Bhatia Berdichevsky/
Primary Examiner, Art Unit 3763

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Bradley Osinski
Sheet	1	of	1	Attorney Docket Number	2005.86USREI3

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Judgment and Order Granting Termination of Proceedings, Paper 10, Entered August 11, 2014, in Case No. IPR2014-00759; Case No. IPR2014-00760; Case No. IPR2014-00761; Case No. IPR2014-00762; and Case No. IPR2014-00763.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00759.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00760.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00761.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00762.	
		Joint Motion to Terminate Filed August 8, 2014, in Case No. IPR2014-00763.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00759.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00760.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00761.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00762.	
		Joint Request to File Settlement Agreement as Business Confidential Information, Filed August 8, 2014, in Case No. IPR2014-00763.	

EXAMINER SIGNATURE	/Bradley Osinski/ (10/27/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	7	Attorney Docket Number	2005.86USREI3

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-8,292,850 B2	10-23-2012	Root et al.
		US-8,142,413 B2	03-27-2012	Root et al.
		US-8,048,032 B2	11-01-2011	Root et al.
		US-7,762,984 B2	07-27-2010	Kumoyama et al.
		US-7,717,899 B2	05-18-2010	Bowe et al.
		US-7,697,996 B2	04-13-2010	Manning et al.
		US-7,544,201 B2	06-09-2009	Pepper
		US-7,294,124 B2	11-13-2007	Eidenschink
		US-6,860,876	03-01-2005	Chen
		US-6,755,812	06-29-2004	Peterson et al.
		US-6,706,018	03-16-2004	Westlund et al.
		US-6,689,144	02-10-2004	Gerberding
		US-6,638,268 B2	10-28-2003	Niazi
		US-6,635,029 B1	10-21-2003	Venturelli
		US-6,610,068	08-26-2003	Yang

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
		EP 0365993	05-02-1990	Terumo Kabushiki Kaisha	
		EP 0313558 (Published as US 5,002,531, also cited)	01-14-1988	BONZEL, Tassilo	
		EP 0380873	08-08-1990	C.R. Bard, Inc.	
		WO84/03633	09-27-1984	FOGARTY, Thomas J.	

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	2	of	7	Attorney Docket Number	2005.86USREI3

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,595,952	07-22-2003	Forsberg
		US-6,591,472 B1	07-15-2003	Noone et al.
		US-6,575,958 B1	06-10-2003	Happ et al.
		US-6,548,010 B1	04-15-2003	Stivland et al.
		US-6,503,353 B1	01-07-2003	Peterson et al.
		US-6,503,223 B1	01-07-2003	Sekido et al.
		US-6,488,655 B1	12-03-2002	Wantink et al.
		US-6,475,195	11-05-2002	Voda
		US-6,409,863 B1	06-25-2002	Williams et al.
		US-6,338,725	01-15-2002	Hermann et al.
		US-6,193,686 B1	02-27-2001	Estrada et al.
		US-6,159,195	12-12-3000	Ha et al.
		US-5,980,486	11-09-1999	Enger
		US-5,911,715	06-15-1999	Berg et al.
		US-5,792,124	08-11-1998	Horrigan et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	3	of	7	Attorney Docket Number	2005.86USREI3

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-5,776,141	07-07-1998	Klein et al.
		US-5,690,613	11-25-1997	Verbeek
		US-5,658,263	08-19-1997	Dang et al.
		US-5,599,326	02-04-1997	Carter
		US-5,549,553	08-27-1996	Ressemann et al.
		US-5,527,292	06-18-1996	Adams et al.
		US-5,472,425	12-05-1995	Teirstein
		US-5,445,624	08-29-1995	Jimenez
		US-5,441,489	08-15-1995	Utsumi et al.
		US-5,368,567	11-29-1994	Lee
		US-5,328,472	07-12-1994	Steinke et al.
		US-5,257,974	11-02-1993	Cox
		US-5,234,416	08-10-1993	Macaulay et al.
		US-5,232,445	08-03-1993	Bonzel
		US-5,122,125	06-16-1992	Deuss

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	4	of	7	Attorney Docket Number	2005.86USREI3

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-5,102,403	04-07-1992	Alt
		US-5,098,412	03-24-1992	Shiu
		US-5,002,531	03-26-1991	Bonzel
		US-4,994,745	02-19-1991	Mizuta
		US-4,946,440	08-07-1990	Hall
		US-4,932,413	06-12-1990	Shockey et al.
		US-4,909,252	03-20-1990	Goldberger
		US-4,832,028	05-23-1989	Patel
		US-4,813,930	03-21-1989	Elliott
		US4,762,129	08-09-1988	Bonzel
		US-4,723,936	02-09-1988	Buchbinder et al.
		US-4,289,128	09-15-1981	Rüsh
		US-2007/0260219	11-08-2007	Root et al.
		US-2005/0182437	08-18-2005	Bonnette et al.
		US-2005/0004523 A1	01-06-2005	Osborne et al.

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	5	of	7	Attorney Docket Number	2005.86USRE13

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-2004/0127927	07-01-2004	Adams
		US-2003/0195546	10-16-2003	Solar et al.
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	6	of	7	Attorney Docket Number	2005.86USREI3

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Saeko TAKAHASHI, et al., "New Method to Increase a Backup Support Of A 6 French Guiding Coronary Catheter", *Catheterization and Cardiovascular Interventions*, 63:452-456 (2004), 5 Pages; Published online in *Wiley InterScience* (www.interscience.wiley.com),	
		Complaint, Jury Trial Demanded, Dated May 15, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 18 Pgs.	
		Amended Complaint, Jury Trial Demanded, Dated May 28, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 20 Pgs.	
		Plaintiff's Memorandum in Support of Motion for Preliminary Injunction, dated June 10, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 40 Pgs.	
		Declaration of Howard Root in Support of Plaintiff's Motion for Preliminary Injunction, Dated June 10, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 55 Pgs.	
		Declaration of Anthony C. Vrba, Dated July 8, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 4 Pgs.	
		Declaration of Tony J. Demartini, M.D., Dated July 8, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 3 Pgs.	
		Placeholder for Declaration of Sam Rasmusen, Dated July 8, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 1 Pg.	
		Boston Scientific Corporation's Answer to Amended Complaint and Counterclaims, Dated July 11, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 22 Pgs.	

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	7	of	7	Attorney Docket Number	2005.86USREI3

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Plaintiff's Reply Memorandum in Suport of Motion for Preliminary Injunction ***REDACTED***, Filed July 24, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 27 Pgs.	
		Second Declaration of Howard Root in Support of Plaintiff's Motion for Preliminary Injunction, Dated July 24, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 22 Pgs.	

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	2005.86USREI3

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-7,232,452 B2	06-19-2007	Adams et al.
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		
		US-		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (07/07/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	63	("20070260219" | "4289128" | "4723936" | "5002531" | "5368567" | "5658263" | "5980486" | "6193686" | "7294124" | "8048032" | "5122125" | "6591472" | "6610068" | "7232452" | "20050182437" | "4762129" | "5102403" | "5234416" | "5441489" | "5527292" | "5776141" | "6689144" | "7762984" | "4994745" | "5257974" | "5690613" | "6503223" | "4813930" | "4946440" | "6159195" | "6488655" | "6638268" | "6706018" | "7697996" | "8142413" | "8292850" | "20030195546" | "4932413" | "5328472" | "5445624" | "5472425" | "6595952" | "6635029" | "20050004523" | "4909252" | "5098412" | "5232445" | "5792124" | "5911715" | "6409863" | "6475195" | "6503353" | "6548010" | "6860876" | "20040127927" | "4832028" | "5549553" | "5599326" | "6338725" | "6575958" | "6755812" | "7544201" | "7717899" | "7232452").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/07/07 09:20
L2	274	(604/103.04).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L3	214	(604/103.09).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L4	429	(604/160-162).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L5	1234	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L6	125	(604/164.02).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L7	573	(604/164.09-164.11).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L8	455	(604/525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:25
L10	1	("7232452").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/07/07 09:41
L11	129	("20010031982" | "20010039411" | "20010044598" | "20010047184" | "20010049517" | "20020016564" | "20020016565" | "20020022859" |	US-PGPUB; USPAT; USOCR	OR	ON	2014/07/07 09:41

		"20020026145" | "20020029031" | "20020052638" | "20020095141" | "20020121472" | "20020123765" | "20020143360" | "20020151927" | "20020165574" | "20020165598" | "20030093106" | "20030093110" | "20030125751" | "20030212429" | "20040049226" | "20040082968" | "20040220609" | "20040260277" | "20050004553" | "20050085842" | "20050131447" | "20050149113" | "20060004405" | "3000380" | "3220411" | "3262449" | "3344791" | "3583391" | "3659610" | "3703174" | "3777743" | "3877429" | "4000743" | "4023559" | "4198981" | "4306562" | "4552554" | "4696667" | "4771777" | "4781682" | "4794928" | "4824435" | "4886500" | "4921478" | "4932413" | "4946440" | "5059183" | "5102415" | "5120323" | "5147377" | "5158535" | "5219335" | "5257974" | "5290247" | "5314408" | "5338300" | "5364376" | "5385562" | "5439445" | "5527292" | "5662671" | "5738667" | "5824044" | "5833644" | "5833650" | "5843027" | "6022319" | "6022336" | "6066100" | "6139573" | "6142987" | "6206868" | "6245089" | "6254610" | "6295989" | "6312444" | "6315778" | "6325815" | "6346116" | "6363900" | "6371970" | "6371971" | "6375787" | "6383205" | "6398773" | "6413235" | "6537294" | "6569180" | "6605102" | "6632236" | "6652505" | "6663651" | "6818006" | "6866677" | "6887257").PN. OR ("7232452").URPN.				
S1	171	(604/510).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2008/11/06 16:26
S2	28	("20050182437" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "6159195" | "6475195" | "6595952" | "6610068" | "6689144" | "6860678").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/06 16:27
S3	70	("3430631" | "3902492" | "4117836" | "4195637" | "4299226" | "4323071" | "4423725" | "4445892" | "4453545" | "4581017" | "4601706" | "4610662" | "4655746" | "4689041").PN. OR ("4832028").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 16:30
S4	51	("3811448" | "4195637" | "4323071" | "4493711" | "4573470" | "4619263" | "4641649" | "4643186" | "4748982" | "4762129" | "4790315" | "4798193" | "4824435" | "5003990" | "5040548" | "5045061" | "5061273" | "5090957" | "5090958" | "5324257" | "5324259" | "5395332" | "5413557" | "5415634" | "5505702" | "5540659" | "5569199" | "5571087" | "5575771" | "5578009" | "5605543" | "5667493" | "5667521" |	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:04

		"5690642" | "5706827" | "5718680" | "5728067" | "5730698" | "5752932" | "5863285" | "5879305" | "5882334" | "6071285" | "6394995" | "6447501" | "6500147" | "RE31800").PN. OR ("6740104").URPN.				
S5	13	("5053007" | "5129887" | "5224939" | "5389090" | "5401258" | "5445625").PN. OR ("5492530").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:10
S6	285	604/103.04	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S7	213	604/103.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S8	540	604/160	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S9	594	604/161	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S10	605	604/162	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S11	1217	604/164.01	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S12	235	604/164.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S13	196	604/164.1	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S14	311	604/164.11	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S15	484	604/525	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:23
S16	12	("4100393" | "4377165" | "4401433" | "4449973" | "4702735" | "4762516" | "4790817" | "4950252" | "4957488" | "4957489" | "D247975").PN. OR ("5971957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 08:54
S17	32	("4166469" | "4243050" | "4345606").PN. OR ("5667514").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 09:15
S18	36	("3352306" | "3565074" | "4230123" | "4581019" | "4629450" | "4772264" | "4911691" | "4978334" | "4994027" | "4995866").PN. OR ("5242410").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 10:45
S19	33	("4323071" | "4456011" | "4995872" | "5053007" | "5053008" | "5108419" | "5147317" | "5151105" | "5190529" | "5242399" | "5330446" | "5531715" | "5549551" | "5702410" | "5702417" | "5769816" | "5814064" | "5843027" | "5846260" | "5849248" | "5891159" |	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 12:58

		"5897567" | "5916193" | "5980503" | "6048331" | "6068621" | "6090097" | "6093173" | "6129713" | "6231544" | "6251119" | "6290710" | "6391044").PN. OR ("6689152").URPN.				
S20	31	("20020103474" | "4790831" | "4886506" | "5290229" | "5336182" | "5505698" | "5584803" | "5643231" | "5690611" | "5782741" | "5785706" | "5807249" | "5824031" | "5846229" | "5879295" | "5916214" | "6001085" | "6002955" | "6006137" | "6022341" | "6080151" | "6090084" | "6093173" | "6122552" | "6179809" | "6228052" | "6273881").PN. OR ("6638268").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 13:04
S21	13	("2541402" | "4909248" | "5067496" | "5222487" | "5279610" | "5323771" | "5546937" | "5791338" | "5919183" | "5937860").PN. OR ("6481436").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 16:11
S22	9	("5667514" | "5868754" | "5947995" | "6001118").PN. OR ("6254610").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/10 13:46
S23	2	"relief cuts" SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S24	2	"relief cut" SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S25	1370	cut SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S26	345	cut with rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S27	95	"relief cuts" SAME rigid$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:51
S28	49	(US-20080058759-$ or US-20070093783-$ or US-20030233068-$ or US-20030195546-$ or US-20020133118-$ or US-20070112302-$	US-PGPUB; USPAT	OR	ON	2008/12/02 17:34

		or US-20060135973-$ or US-20060129101-$ or US-20050004523-$ or US-20040138562-$ or US-20060135962-$ or US-20080172036-$ or US-20010034514-$ or US-20050159767-$ or US-20040225308-$).did. or (US-5484412-$ or US-5059178-$ or US-4581017-$ or US-7141050-$ or US-6746464-$ or US-6740104-$ or US-6447501-$ or US-4994027-$ or US-6780199-$ or US-6692482-$ or US-6976991-$ or US-7306618-$ or US-5971957-$ or US-5667514-$ or US-6254610-$ or US-5242410-$ or US-5169387-$ or US-5688253-$ or US-5158543-$ or US-6692462-$ or US-6689152-$ or US-6093173-$ or US-6641564-$ or US-6638268-$ or US-6338725-$ or US-7056294-$).did. or (US-6702782-$ or US-6645194-$ or US-7169105-$ or US-6481436-$ or US-6179809-$ or US-6165163-$ or US-6099518-$ or US-6053903-$).did.				
S29	7	S28 and (metal with (coil braid))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/02 17:34
S30	2	"5601586".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/06/05 12:33
S31	3	("2003/0195546").URPN.	USPAT	OR	ON	2009/11/09 16:32
S32	208	("20010001890" | "20010049548" | "20020019664" | "20020019665" | "20020022874" | "20020038140" | "20020038141" | "20020052640" | "20020072755" | "20020111675" | "20020116045" | "20020120320" | "20020138966" | "20020165598" | "20030023298" | "20030055483" | "20030055484" | "20030130716" | "20030144671" | "20030181923" | "20030192164" | "20030195546" | "20040172119" | "20040199239" | "20040260379" | "20050149161" | "20050154442" | "20050273149" | "3792603" | "4448195" | "4461163" | "4484585" | "4578982" | "4601701" | "4769005" | "4776337" | "4913141" | "4994071" | "4998923" | "5019085" | "5092152" | "5120308" | "5122154" | "5195984" | "5219355" | "5261263" | "5316023" | "5380299" | "5397305" | "5449343" | "5449353" | "5449382" | "5477856" | "5556413" | "5571086" |	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/09 16:33

		"5609627" | "5632763" | "5643278" | "5644945" | "5670161" | "5672169" | "5681345" | "5683345" | "5697971" | "5725519" | "5744515" | "5749825" | "5755734" | "5755735" | "5755778" | "5772669" | "5776141" | "5776142" | "5788707" | "5797952" | "5817100" | "5824055" | "5833694" | "5836952" | "5843027" | "5873906" | "5876374" | "5893868" | "5906640" | "5906759" | "5908405" | "5921995" | "5935161" | "5941908" | "5944727" | "5951569" | "5957929" | "5957941" | "5961546" | "5961548" | "5968052" | "6013092" | "6015424" | "6017362" | "6027460" | "6033434" | "6048350" | "6048361" | "6056722" | "6056775" | "6059813" | "6066155" | "6071286" | "6077297" | "6082990" | "6090127" | "6096045" | "6096073" | "6099497" | "6110191").PN. OR ("6117156" | "6120522" | "6132450" | "6143014" | "6146415" | "6152944" | "6165195" | "6165210" | "6176116" | "6178802" | "6187015" | "6190360" | "6190393" | "6210380" | "6210431" | "6214036" | "6221090" | "6221097" | "6224587" | "6238410" | "6246914" | "6254593" | "6258052" | "6258073" | "6264688" | "6280466" | "6287277" | "6287330" | "6290673" | "6299636" | "6302906" | "6319275" | "6322548" | "6331186" | "6342066" | "6350277" | "6350278" | "6360577" | "6361544" | "6361555" | "6364893" | "6371978" | "6375660" | "6379372" | "6387117" | "6387120" | "6391050" | "6406487" | "6406489" | "6416529" | "6436104" | "6443880" | "6443980" | "6471672" | "6475166" | "6478814" | "6482211" | "6488694" | "6508835" | "6510722" | "6514261" | "6514281" | "6517558" | "6520983" | "6520988" | "6530947" | "6533805" | "6540719" | "6544278" | "6554841" | "6568235" | "6569180" | "6582459" | "6589262" | "6596020" | "6599315" | "6602226" | "6607506" | "6607552" | "6613067" | "6623518" | "6629350" | "6629981" | "6651478" | "6660030" | "6669718" | "6692483" | "6695862" | "6699275" | "6739033" | "6925847").PN. OR ("7225518" | "7314480" | "7367989").URPN.				
S33	160	("20010037137" | "20010049548" | "20010056297" | "2845959" | "2978787" | "2990605" | "3029819" | "3096560" | "3142067" | "3657744" | "3908662" | "3945052" | "4041931" | "4047252" | "4061134" | "4108161" | "4140126" | "4193137" | "4202349" | "4214587" | "4517687" | "4560374" | "4562596" | "4577631" | "4617932" | "4652263" | "4693249" | "4728328" | "4732152" | "4739762" | "4774949" | "4787899" | "4793348" | "4795458" | "4795465" |	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/09 16:36

		"4817624" | "4830003" | "4872874" | "4878906" | "4892539" | "4969890" | "4969896" | "4994071" | "5026377" | "5047050" | "5104399" | "5108424" | "5127919" | "5156619" | "5178630" | "5178634" | "5197976" | "5197977" | "5304220" | "5316023" | "5360443" | "5413560" | "5443497" | "5443498" | "5456712" | "5522880" | "5527355" | "5562724" | "5571170" | "5571171" | "5571173" | "5575817" | "5578072" | "5591228" | "5591229" | "5603721" | "5609627" | "5613980" | "5617878" | "5632763" | "5639278" | "5643340" | "5669924" | "5676696" | "5676697" | "5683450" | "5683452" | "5683453" | "5693084" | "5693086" | "5693087" | "5693088" | "5695517" | "5709713" | "5713363" | "5713917" | "5718724" | "5720735" | "5749825" | "5755734" | "5755735" | "5755771" | "5776180" | "5782906" | "5800508" | "5800520" | "5827320" | "5893887" | "5895407" | "5916234" | "5916263" | "5919225" | "5921995" | "5938696" | "5947977" | "5954693" | "5972017" | "5976155" | "6030413" | "6030414" | "6030415" | "6033434" | "6033435" | "6039754" | "6048361" | "6051020" | "6096073" | "6106548" | "6123682").PN. OR ("6129754" | "6159237" | "6165195" | "6183509" | "6210429" | "6214041" | "6221080" | "6221098" | "6231597" | "6238430" | "6254593" | "6258116" | "6261305" | "6264682" | "6346089" | "6361555" | "6371978" | "6383213" | "6387120" | "6428567" | "6436104" | "D376011").PN. OR ("6599315").URPN.				
S34	81	("4573966" | "4655746" | "4748982" | "4762129" | "4911163" | "4947864" | "4988356" | "5040548" | "5061273" | "5135535" | "5180367" | "5195978" | "5232445" | "5263963" | "5281203" | "5300085" | "5328472" | "5334147" | "5336184" | "5346505" | "5350395" | "5364376" | "5380283" | "5383853" | "5395335" | "5413559" | "5451233" | "5458613" | "5460185" | "5462529" | "5468225" | "5472425" | "5501227" | "5531690" | "5533968" | "5545134" | "5554118" | "5571094" | "5607406" | "5620417" | "5626600" | "5685312" | "5709658" | "5728067" | "5738667" | "5749888" | "5755685" | "5769868" | "5776141" | "5800391" | "5807355" | "5810869" | "5814061" | "5827241" | "5830227" | "5833659" | "5846246" | "5891056" | "5919164" | "5919175" | "5921971" | "5944691" | "5947927" | "5980486" | "6007517" | "6048484" | "6056722" | "6168579" | "6196995" | "6200305" | "6299595").PN. OR ("6569180").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/09 16:45
S35	734	(604/164.01).CCLS.	US-PGPUB;	OR	OFF	2009/11/10

			USPAT; USOCR			10:13
S36	1	("20040127927").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/17 15:05
S37	1	("5411514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/17 15:06
S38	40	("20020103474" | "4790831" | "4886506" | "5290229" | "5336182" | "5505698" | "5584803" | "5643231" | "5690611" | "5782741" | "5785706" | "5807249" | "5824031" | "5846229" | "5879295" | "5916214" | "6001085" | "6002955" | "6006137" | "6022341" | "6080151" | "6090084" | "6093173" | "6122552" | "6179809" | "6228052" | "6273881").PN. OR ("6638268").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/05/20 12:04
S39	947	"604"/$.ccls. and (pushrod "push rod")	US-PGPUB; USPAT; USOCR	OR	ON	2010/05/20 15:24
S40	19	("20010014813" | "20010037117" | "2721387" | "4142526" | "4687480" | "4773858" | "5342348" | "5443458" | "5512291" | "5766710" | "5769883" | "5968047" | "6013853" | "6228111" | "6248112" | "6263880" | "6363938" | "6652582").PN. OR ("6962574").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2010/05/20 17:45
S41	17	("20030195546" | "20070260219" | "5776141" | "6638268" | "6706018" | "6755812" | "7697996" | "7717899").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/07/28 19:31
S42	49	("20030195546" | "20030195546" | "20040127927" | "20050182437" | "20070260219" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "5776141" | "6159195" | "6338725" | "6475195" | "6595952" | "6610068" | "6638268" | "6638268" | "6689144" | "6706018" | "6755812" | "6860678" | "7697996" | "7717899").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/13 18:00
S43	742	(604/524-525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/12/14 09:21
S44	4	("20060247661" | "5534007").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 09:46
S45	24366	push$4 with (rectang$4 semi$4 square)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2010/12/14 11:51

			DERWENT; IBM_TDB			
S46	6514	S45 and (catheter tube medica$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:51
S49	5948	S45 and (catheter tube)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:52
S50	2092	S45 same (catheter tube)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:52
S51	156	S50 and catheter	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 12:40
S52	13	("5667514" | "5868754" | "5947995" | "6001118").PN. OR ("6254610").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2011/07/26 15:45
S53	910	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S54	94	(604/164.02).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S55	112	(604/164.1).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S56	337	(604/525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S57	238	(howard and root).in. (gregg and sutton).in. (jeffrey and welch).in. (jason and garrity).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/07/27 15:35
S58	49	("20030195546" | "20030195546" | "20040127927" | "20050182437" | "20070260219" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "5776141" | "6159195" | "6338725" | "6475195" | "6595952" | "6610068" | "6638268" | "6638268" | "6689144" | "6706018" |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/07/27 15:36

		"6755812" | "6860678" | "7697996" | "7717899").PN.				
S61	2	(("6638268") or ("20050004523")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/08/26 10:02
S62	119	(604/164.1).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/12/27 13:25
S63	246	(604/510).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/12/27 13:25
S64	353	(604/525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/12/27 13:25
S65	945	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/12/27 13:26
S66	481	(604/164.09-164.11).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/12/27 13:26
S67	53	("5658263" | "6706018" | "5122125" | "6610068" | "20070260219" | "20050182437" | "6689144" | "5776141" | "20030195546" | "4813930" | "6159195" | "6638268" | "6755812" | "7697996" | "4932413" | "5472425" | "6595952" | "20030195546" | "5098412" | "6475195" | "6638268" | "4832028" | "6860678" | "20040127927" | "6338725" | "7717899" | "20050004523").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/27 13:26
S68	61	("20020103474" | "4790831" | "4886506" | "5290229" | "5336182" | "5505698" | "5584803" | "5643231" | "5690611" | "5782741" | "5785706" | "5807249" | "5824031" | "5846229" | "5879295" | "5916214" | "6001085" | "6002955" | "6006137" | "6022341" | "6080151" | "6090084" | "6093173" | "6122552" | "6179809" | "6228052" | "6273881").PN. OR ("6638268").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2011/12/27 13:28
S69	345	("20010011174" | "20010023349" | "20020013600" | "20020026195" | "20020068974" | "20020077595" | "20020082605" | "20020115742" | "20020156483" | "20020188299" | "20030032929" | "20030043963" | "20030050644" | "20030073979" | "20030130664" | "20030191489" | "20030195547" | "20030220414" | "20030225432" | "20030233096" | "20040023784" | "20040024081" | "20040024409" | "20040024410" | "20040034384" | "20040044350" | "20040087994" | "20040092946" | "20040097612" | "20040127987" | "20040138758" | "20040153064" | "20040153115" | "20040167561" | "20040167562" | "20040167625" | "20040210231" | "20040215343" | "20040220680" | "20040225296" | "20040226479" | "20040230309" |	US-PGPUB; USPAT; USOCR	OR	ON	2011/12/27 13:31

		"20040236186"	"20040247644"						
		"20040267271"	"20050027245"						
		"20050033303"	"20050038383"						
		"20050043737"	"20050060030"						
		"20050070844"	"20050070912"						
		"20050090852"	"20050113836"						
		"20050124989"	"20050143827"						
		"20050182412"	"20050182413"						
		"20050187556"	"20050199156"						
		"20050209557"	"20050216018"						
		"20050228391"	"20050234425"						
		"20050240193"	"20050251266"						
		"20050251267"	"20050261683"						
		"20060024348"	"20060041033"						
		"20060052743"	"20060064101"						
		"20060074433"	"20060100635"						
		"20060100706"	"20060106392"						
		"20060106459"	"20060116689"						
		"20060142732"	"20060149268"						
		"20060149281"	"20060156959"						
		"20060184106"	"20060184192"						
		"20060206116"	"20060206136"						
		"20060217736"	"20060229625"						
		"20060229631"	"20060235417"						
		"20060264945"	"20060266372"						
		"20060270750").PN. OR ("20060271061"							
		"20060276797"	"20060276819"						
		"20060293687"	"20070010845"						
		"20070016130"	"20070016211"						
		"20070021769"	"20070043373"						
		"20070055201"	"20070055266"						
		"20070055275"	"20070055277"						
		"20070055278"	"20070055279"						
		"20070055283"	"20070055284"						
		"20070055285"	"20070055300"						
		"20070055382"	"20070059281"						
		"20070067034"	"20070114248"						
		"20070118142"	"20070162042"						
		"20070173939"	"20070185231"						
		"20070197935"	"20070211563"						
		"20070233146"	"20070260223"						
		"20070270876"	"20080058840"						
		"20080195112"	"20080249481"						
		"20090131867"	"20090131886"						
		"20090131945"	"20090131950"						
		"20090182427"	"3625200"	"3908637"					
		"4033331"	"4131597"	"4236520"					
		"4276880"	"4294251"	"4337773"					
		"4399814"	"4578061"	"4627434"					
		"4653489"	"4668295"	"4722948"					
		"4731054"	"4747840"	"4748969"					
		"4784638"	"4842603"	"4843112"					
		"4846814"	"4865586"	"4869906"					
		"4888366"	"4900303"	"4961731"					
		"4963151"	"4969870"	"4969888"					
		"4982730"	"5004501"	"5017627"					
		"5029558"	"5049137"	"5049157"					
		"5059193"	"5085861"	"5088991"					
		"5092891"	"5108404"	"5112303"					
		"5147334"	"5156606"	"5163431"					
		"5184757"	"5188619"	"5196201"					
		"5197971"	"5211631"	"5242082"					
		"5264214"	"5266248"	"5269750"					
		"5285795"	"5295980"	"5296026"					

		"5308342" | "5336699" | "5343877" | "5352715" | "5356629" | "5360416" | "5368598" | "5372587" | "5378234" | "5380307" | "5385563" | "5389073" | "5425770" | "5431168" | "5431639").PN. OR ("5480382" | "5484424" | "5489275" | "5496330" | "5512610" | "5514137" | "5531715" | "5533985" | "5535922" | "5549542" | "5549679" | "5554114" | "5571085" | "5574075" | "5616121" | "5624396" | "5637091" | "5681289" | "5681317" | "5685826" | "5709697" | "5725568" | "5735829" | "5741320" | "5800408" | "5810867" | "5820592" | "5847046" | "5858003" | "5860952" | "5876373" | "5902839" | "5914356" | "5928239" | "5931829" | "5972015" | "5997581" | "6019765" | "6027487" | "6030360" | "6059739" | "6066154" | "6066176" | "6080801" | "6099514" | "6110155" | "6127597" | "6146355" | "6183435" | "6203507" | "6203574" | "6228052" | "6228904" | "6235043" | "6241734" | "6248110" | "6251092" | "6280413" | "6280434" | "6280456" | "6280473" | "6291547" | "6332894" | "6358251" | "6383188" | "6437019" | "6440138" | "6447514" | "6479565" | "6484904" | "6506217" | "6511471" | "6524296" | "6565588" | "6575978" | "6576249" | "6592559" | "6599961" | "6620162" | "6623448" | "6638268" | "6663647" | "6676665" | "6679886" | "6689823" | "6692532" | "6719761" | "6719773" | "6743239" | "6746451" | "6752863" | "6753007" | "6770079" | "6814734" | "6814736" | "6818001" | "6832984" | "6835193" | "6837867" | "6863672" | "6869445" | "6875219" | "6899715" | "6899719" | "6913594" | "6916306" | "6923813" | "6945956" | "6953594" | "6955716" | "6976987" | "6979312" | "6979352" | "6981981" | "6991616" | "6998128" | "7004945" | "7008433" | "7018460" | "7029468" | "7044954" | "7059330" | "7063682" | "7066942" | "7081122").PN. OR ("7081161" | "7091258" | "7091260" | "7094202" | "7094286" | "7109254" | "7112205" | "7114501" | "7138442" | "7153306" | "7153307" | "7166121" | "7172629" | "7186761" | "7226481" | "7465318" | "RE92196").PN. OR ("7842041").URPN.				
S73	407	((604/103.04) or (604/103.09)).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/08/07 15:41
S74	413	(604/160-162).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/08/07 15:41
S75	1114	(604/164.01-164.02).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/08/07 15:42

S76	501	(604/164.09-164.11).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/08/07 15:42
S77	372	(604/525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/08/07 15:42
S78	25	("20030195546" | "20040127927" | "20050004523" | "20050182437" | "20070260219" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "5776141" | "6159195" | "6338725" | "6475195" | "6595952" | "6610068" | "6638268" | "6689144" | "6706018" | "6755812" | "6860876" | "7697996" | "7717899").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/08/07 15:43
S79	0	("2010/0228263").URPN.	USPAT	OR	ON	2012/08/07 15:44
S80	54	("3352306" | "3565074" | "4230123" | "4581019" | "4629450" | "4772264" | "4911691" | "4978334" | "4994027" | "4995866").PN. OR ("5242410").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/08/07 15:44
S81	70	("3769981" | "4085757" | "4748982" | "4762129" | "4771777" | "4820271" | "4988356" | "5002556" | "5024658" | "5040548" | "5061273" | "5087247" | "5092839" | "5171222" | "5205822" | "5222970" | "5267958" | "5425714" | "5439445").PN. OR ("5578009").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/08/07 15:44
S82	90	("20010031979" | "20020065550" | "20020077654" | "20020082556" | "20030050661" | "20040122509" | "3105492" | "3953566" | "4187390" | "4235231" | "4552554" | "4574477" | "4601713" | "4732152" | "4762129" | "4877661" | "4988356" | "5024234" | "5030210" | "5061273" | "5102403" | "5107852" | "5135535" | "5171222" | "5195978" | "5205822" | "5273042" | "5324269" | "5334147" | "5334153" | "5334169" | "5336184" | "5364353" | "5380283" | "5380290" | "5389087" | "5395335" | "5413559" | "5425723" | "5445646" | "5458613" | "5466222" | "5472423" | "5472425" | "5476589" | "5489271" | "5531700" | "5534007" | "5571135" | "5573520" | "5578009" | "5591194" | "5647857" | "5662703" | "5690644" | "5709658" | "5718680" | "5752932" | "5752934" | "5788707" | "5807355" | "5846259" | "5879794" | "5919164" | "5968012" | "5972441" | "5993460" | "6016848" | "6027779" | "6056719" | "6059813" | "6095990" | "6099496" | "6107004" | "6159565" | "6200305" | "6203558" | "6238410" | "6273899" | "6299595" | "6398799" | "6423032" | "6447540" | "6458099" | "6544278" | "6589207" | "6673102" | "6783522" | "6929634").PN. OR ("8016752").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/08/07 15:44
S83	60	("4166469" | "4243050" |	US-PGPUB;	OR	ON	2012/08/07

		"4345606").PN. OR ("5667514").URPN.	USPAT; USOCR			15:45
S84	134	("4292974" | "4323071" | "4665918" | "4733665" | "4762129" | "4775371" | "4776337" | "4839623" | "4877030" | "4950227" | "5014089" | "5019090" | "5026377" | "5102417" | "5108416" | "5123917" | "5158548" | "5163952" | "5195984" | "5219355" | "5242399" | "5344426" | "5360401" | "5360443" | "5382261" | "5409495" | "5443500" | "5445646" | "5507768" | "5534007" | "5545209" | "5549563" | "5571086" | "5591222" | "5620457").PN. OR ("5776141").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2012/08/07 15:45
S86	17	("2003/0195546").URPN.	USPAT	OR	ON	2014/06/17 12:10
S87	74	("3769981" | "4085757" | "4748982" | "4762129" | "4771777" | "4820271" | "4988356" | "5002556" | "5024658" | "5040548" | "5061273" | "5087247" | "5092839" | "5171222" | "5205822" | "5222970" | "5267958" | "5425714" | "5439445").PN. OR ("5578009").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/17 12:16
S88	64	("3811448" | "4195637" | "4323071" | "4493711" | "4573470" | "4619263" | "4641649" | "4643186" | "4748982" | "4762129" | "4790315" | "4798193" | "4824435" | "5003990" | "5040548" | "5045061" | "5061273" | "5090958" | "5324257" | "5395332" | "5413557" | "5415634" | "5423885" | "5540659" | "5569199" | "5578009" | "5667493" | "5667521" | "5690642" | "5718680" | "5728067" | "5730698" | "5863285" | "5879305" | "5882334" | "6007517" | "6071285" | "RE31800").PN. OR ("6780199").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/17 12:19
S89	2	(11/416629).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/23 16:58
S90	2	(13/359059).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/23 16:58
S91	18	("5667514" | "5868754" | "5947995" | "6001118").PN. OR ("6254610").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/23 18:00
S92	1	("7757333").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/23 19:03
S93	1	("7747333").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/23 19:03
S94	15	("8048032" | "6610068" | "6689144" | "7762984" | "6638268" | "6706018" | "7697996" | "8142413" | "8292850" | "6635029" | "6860876" | "6755812" | "7544201" | "7717899" | "7232452").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/23 19:16
S95	156	("1596284" | "20020058960" |	US-PGPUB;	OR	ON	2014/06/23

		"20020077653" | "20020161388" | "20040015182" | "20040039332" | "20040073163" | "20040073299" | "20040082965" | "20040109964" | "20040176740" | "20050027249" | "20050033225" | "20050102020" | "20050123702" | "20050267408" | "20060015133" | "20080082050" | "2043083" | "3769981" | "3981415" | "4367396" | "4482516" | "4572186" | "4637396" | "4652258" | "4702252" | "4704130" | "4706670" | "4748982" | "4796629" | "4834755" | "4884573" | "4952357" | "4983167" | "4998421" | "5042985" | "5046497" | "5061273" | "5078727" | "5108415" | "5112304" | "5116360" | "5171297" | "5201706" | "5207700" | "5264260" | "5270086" | "5290306" | "5295960" | "5304340" | "5306245" | "5306246" | "5314443" | "5330429" | "5338299" | "5344401" | "5358486" | "5410797" | "5451209" | "5451233" | "5464394" | "5470314" | "5477886" | "5478320" | "5492532" | "5549552" | "5549556" | "5554120" | "5575771" | "5587125" | "5599576" | "5620649" | "5647848" | "5690642" | "5728063" | "5741325" | "5752934" | "5755690" | "5759172" | "5769817" | "5772681" | "5788979" | "5797877" | "5820613" | "5868779" | "5879369" | "5928181" | "5972441" | "5980486" | "6007544" | "6010480" | "6012457" | "6015430" | "6024722" | "6024740" | "6027779" | "6036697" | "6036715" | "6117101" | "6124007" | "6127597" | "6129708" | "6156254" | "6159238" | "6164283" | "6171297" | "6183492" | "6186978" | "6187013" | "6234995" | "6245064" | "6254599" | "6263236" | "6270902" | "6290485" | "6305378" | "6306154" | "6309379").PN. OR ("6315751" | "6328925" | "6361529" | "6394995" | "6544219" | "6626889" | "6663648" | "6702750" | "6702782" | "6706051" | "6733487" | "6743196" | "6746425" | "6755845" | "6761708" | "6905743" | "6911038" | "6942680" | "6977103" | "7300415").PN. OR ("7544201").URPN.	USPAT; USOCR			19:18
S96	181	("1747407" | "3038465" | "3853130" | "3995623" | "4456013" | "4613323" | "4771782").PN. OR ("5046497").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/23 19:21
S97	1	("8292850").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/24 12:37
S98	2	(11/416629).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/24 12:43
S99	2	(13/359059).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/24 12:44

S100	1	("20040127927").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/24 16:07
S101	192	nitinol and (relief with cut)	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:08
S102	1	("8292850").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/24 16:50
S103	25	("20030195546" | "20040127927" | "20050004523" | "20050182437" | "20070260219" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "5776141" | "6159195" | "6338725" | "6475195" | "6595952" | "6610068" | "6638268" | "6689144" | "6706018" | "6755812" | "6860876" | "7697996" | "7717899").PN. OR ("8292850").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:51
S104	562	604/103.04	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S105	494	604/103.09	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S106	691	604/160	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S107	800	604/161	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S108	798	604/162	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S109	2722	S104 S105 S106 S107 S108	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S110	2957	604/164.01	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S111	2957	S110	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S112	478	604/164.09	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S113	473	604/164.1	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S114	698	604/164.11	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S115	980	604/525	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55
S116	2281	S112 S113 S114 S115	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55

S117	154	("3472230" | "3952747" | "3996938" | "4046150" | "4425908" | "4590938" | "4619246" | "4650466" | "4706671" | "4723549" | "4790812" | "4790813" | "4794928" | "4807626" | "4842579" | "4873978" | "4921478" | "4921484" | "4926858" | "4969891" | "4998539" | "5002560" | "5011488" | "5053008" | "5071407" | "5100423" | "5102415" | "5133733" | "5152771" | "5152777" | "5160342" | "5224953" | "5300086" | "5329942" | "5330484" | "5354310" | "5376100" | "5421832" | "5423742" | "5449372" | "5456667" | "5462529" | "5536242" | "5549626" | "5658296" | "5662671" | "5695519" | "5720764" | "5728066" | "5749848" | "5769816" | "5779716" | "5792157" | "5795322" | "5800457" | "5800525" | "5810874" | "5814064" | "5827324" | "5833644" | "5833650" | "5846260" | "5848964" | "5876367" | "5895399" | "5910154" | "5911734" | "5925016" | "5925060" | "5925062" | "5935139" | "5941869" | "5941896" | "5947995" | "5954745" | "5980555" | "5989281" | "5993469" | "5997557" | "6001118" | "6007557" | "6010522" | "6013085" | "6027520" | "6042598" | "6051014" | "6051015" | "6053932" | "6059814" | "6066149" | "6066158" | "6068645" | "6086605" | "6117154" | "6129739" | "6136016" | "6142987" | "6152946" | "6165200" | "6168579" | "6171327" | "6171328" | "6179851" | "6179859" | "6179861" | "6203561" | "6206868" | "6214026" | "6221006" | "6224620" | "6231544" | "6235044" | "6235045" | "6238412" | "6245087" | "6245088" | "6245089" | "6258115" | "6264663" | "6264672" | "6270513" | "6277138" | "6277139" | "6280413" | "6287321").PN. OR ("6290710" | "6309399" | "6319268" | "6344049" | "6499487" | "6530939" | "6589263").PN. OR ("7306618").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/06/24 16:55

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S59	0	(604/164.1).CCLS.	UPAD	OR	OFF	2011/07/27 15:34
S60	0	(604/525).CCLS.	UPAD	OR	OFF	2011/07/27 15:34
S70	0	(604/164.1).CCLS.	UPAD	OR	OFF	2011/12/27 13:25
S71	0	(604/510).CCLS.	UPAD	OR	OFF	2011/12/27 13:25
S72	0	(604/525).CCLS.	UPAD	OR	OFF	2011/12/27 13:25
S85	2	((604/164.01) or (604/525)).CCLS.	UPAD	OR	OFF	2012/08/07 15:42

7/7/2014 10:44:42 AM
C:\Users\bosinski\Documents\EAST\Workspaces\11416629.wsp

1 of 1 DOCUMENT

UNITED STATES PATENT AND TRADEMARK OFFICE GRANTED PATENT

8292850

Link to Claims Section

October 23, 2012

Coaxial guide catheter for interventional cardiology procedures

REEXAM-LITIGATE:

NOTICE OF LITIGATION

Vascular Solutions, Inc. v. Boston Scientific Corporation, Filed May 16, 2013, D.C. Minnesota, Doc. No. 0:13cv1172

REISSUE:
November 1, 2013 - Reissue Application filed, Ex. Gp.: 3767; Re. S.N. 14/070,161 , (O.G. March 4, 2014)
March 3, 2014 - Reissue Application filed, Ex. Gp.: 3767; , (O.G. May 6, 2014)
March 3, 2014 - Reissue Application filed, Ex. Gp.: 3767; Re. S.N: 14/195,385 , (O.G. May 27, 2014)

INVENTOR: Root, Howard - Excelsior, Minnesota, United States of America (US), United States of America () ; Sutton, Gregg - Maple Grove, Minnesota, United States of America (US), United States of America () ; Welch, Jeffrey M - Maple Grove, Minnesota, United States of America (US), United States of America () ; Garrity, Jason M - Minneapolis, Minnesota, United States of America (US), United States of America ()

CERT-CORRECTION:
January 22, 2013 - a Certificate of Correction was issued for this patent (O.G. February 12, 2013)

APPL-NO: 359059 (13)

FILED-DATE: January 26, 2012

GRANTED-DATE: October 23, 2012

PRIORITY: January 26, 2012 - 13359059, United States of America (US)

ASSIGNEE-PRE-ISSUE:
February 20, 2012 - ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS)., VASCULAR SOLUTIONS, INC., 6464 SYCAMORE COURT NORTH, MINNEAPOLIS, MINNESOTA, UNITED STATES OF AMERICA (US), 55369, Reel and Frame Number: 027729/0760
April 2, 2012 - ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS)., VASCULAR SOLUTIONS, INC., 6464 SYCAMORE COURT NORTH, MINNEAPOLIS, MINNESOTA, UNITED STATES OF AMERICA (US), 55369, Reel and Frame Number: 027973/0984

ASSIGNEE-AT-ISSUE:
Vascular Solutions, Inc., Minneapolis, Minnesota, United States of America (US), United States company or corporation (02)

LEGAL-REP: Patterson Thuente Christensen Pedersen, P.A.

PUB-TYPE: October 23, 2012 - Patent with a pre-grant publication (B2)

PUB-COUNTRY: United States of America (US)

LEGAL-STATUS:

February 20, 2012 - ASSIGNMENT
April 2, 2012 - ASSIGNMENT
January 22, 2013 - CERTIFICATE OF CORRECTION
March 4, 2014 - REISSUE APPLICATION FILED
May 6, 2014 - REISSUE APPLICATION FILED

FILING-LANG: English (EN) (ENG)

PUB-LANG: English (EN) (ENG)

REL-DATA:

Division of Ser. No. 12824734, June 28, 2010, GRANTED 8142413
, which is a Division of Ser. No. 11416629, May 3, 2006, GRANTED
8048032
Prior Publication 20120165756, June 28, 2012, Patent Application Publication (A1)

US-MAIN-CL: 604#164.01

US-ADDL-CL: 604#525

CL: 604

SEARCH-FLD: 604#103.04, 604#103.09, 604#160-162, 604#164.01, 604#164.02, 604#164.09-164.11, 604#525

IPC-MAIN-CL: [8] A61M 005#178 (20060101) Advanced Inventive 20121023 (A F I B H US)

IPC-ADDL-CL: [8] A61M 025#00 (20060101) Advanced Inventive 20121023 (A L I B H US)

PRIM-EXMR: Sirmons, Kevin C

ASST-EXMR: Osinski, Bradley

REF-CITED:

4813930, March 21, 1989, Elliott, United States of America (US)
4832028, May 23, 1989, Patel, United States of America (US)
4932413, June 12, 1990, Shockey et al., United States of America (US)

5098412, March 24, 1992, Shiu, United States of America (US)
5122125, June 16, 1992, Deuss, United States of America (US)
5472425, December 5, 1995, Teirstein, United States of America (US)
5658263, August 19, 1997, Dang et al., United States of America (US)
5776141, July 7, 1998, Klein et al., United States of America (US)
6159195, December 12, 2000, Ha et al., United States of America (US)
6338725, January 15, 2002, Hermann et al., United States of America (US)
6475195, November 5, 2002, Voda, United States of America (US)
6595952, July 22, 2003, Forsberg, United States of America (US)
6610068, August 26, 2003, Yang, United States of America (US)
6638268, October 28, 2003, Niazi, United States of America (US)
6689144, February 10, 2004, Gerberding, United States of America (US)
6706018, March 16, 2004, Westlund et al., United States of America (US)
6755812, June 29, 2004, Peterson et al., United States of America (US)
6860876, March 1, 2005, Chen, United States of America (US)
7697996, April 13, 2010, Manning et al., United States of America (US)
7717899, May 18, 2010, Bowe et al., United States of America (US)
20030195546, October 16, 2003, Solar et al., United States of America (US)
20040127927, July 1, 2004, Adams, United States of America (US)
20050004523, January 6, 2005, Osborne et al., United States of America (US)
20050182437, August 18, 2005, Bonnette et al., United States of America (US)
20070260219, November 8, 2007, Root et al., United States of America (US)

NON-PATENT LITERATURE:

Saeko Takahashi et al.; New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter; Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages; Published online in Wiley InterScience (www.interscience.wiley.com).9644276998
U.S. Appl. No. 11/416,629, filed Jun. 28, 2010; Howard Root et al.
U.S. Appl. No. 12/824,734, filed Jun. 28, 2010, Howard Root et al.

ENGLISH-ABST:

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

NO-OF-CLAIMS: 24

EXMPL-CLAIM: 1

NO-OF-FIGURES: 22

NO-DRWNG-PP: 13

PARENT-PAT-INFO:

RELATED APPLICATIONS

[0001]This application is a divisional of application Ser. No. 12/824,734, filed Jun. 28, 2010 now U.S. Pat. No. 8,142,413 entitled Coaxial Guide Catheter for Interventional Cardiology Procedures, which is divisional of application Ser. No. 11/416,629, filed May 3, 2006 now U.S. Pat. No. 8,048,032 entitled Coaxial Guide Catheter for Interventional Cardiology Procedures.

SUMMARY:

FIELD OF THE INVENTION

[0002]The present invention relates generally to catheters used in interventional cardiology procedures. More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.

BACKGROUND OF THE INVENTION

[0003]Interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters. In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions. These lesions may totally obstruct the lumen of the artery or may dramatically narrow the lumen of the artery. Narrowing is referred to as stenosis. In order to diagnose and treat obstructive coronary artery disease it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery.

[0004]In treating a stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery. This is sometimes accomplished with the aid of a guidewire. A guide catheter is typically seated into the opening or ostium of the artery to be treated and a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis. Crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated. This can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.

[0005]Prior attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as "backup support") fall generally into four categories.

[0006]First are guiding catheters that, through a combination of shape and stiffness, are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed. Examples of this approach can be found in U.S. Pat. No. 6,475,195 issued to Voda and U.S. Pat. No. 5,658,263 issued to Dang et al. These guiding catheters all share the common limitation that a guide catheter stiff enough to provide adequate backup support is often too stiff to be safely inserted into the aorta without the possibility of causing damage to the aortic wall. In addition, attempts to deep seat the guide catheter have been made but the rigid nature of the guide catheter creates the risk that the guide catheter may damage the coronary artery wall or that the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

[0007]Second are guiding catheters that include a retractable appendage. The appendage in these catheters can be extended to engage the opposing wall of the aortic arch to provide backup support or the appendage may be placed under tension to stiffen a bend in the catheter to provide backup support. Examples of this approach may be found in U.S. Pat. No. 4,813,930 issued to Elliot; U.S. Pat. No. 5,098,412 issued to Shiu; and U.S. Pat. No. 6,860,876 issued to

Chen. These guiding catheters tend to be somewhat mechanically complex and have not been widely adopted by practitioners.

[0008]Third are guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium of the coronary artery to provide a force acting in opposition to the backward forces created when trying to maneuver a therapeutic device past a lesion or blockage in the coronary artery. These devices can include a balloon secured to a guidewire or a catheter or another device for expanding to grip the walls of the coronary artery from within. Examples of this approach may be found in U.S. Pat. No. 4,832,028 issued to Patel; U.S. Pat. No. 6,595,952 issued to Forsberg; and U.S. Published Application No. 2005/0182437 by Bonnette et al. Again, these devices tend to be mechanically complex and can completely occlude the coronary ostium thus stopping perfusion of the coronary artery.

[0009]A fourth technique includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents. This technique has been described in an article by Takahashi entitled "New Method to Increase a Backup Support of Six French Guiding Coronary Catheter," published in Catheterization and Cardiovascular Interventions, 63:452-456 (2004). This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

[0010]Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

[0011]Thus, the interventional cardiology art would benefit from the availability of a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery.

SUMMARY OF THE INVENTION

[0012]The present invention is a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. The coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery. This feature also allows removal of the tapered inner catheter after the coaxial guide catheter is in place. The tapered inner catheter provides a gradual transition from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French.

[0013]The coaxial guide catheter preferably can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter. In addition, the coaxial guide catheter preferably has an inner diameter that is appropriate for delivering standard coronary treatment devices after it is placed in the coronary artery.

[0014]In one embodiment, the coaxial guide catheter is made in at least three sizes corresponding to the internal capacity of 8 French, 7 French, and 6 French guide catheters that are commonly used in interventional cardiology procedures. An 8 French catheter has an internal diameter greater than or equal to 0.088 inches. A 7 French catheter has an internal diameter greater than or equal to 0.078 inches. A 6 French guide catheter has an internal diameter greater

than or equal to 0.070 inches. Thus, for three exemplary sizes the effective internal diameter of the coaxial guide catheter may be as follows. For a 7 French in 8 French coaxial guide catheter, the internal diameter should be greater than or equal to 0.078 inches. For a 6 French in 7 French coaxial guide catheter the internal diameter should be greater than or equal to 0.070 inches. For a 5 French in 6 French coaxial guide catheter the internal diameter should be greater than or equal to 0.056 inches.

[0015]Interventional cardiology procedures are typically carried out under fluoroscopy or another x-ray or imaging technique. Therefore, one embodiment of the coaxial guide catheter of the present invention includes a radiopaque marker at its distal tip to facilitate positioning and manipulation of the coaxial guide catheter.

[0016]The present invention generally includes the coaxial guide catheter and a tapered inner catheter. The coaxial guide catheter includes a tip portion, a reinforced portion, and a substantially rigid portion. The coaxial guide catheter will generally have an overall length of preferably approximately 125 cm, though this should not be considered limiting.

[0017]In one embodiment, the tip portion may include a soft tip and a marker band. The soft tip is tapered and may be formed from a low durometer polymer or elastomer material such as polyether block amide polymer, (PEBA, Pebax[#174]) the marker band may be formed from a platinum iridium alloy sandwiched between the Pebax[#174] that extends from the bump tip and a PTFE liner.

[0018]In one embodiment, the reinforced portion may be reinforced, preferably with metallic fibers in a braided or coiled pattern. The braided or coiled portion is lined by a PTFE liner and may be covered on its exterior with Pebax[#174]. The braided or coiled portion may extend approximately 20 to 110 cm in length. In one exemplary embodiment, the braided portion extends approximately 32 to 36 cm.

[0019]Preferably, the rigid portion may be advantageously formed from a stainless steel or Nitinol tube. The rigid portion may be joined to the braid or coil portion by welding. The rigid portion may include a cutout portion and a full circumference portion. For example, the cutout portion may include a section where about 45% of the circumference of the cylindrical tubular structure has been removed. The cutout portion may also include a section where 75-90% of the circumference of the tubular structure has been removed. In one exemplary embodiment, the portion having approximately 45% removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm.

[0020]The full circumference portion of the rigid portion is typically located at the most proximal end of the coaxial guide catheter.

[0021]The rigid portion may include a plurality of radially oriented slits or other cuts in its distal portion to increase and control the flexibility of the rigid portion

[0022]In an exemplary embodiment, the tapered inner catheter generally includes a tapered inner catheter tip and a cutout portion. The tapered inner catheter tip includes a tapered portion and a straight portion. The tapered portion is typically at the most distal end of the tapered inner catheter. Both the straight portion and the tapered portion are pierced by a lumen through which a guidewire may be passed.

[0023]The cutout portion supports a track passing along the concave side thereof that continues from the lumen that passes through the straight portion and the tapered portion. The tapered inner catheter may also have a clip or snap attachment at its proximal end to releasably join the tapered inner catheter to the coaxial guide catheter.

[0024]In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. The tapered inner catheter is positioned so that the tapered inner catheter tip extends beyond the tip portion of the coaxial guide catheter. The coaxial guide catheter-tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta. The coaxial guide catheter-tapered inner catheter combination may be threaded over a preplaced 0.014 inch guidewire. The tapered inner catheter-coaxial guide catheter combination is advanced up the aorta

until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed. During this entire process at least part of the coaxial guide catheter-tapered inner catheter combination is located inside of the guide catheter.

[0025]Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion such as a stenosis or a chronic arterial occlusion.

[0026]A guide catheter inserted into the ostium of a branch artery where it branches off from a larger artery is subject to force vectors that tend to dislodge the distal end of the guide catheter from the ostium of the branch artery when a physician attempts to direct a guidewire or other interventional cardiology device past an occlusive or stenotic lesion in the branch artery. This discussion will refer to a guide wire but it is to be understood that similar principles apply to other interventional cardiology devices including balloon catheters and stent catheters.

[0027]One of the forces that act on the guide catheter is an axial force substantially along the axis of the branch artery and the portion of the guide catheter that is seated in the ostium. This force vector is a reactive force created by the pushing back of the guide wire against the guide catheter as the physician tries to force the guidewire through or past the lesion. It tends to push the distal end of the catheter out of the ostium in a direction parallel to the axis of the branch artery and the axis of the distal end of the guide catheter.

[0028]Another of the force vectors that acts on the guide catheter is a shearing force that tends to dislodge the distal end of the guide catheter from the ostium of the branch artery in a direction perpendicular to the axis of the branch artery and the axis of the distal end of the guide catheter. This force vector arises from curvature of the guide catheter near its distal end and the guide wire pushing on the curved portion of the guide catheter as the physician applies force to the guidewire. The coaxial guide catheter of the present invention assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.

[0029]The system is deliverable using standard techniques utilizing currently available equipment. The present invention also allows atraumatic placement within the coronary artery. Further, the invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters. Finally, the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel.

DRWDESC:

BRIEF DESCRIPTION OF THE DRAWINGS

[0030]FIG. 1 is a schematic depiction of the coaxial guide catheter and a tapered inner catheter in accordance with the present invention;

[0031]FIG. 2 is schematic depiction of the coaxial guide catheter and tapered inner catheter assembled in accordance with the present invention;

[0032]FIG. 3 is a plan view of a guide catheter, the coaxial guide catheter, and a treatment catheter in accordance with the present invention;

[0033]FIG. 4 is a sectional view of the coaxial guide catheter in accordance with the present invention;

[0034]FIG. 5 is a cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

[0035]FIG. 6 is another cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

[0036]FIG. 7 is a schematic view of a guide catheter and a guidewire located in an aortic arch and a coronary artery and the guide catheter and guidewire in a second position depicted in phantom;

[0037]FIG. 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter in accordance with the present invention and a tapered inner catheter located in the aortic arch and coronary artery;

[0038]FIG. 9 is a schematic view of a guide catheter, a guidewire and a coaxial guide catheter in accordance with the present invention located in the aortic arch and coronary artery;

[0039]FIG. 10 is a flat pattern for making relief cuts in a curved rigid portion of the coaxial guide catheter in accordance with the present invention;

[0040]FIG. 11 is a detailed view taken from FIG. 10;

[0041]FIG. 12 is a plan view of the rigid portion in accordance with the present invention;

[0042]FIG. 13 is an elevational view of the rigid portion;

[0043]FIG. 14 is a sectional view of the rigid portion taken along section line **14-14** of FIG. 13; and

[0044]FIG. 15 is a sectional view of the rigid portion taken along section line **15-15** of FIG. 13.

[0045]FIG. 16 is a sectional view of the rigid portion taken along section line **16-16** of FIG. 13.

[0046]FIG. 17 is a plan view of a coaxial guide catheter having a longer rail segment and a tapered inner catheter in accordance with the present invention.

[0047]FIG. 18 is a plan view of the tapered inner catheter as depicted in the FIG. 17.

[0048]FIG. 19 is a cross-sectional view of the tapered inner catheter taken along section lines **19-19** of FIG. 18.

[0049]FIG. 20 is a plan view of a coaxial guide catheter in accordance with the present invention.

[0050]FIG. 21 is an elevational view of a coaxial guide catheter in accordance with the present invention.

[0051]FIG. 22 is a cross-sectional view taken along section line **22-22** of FIG. 21.

DETDESC:

DETAILED DESCRIPTION OF THE DRAWINGS

[0052]Referring to FIGS. 1 and 2, coaxial guide catheter assembly **10** of the present invention generally includes coaxial guide catheter **12** and tapered inner catheter **14**.

[0053]Coaxial guide catheter **12** generally includes tip portion **16**, reinforced portion **18**, and rigid portion **20**. The overall length of the coaxial guide catheter typically can be approximately 125 cm. This length should not be considered

limiting.

[0054]Tip portion **16** generally includes bump tip **22** and marker band **24**. Bump tip **22** includes taper **26**. Bump tip **24** is relatively flexible and may be formed, for example, from 4033 Pebax[#174]. Bump tip **22** may be yellow or another high visibility color for ease of handling.

[0055]Marker band **24** is formed of a radiopaque material such as platinum/iridium alloy usually at a 90/10 ratio. Marker band **24** may be sandwiched between an outer Pebax[#174] material **28** and a PTFE liner **30**. Outer Pebax[#174] material **28** in this location may be formed of 5533 Pebax, for example.

[0056]Reinforced portion **18** includes braid or coil reinforcement **32**. Braid or coil reinforcement **32** may be formed of metal, plastic, graphite, or composite structures known to the art. Reinforced portion **18** may be lined on the interior by PTFE liner **30** and covered on the exterior by Pebax[#174] material **28**. Tip portion **16** and reinforced portion **18** together form a substantially cylindrical structure. Braid or coil reinforcement **32** may extend approximately 20 to 30 cm. In one exemplary embodiment, braid or coiled portion has a length of approximately 32 to 36 cm.

[0057]Rigid portion **20** may be secured to braid or coil reinforcement by, for example, welding or bonding. Rigid portion **20** may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well. Rigid portion **20** includes first full circumference portion **34**, hemicylindrical portion **36**, arcuate portion **38**, and second full circumference portion **40**.

[0058]First full circumference portion **34** is joined to braid or coil reinforcement **32**. First full circumference portion **34** extends for a relatively short distance, for example, 0.25 cm.

[0059]Hemicylindrical portion **36** desirably includes 40% to 70% of the circumference of the tube. Hemicylindrical portion **36** may extend, for example, approximately 20 to 75 cm in length.

[0060]Hemicylindrical portion **36** tapers into arcuate portion **38**.

[0061]Arcuate portion **38** extends from 25% to 40% of the circumference of the tube. Arcuate portion **38** may extend linearly, for example, for about 15 cm.

[0062]Arcuate portion **38** connects to second full circumference portion **40**. Second full circumference portion **40** may extend for a short distance, for example, approximately 3 cm.

[0063]Tapered inner catheter **14** generally includes tapered inner catheter tip **42** and cutout portion **44**. Tapered inner catheter tip **42** tapers gradually from the diameter of a guide wire to the diameter of tip portion **16**.

[0064]Tapered inner catheter tip **42** includes tapered portion **46** at a distal end thereof, and straight portion **48**. Both tapered portion **46** and straight portion **48** are pierced by lumen **50**.

[0065]Cutout portion **44** defines a concave track **52** along its length. Concave track **52** is continuous with lumen **50**.

[0066]Tapered inner catheter **14** may also include clip **54** at a proximal end thereof to releasably join tapered inner catheter **14** to coaxial guide catheter **12**. Thus, tapered inner catheter **14** is keyed to coaxial guide catheter **12**.

[0067]Coaxial guide catheter **12** may include, starting at its distal end, a first portion having a flexural modulus of about 13,000 PSI plus or minus 5000 PSI, a second portion having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, a third portion having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI and a fourth portion having a flexural modulus of about 107,000 PSI plus or minus 20,000 PSI. Coaxial guide catheter **12** may be formed, for example, of 4033 Pebax[#174] at bump tip **22** for the first 0.1 cm. This portion may followed by a section about three cm long of 5533 Pebax[#174] that covers marker band **24** and the distal portion of braid or coil reinforcement **32**. Next may come an approximately five cm portion of 6333 Pebax[#174] which encloses part of braid

or coil reinforcement **32** followed by an approximately twenty seven cm portion of 7233 Pebax[#174] covering the most proximal portion of braid or coil reinforcement **32**. Braid or coil reinforcement **32** is bonded to rigid portion **20** which may be formed from stainless steel or a similar biocompatible material. Rigid portion **20** may extend for approximately ninety cm and include first full circumference portion **34** (approximately 0.25 cm), hemicylindrical portion **36** (approximately seventy five cm), arcuate portion (approximately fifteen cm) and second full circumference portion (approximately three cm.) Rigid portion **20** may be formed from a stainless steel or Nitinol hypo tube.

[0068]FIG. 7 depicts a typical guide catheter **56** passing through aortic arch **58** into ostium **60** of coronary artery **62**. FIG. 7 also depicts guidewire **64** passing through the guide catheter **56** and into coronary artery **62**. Located in coronary artery **62** is stenotic lesion **66**. In a typical procedure, guidewire **64** is placed through the aortic arch **58** and into the ostium **60** of the coronary artery. **62**. The guide catheter **56** is passed over guidewire **64** until distal end **68** of guide catheter **56** is seated in ostium **60** of coronary artery **62**. Force is then applied to the guidewire **64** to push guidewire **64** past stenotic lesion **66** or an occlusive lesion (not shown). Once the guidewire **64** is pushed past stenotic lesion **66** or occlusive lesion (not shown), a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion **66** or occlusive lesion (not shown). The lesion can then be treated.

[0069]As can be seen in phantom, in FIG. 7, the application of force to guidewire **64** can cause guide catheter **56** to dislodge from ostium **60** of coronary artery **62**. This can occur in the case of a tough stenotic lesion **66** or occlusive lesion (not shown) when it is difficult to pass the guidewire **64** beyond the stenotic lesion **66** or occlusive lesion (not shown).

[0070]Referring the FIG. 8 coaxial guide catheter **12** is depicted as used with guide catheter **56**, guidewire **64**, and tapered inner catheter **14**. Here, coaxial guide catheter **12** with tapered inner catheter **14** is passed through guide catheter **56** and over guidewire **64** into coronary artery **62** after the guide catheter **56** has been placed in the ostium **60** of coronary artery **62**, as depicted in FIG. 7. Coaxial guide catheter **12**, with tapered inner catheter **14**, provides an inner support member for proper translation over guidewire **64**. Tapered inner catheter tip **42** provides a distal tapered transition from guidewire **64** to coaxial guide catheter **12**. Once coaxial guide catheter **12** is in place, tapered inner catheter **14** is removed from the inside of coaxial guide catheter **12**.

[0071]Coaxial guide catheter **12** is now ready to accept a treatment catheter such as a stent or balloon catheter. Referring to FIG. 9, the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion. In addition, the improved back up support assists in the positioning of a treating catheter that may include a stent or balloon.

[0072]Referring to FIGS. 10 and 11, in some embodiments of coaxial guide catheter **12**, rigid portion **20** may be perforated by relief cuts **70**. Relief cuts **70** may be classed into first group **72** and second group **74**.

[0073]First group **72** may be located near to the juncture between rigid portion **20** and reinforced portion **18**. First group **72** of relief cuts **70**, are relatively closely spaced. For example, first group **72** of relief cuts **70** may be spaced approximately 0.010 inches apart. First group **72** of relief cuts **70** extends for a relatively short distance, for example, approximately 2 inches.

[0074]Second group **74** of relief cuts **70** may extend for a relatively long distance, for example, approximately 30-35 inches. Second group **74** of relief cuts **70** are spaced farther apart than first group **72**. For example, relief cuts **70** of second group **74** may be spaced approximately 0.020 inches between cuts. Referring particularly to FIG. 11, relief cuts **70** may include single cuts **76** and double cuts **78**. Single cuts **76** may include an individual linear cut, as can be seen in FIG. 11. Double cuts **78** may include two linear cuts along a single line but separated by a short section of uncut

structure. Typically, single cuts **76** and double cuts **78** are alternated along the length of rigid portion **20**. Generally, the overall length of single cut **76** may be less than the overall length of two double cuts **78**.

[0075]In an embodiment depicted in FIGS. 12-15, rigid portion includes full circumference portion **80**, greater than 180° portion **82**, and less than 180° portion **84**. Greater than 180° portion **82** may, for example, include structure forming approximately 300° of the circumference of the cylinder. Less than 180° portion may include, for example, structure forming approximately 90° of the circumference of a cylinder. Greater than 180° portion **82** may extend approximately 22-25 inches. Greater than 180° portion **82** holds tapered inner catheter **14** within rigid portion **20**.

[0076]When tapered inner catheter is inserted into coaxial guide catheter **12** greater than 180°, portion **82** grips tapered inner catheter **14** which is exposed through the opening in greater than 180° portion **82**. Thus, the overall structure of tapered inner catheter **14** along with greater than 180° portion **82** is substantially cylindrical. Accordingly, when inserted through a guide catheter **56** having a Touhey-Borst style adapter, the Touhey-Borst style adapter can still seal around rigid portion **20** and enclosed inner tapered catheter **14**.

[0077]Referring to FIG. 16, another embodiment of coaxial guide catheter assembly **10** includes coaxial guide catheter **12** and tapered inner catheter **14**. Tapered inner catheter **14** is keyed to coaxial guide catheter **12** at hub **86**.

[0078]Referring to FIGS. 17 and 18, tapered inner catheter **14** generally includes connector hub **88** and catheter tube **90**.

[0079]Connector hub **88** generally includes connector portion **92**, grip portion **94** and joining portion **96**. Connector hub **88** defines funnel portion **98** therein.

[0080]Catheter tube **90** generally includes straight portion **100**, tapered portion **102** and marker band tip **104**. Catheter tube **90** is joined to connector hub **88** at joining portion **96**. Tapered inner catheter **14** may be formed in whole or in part from low-density polyethylene plastic, for example. Other suitable materials known to the catheter arts may be used as well.

[0081]Grip portion **94** desirably includes gripping ears **106**. Gripping ears **106** may extend outwardly from grip portion **94** substantially radially and be shaped for convenient gripping by a physician.

[0082]Referring to FIGS. 19 through 21, in this embodiment, coaxial guide catheter **12** includes interrupted hub **108**, hemi-tube portion **110**, braided portion **112** and tip portion **114**.

[0083]Interrupted hub **108** defines an opening **116**, along a side thereof. Interrupted hub **108** may be substantially C-shaped or U-shaped in cross section. Opening **116** is sized so that tapered inner catheter **14** may be passed readily therethrough in a direction perpendicular to the long axes of both interrupted hub **108** and tapered inner catheter **14**. Hemi-tube portion **110** is immediately distal to interrupted hub **108**. Hemi-tube portion **110** may be formed, for example, from a metal hypo tube forming approximately 50% of the circumference of a cylinder. Hemi-tube portion **110** is aligned so that opening **116** of interrupted hub **108** is coextensive with opening **118** of hemi-tube portion **110**. Hemi-tube portion **110** is joined to braided portion **112**, for example, by adhesive, bonding or welding. The location where hemi-tube portion **110** and braided portion **112** join defines the entire circumference of a cylinder.

[0084]Braided portion **112** may be reinforced by a coil or braid, **120**. Coil or braid **120** may be formed of metal or another suitable reinforcing material.

[0085]Tip portion **114** is generally not reinforced and is substantially soft. Tip portion **114** is similarly structured to tapered inner catheter tip **42**. Tip portion **114** may include a radiopaque marker band **24**.

[0086]Beginning at the distal end of coaxial guide catheter **12**, tip portion **114** may be formed substantially of, for example, 2533 Pebax[#174] This may be followed by a section of 3533 Pebax[#174], then by a section of 5533

Pebax[#174], then by a further section of 7233 Pebax[#174]. These Pebax[#174] portions may all incorporate, for example, about 20% barium sulfate ($BaSO_{(4)}$).

[0087]In one embodiment, tip portion **114** and braided portion **112** may have an overall length together of approximately one hundred nine centimeters. Hemi-tube portion **110** and interrupted hub **108** may together have an overall length of approximately eighteen centimeters.

[0088]In this embodiment, coaxial guide catheter **12** may be lined with a PTFE liner **122**.

[0089]In operation, a guide catheter **56** is inserted into a major blood vessel in the body such as aortic arch **58** over guidewire **64** and the distal end **68** of guide catheter **56** is brought into proximity of ostium **60** of a smaller branch blood vessel, such as coronary artery **62**, that it is desired to enter. Coaxial guide catheter **12**, with tapered inner catheter **14**, is inserted through guide catheter **56** and over guidewire **64**. Guide catheter **56**, guidewire **64**, coaxial guide catheter **12**, and tapered inner catheter **14** are manipulated to insert tapered inner catheter tip **42** into the ostium **60** of the blood vessel that branches off from the major blood vessel. The bump tip **22** of coaxial guide catheter **12** is inserted with tapered inner catheter tip **42** well into ostium **60** of coronary artery **62** or other blood vessel until bump tip **22** of coaxial guide catheter **12** achieves a deep seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

[0090]When the interventional cardiology device reaches a stenosis or blockage in coronary artery **62** or another branch blood vessel, force may be applied to the interventional cardiology device catheter while reinforced portion **18** and rigid portion **20** of coaxial guide catheter **12** provide back up support. The back force that would tend to dislodge bump tip **22** from a deep seated position in the ostium in the branch blood vessel is transferred through reinforced portion **18** to rigid portion **20** of coaxial guide catheter **12**. A physician may apply a force to the proximal end of the coaxial guide catheter **12** to resist dislodging of bump tip **22** from the ostium of the branch artery.

[0091]One advantage of the present invention over prior art approaches is that the present invention does not interfere with the injection of fluids via the Y-adapter of guide catheter **56** as does the use of a smaller catheter within a larger catheter.

[0092]The present invention may be embodied in other specific forms without departing from the spirit of the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

ENGLISH-CLAIMS:

Return to Top of Patent

The invention claimed is:

1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

- -

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

- -

a device adapted for use with the guide catheter, including:

- -

structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

- -

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis rain a structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

2. The system of claim 1, wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

4. The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

5. The system of claim 1, wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

6. The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

7. The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

9. The system of claim 1, wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

10. The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

11. The system of claim 1, further comprising a kit that includes the guide catheter and the device in a common sterile package.

12. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

- -

  a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

- -

  a device adapted for use with the guide catheter, including:
  - -

    an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

  - -

    structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;

  - -

    a reinforced portion proximal to the flexible tip portion; and

  - -

    a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

13. The system of claim 12, wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

14. The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

15. The system of claim 12, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.

16. The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

17. The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.

18. The system of claim 12, wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

19. The system of claim 12, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

20. The system of claim 12, wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

21. The system of claim 20, in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

22. The system of claim 20, in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.

23. The system of claim 12, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

24. The system of claim 12, further comprising a kit that includes the guide catheter and the device in a common sterile package.

No Documents Found

Qrlgrfxp hqwhz hubtrxqg#ru#|rxu#hdufk#wkp v#

"8292850 or 8,292,850"

Fdfn#Vdyh#k#hdufk#hvkqDoumh#vfrhgzdu#|rxu#hdufk#wrlqtkqh#kzwoh#

ORU#

Fdfn#Vhdufk#VkjjhQdwuoDdqjxdjh#wxq#|rxu#hdufk#hvQdwudqDdqjzdjh#hdufk#

ORU#

Fdfn#Hgk#Vhdufk#wrih#wxqhwrqh#ch#hdufk#rup #kqgh zgh|#|rxu#hdufk#

Vzjhvwdrqv=#

- Fhfn#rq#rvwdqgdug#vhdufk#
- Uhp ryh#ry h#vhdufk#rup v#
- Xvh#p rduFrp p rq#hdufk#rup v/#ocfk#hvkrvh#ivh#qh#Vzjhvwdg#Z rugvkqg# Prqfhswlv#
- Xvh#hvvhqwldo#vhdufk#qdvh#dqjh#
- Xvh#Qhtkqhlwh hhq#rup v#ur#Mdufkturuhqh#rup #ruekhtvkhu#

| Save this Search as an Alert || Search Using Natural Language || Edit Search |

No Documents Found

Qrilgrfkp hqwkz hdwlrqg#lru#|rxu#hdufk#wkdw v#

"8292850 or 8,292,850"

Fdfn#Vdyh#k#hdufk#lv#iqDouwkhu#|rx#hdufk#lru#xq#qk#hzwrdl#

ORU#

Fdfn#Vhdufk#Vkjjhqdwuxo#Odqjxdjh#k#hu#xq#|rx#hdufk#lv#Qdwudq#Ddqjxdjh#hdufk#

OPU#D

Fdfn#Hgkd#Vhdufk#hu#khwrqkuh#hdufk#lrup#klqgkr rgh|#|rx#hdufk#

Vxjjhvwhqv=#

- Fkbfn#lru#vhdkjh#uuruv#
- Uhp ryh#ry h#vhdufk#lrup v#
- Xvh#p rdu#rp p rq#hdufk#lrup v/#ocfk#lv#k#rvh#hvhg#q#Vxjjhvwhg#Z rugv#iqg# Prqfhsw#
- Xvh#lrvv#hvwdfkjh#gdvh#dqjh#
- Xvh#P Uhfqh#hu hhq#lrup v#ru#Mdufk#uruhqh#lrup #ru#khtvkhu#

| Save this Search as an Alert || Search Using Natural Language || Edit Search |

5. Benzinga.com, May 16, 2013, 330008780, 674 words, Vascular Solutions Files Patent Infringement Complaint Against Boston Scientific.

... U.S. Patents 8,048,032, 8,142,413 and **8,292,850,** comprising 60 claims in total and having an initial filing date of May 2006, were issued by the U.S. Patent & Trademark Office to Howard Root, et. al. and assigned to ...

7. Benzinga.com, May 16, 2013, 330008898, 242 words, Vascular Solutions Issues Patent Infringement Complaint Against Boston Scientific.

U.S. Patents 8,048,032, 8,142,413 and **8,292,850,** comprising 60 claims in total and having an initial ...

10. Targeted News Service, October 30, 2012 Tuesday 12:37 PM EST, , 266 words, Vascular Solutions Assigned Patent, Targeted News Service, Alexandria, Va.

... 30 -- Vascular Solutions, Minneapolis, has been assigned a patent **(8,292,850)** developed by four co-inventors for a "
...
... G&l=50&co1=AND&d=PTXT&s1=**8,292,850**&OS=**8,292,850**&RS=**8,292,850** Written by Arpi Sharma; edited by Anand ...

United States Patent Trial and Appeals Board

US Patent Trial and Appeals Board - Alexandria
(Alexandria)

IPR2014-00763

Boston Scientific Corporation Vs. Vascular Solutions, Inc.

This case was retrieved from the court on Thursday, July 31, 2014

Header

Case Number: IPR2014-00763
Date Filed: 05/16/2014
Date Full Case Retrieved: 07/31/2014
Status: Open
Misc: Civil

[Summary] [Participants] [Proceedings]

Summary

Court Case Status: Pending
Case Type: IPR: Inter partes review
Technical Center Number: 3700
Patent Application Number: 13359059
Patent Number: 8292850

Back to Top

Participants

Litigants

Boston Scientific Corporation
Petitioner

Vascular Solutions, Inc.
PatentOwner

Back to Top

Proceedings

File Date	Details	Document Type	Paper/ Exhibit No.	Filed By	Public?
05/16/2014	U.S. Patent No. 8,292,850 B2 to Root, et al.	Exhibit	1001	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,292,850	Exhibit	1002	Petitioner	Yes
05/16/2014	Declaration of Ronald Jay Solar, Ph.D.	Exhibit	1003	Petitioner	Yes
05/16/2014	U.S. Patent No. 8,048,032 to Root, et al.	Exhibit	1004	Petitioner	Yes
05/16/2014	U.S. Patent No. 8,142,413 to Root, et al.	Exhibit	1005	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,048,032 (Part 2 of 2)	Exhibit	1006	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,048,032 (Part 1 of 2)	Exhibit	1006	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,142,413	Exhibit	1007	Petitioner	Yes
05/16/2014	Copy of a Second Petition for Inter Partes Review Filed Concurrently by Petitioner on the '850 Patent	Exhibit	1008	Petitioner	Yes
05/16/2014	U.S. Publication No. 2004/0236215 A1 to	Exhibit	1009	Petitioner	Yes

	Mihara et al.				
05/16/2014	Translation of Japanese Patent Application No. 2003-070808	Exhibit	1010	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,527,292 to Adams et al.	Exhibit	1011	Petitioner	Yes
05/16/2014	U.S. Publication No. 2007/0260219 A1 to Root et al.	Exhibit	1012	Petitioner	Yes
05/16/2014	U.S. Publication No. 2003/0195546 A1 to Solar, et al.	Exhibit	1013	Petitioner	Yes
05/16/2014	U.S. Patent No. 6,638,268 to Niazi	Exhibit	1014	Petitioner	Yes
05/16/2014	U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	Exhibit	1015	Petitioner	Yes
05/16/2014	U.S. Publication No. 2004/0127927 to Adams	Exhibit	1016	Petitioner	Yes
05/16/2014	U.S. Patent No. 6,338,725 B1 to Hermann et al.	Exhibit	1017	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,776,141 to Klein et al.	Exhibit	1018	Petitioner	Yes
05/16/2014	U.S. Patent No. 7,232,452 to Adams et al.	Exhibit	1019	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,328,472 to Steinke et al.	Exhibit	1020	Petitioner	Yes
05/16/2014	Takahashi et al.	Exhibit	1021	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,690,613 to Verbeek	Exhibit	1022	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,156,594 to Keith	Exhibit	1023	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,102,403 to Alt	Exhibit	1024	Petitioner	Yes
05/16/2014	Kucklick, Theodore R., The Medical Device RD Handbook	Exhibit	1025	Petitioner	Yes
05/16/2014	Amended Complaint filed by VSI	Exhibit	1026	Petitioner	Yes
05/16/2014	Memorandum In Support of Motion for Preliminary Injunction filed by VSI in VSI v. BSC	Exhibit	1027	Petitioner	Yes
05/16/2014	Declaration of Howard Root (Part 3 of 3)	Exhibit	1028	Petitioner	Yes
05/16/2014	Declaration of Howard Root (Part 2 of 3)	Exhibit	1028	Petitioner	Yes
05/16/2014	Declaration of Howard Root (Part 1 of 3)	Exhibit	1028	Petitioner	Yes
05/16/2014	BSC's Opposition to VSI's Motion for Preliminary Injunction	Exhibit	1029	Petitioner	Yes
05/16/2014	Non-Confidential Memorandum Opinion and Order in VSI v. BSC	Exhibit	1030	Petitioner	Yes
05/16/2014	BSC's Motion for an Interim Stay and Stay Pending Appeal	Exhibit	1031	Petitioner	Yes
05/16/2014	VSI's Opposition to BSC's Motion for an Interim Stay and Stay Pending Appeal	Exhibit	1032	Petitioner	Yes
05/16/2014	BSC's Non-Confidential Opening Brief	Exhibit	1033	Petitioner	Yes
05/16/2014	VSI's Non-Confidential Responsive Brief	Exhibit	1034	Petitioner	Yes
05/16/2014	BSC's Reply Brief	Exhibit	1035	Petitioner	Yes
05/16/2014	Transcript of Oral Argument Proceedings held on April 8, 2014	Exhibit	1036	Petitioner	Yes
05/16/2014	Federal Circuit Order Vacating Preliminary Injunction	Exhibit	1037	Petitioner	Yes
05/16/2014	Joint Claim Construction Statement filed in VSI v. BSC	Exhibit	1038	Petitioner	Yes
05/16/2014	U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	Exhibit	1039	Petitioner	Yes
05/16/2014	Monorail Piccolino Publication	Exhibit	1040	Petitioner	Yes
05/16/2014	U.S. Publication No. 2002/0165598 A1 to Wahr et al.	Exhibit	1041	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,267,958 to Buchbinder et al.	Exhibit	1042	Petitioner	Yes
05/16/2014	Petition for Inter Partes Review	Petition	1	Petitioner	Yes
05/16/2014	Power of Attorney	Power of Attorney	2	Petitioner	Yes
05/16/2014	Petitioner's Motion to Expunge	Motion	3	Petitioner	Yes
05/16/2014	Petitioner's Corrected Petition for Inter	Motion	4	Petitioner	Yes

	Partes Review				
05/28/2014	Expunged	Order	5	Board	Yes
05/28/2014	Notice of Filing Date Accorded to Petition	Notice of Filing Date Accorded to Petition	6	Board	Yes
06/05/2014	Power of Attorney	Power of Attorney	7	Potential Patent Owner	Yes
06/05/2014	Related Matters	Notice	8	Potential Patent Owner	Yes

Back to Top

United States Patent Trial and Appeals Board

US Patent Trial and Appeals Board - Alexandria
(Alexandria)

IPR2014-00762

Boston Scientific Corporation Vs. Vascular Solutions, Inc.

This case was retrieved from the court on Thursday, July 31, 2014

Header

Case Number: IPR2014-00762
Date Filed: 05/16/2014
Date Full Case Retrieved: 07/31/2014
Status: Open
Misc: Civil

[Summary] [Participants] [Proceedings]

Summary

Court Case Status: Pending
Case Type: IPR: Inter partes review
Technical Center Number: 3700
Patent Application Number: 13359059
Patent Number: 8292850

Back to Top

Participants

Litigants

Boston Scientific Corporation
Petitioner

Vascular Solutions, Inc.
PatentOwner

Back to Top

Proceedings

File Date	Details	Document Type	Paper/ Exhibit No.	Filed By	Public?
05/16/2014	U.S. Patent No. 8,292,850 B2 to Root, et al.	Exhibit	1001	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,292,850	Exhibit	1002	Petitioner	Yes
05/16/2014	Declaration of Ronald Jay Solar, Ph.D.	Exhibit	1003	Petitioner	Yes
05/16/2014	Declaration of Ronald Jay Solar, Ph.D.	Exhibit	1003	Petitioner	Yes
05/16/2014	U.S. Patent No. 8,048,032 to Root, et al.	Exhibit	1004	Petitioner	Yes
05/16/2014	U.S. Patent No. 8,142,413 to Root, et al.	Exhibit	1005	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,048,032 (Part 2 of 2)	Exhibit	1006	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,048,032 (Part 1 of 2)	Exhibit	1006	Petitioner	Yes
05/16/2014	File History for U.S. Patent No. 8,142,413	Exhibit	1007	Petitioner	Yes
05/16/2014	Copy of BSC Petition for IPR of USP 8292850 Filed Concurrently Herewith	Exhibit	1008	Petitioner	Yes
05/16/2014	U.S. Publication No. 2004/0236215 A1 to	Exhibit	1009	Petitioner	Yes

	Mihara et al.				
05/16/2014	Translation of Japanese Patent Application No. 2003-070808	Exhibit	1010	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,527,292 to Adams et al.	Exhibit	1011	Petitioner	Yes
05/16/2014	U.S. Publication No. 2007/0260219 A1 to Root et al.	Exhibit	1012	Petitioner	Yes
05/16/2014	U.S. Publication No. 2003/0195546 A1 to Solar, et al.	Exhibit	1013	Petitioner	Yes
05/16/2014	U.S. Patent No. 6,638,268 to Niazi	Exhibit	1014	Petitioner	Yes
05/16/2014	U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	Exhibit	1015	Petitioner	Yes
05/16/2014	U.S. Publication No. 2004/0127927 to Adams	Exhibit	1016	Petitioner	Yes
05/16/2014	U.S. Patent No. 6,338,725 B1 to Hermann et al.	Exhibit	1017	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,776,141 to Klein et al.	Exhibit	1018	Petitioner	Yes
05/16/2014	U.S. Patent No. 7,232,452 to Adams et al.	Exhibit	1019	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,328,472 to Steinke et al.	Exhibit	1020	Petitioner	Yes
05/16/2014	Takahashi et al. (2004)	Exhibit	1021	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,690,613 to Verbeek	Exhibit	1022	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,156,594 to Keith	Exhibit	1023	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,102,403 to Alt	Exhibit	1024	Petitioner	Yes
05/16/2014	Kucklick, Theodore R., The Medical Device R and D Handbook (2006)	Exhibit	1025	Petitioner	Yes
05/16/2014	VSI Amended Complaint, No. 13-cv-1172 (JRT-SER) (D. Minn).	Exhibit	1026	Petitioner	Yes
05/16/2014	VSI's Memo in Support of Motion for PI, 13-cv-1172 (JRT-SER) (D. Minn).	Exhibit	1027	Petitioner	Yes
05/16/2014	Root Declaration in Support of VSI's Motion for PI, 13-cv-1172 (JRT-SER) (D. Minn) (Part 1 of 3)	Exhibit	1028	Petitioner	Yes
05/16/2014	Root Declaration in Support of VSI's Motin for PI, 13-cv-1172 (JRT-SER) (D. Minn) (Part 2 of 3)	Exhibit	1028	Petitioner	Yes
05/16/2014	Root Declaration in Support of VSI's Motin for PI, 13-cv-1172 (JRT-SER) (D. Minn) (Part 3 of 3)	Exhibit	1028	Petitioner	Yes
05/16/2014	BSC Oppositon to VSI's Motion for PI, No. 13-cv-1172 (JRT-SER) (D. Minn).	Exhibit	1029	Petitioner	Yes
05/16/2014	Opinion and Order Granting PI, No. 13-cv-1172 (JRT-SER) (D. Minn).	Exhibit	1030	Petitioner	Yes
05/16/2014	BSC Motion for Stay, No. 2014-1185 (Fed. Cir).	Exhibit	1031	Petitioner	Yes
05/16/2014	VSI's Opposition to BSC's Motion for Stay, No. 2014-1185 (Fed. Cir).	Exhibit	1032	Petitioner	Yes
05/16/2014	BSI's Opening Brief, No. 2014-1185 (Fed. Cir).	Exhibit	1033	Petitioner	Yes
05/16/2014	VSI's Responsive Brief, No. 2014-1185 (Fed. Cir).	Exhibit	1034	Petitioner	Yes
05/16/2014	BSC's Reply Brief, No. 2014-1185 (Fed. Cir).	Exhibit	1035	Petitioner	Yes
05/16/2014	Transcript of Oral Argument 4-8-14	Exhibit	1036	Petitioner	Yes
05/16/2014	Federal Circuit Opinion and Judgment	Exhibit	1037	Petitioner	Yes
05/16/2014	Joint Claim Construction, No. 13-cv-1172 (JRT-SER)(D. Minn)	Exhibit	1038	Petitioner	Yes
05/16/2014	U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	Exhibit	1039	Petitioner	Yes
05/16/2014	Monorail Piccolino Publication	Exhibit	1040	Petitioner	Yes
05/16/2014	U.S. Publication No. 2002/0165598 A1 to Wahr et al.	Exhibit	1041	Petitioner	Yes
05/16/2014	U.S. Patent No. 5,267,958 to Buchbinder et	Exhibit	1042	Petitioner	Yes

	al.				
05/16/2014	Petition for Inter Partes Review	Petition	1	Petitioner	Yes
05/16/2014	Power of Attorney	Power of Attorney	2	Petitioner	Yes
05/28/2014	Notice of Filing Date Accorded to Petition	Notice of Filing Date Accorded to Petition	3	Board	Yes
06/05/2014	Power of Attorney	Power of Attorney	4	Potential Patent Owner	Yes
06/05/2014	Related Matters	Notice	5	Potential Patent Owner	Yes

Back to Top

US District Court Civil Docket

U.S. District - Minnesota
(Dmn)

0:13cv1172

Vascular Solutions, Inc. v. Boston Scientific Corporation

Date Filed: **05/16/2013**
Assigned To: **Judge John R. Tunheim**
Referred To: **Magistrate Judge Steven E. Rau**
Nature of suit: **Patent (830)**
Cause: **Patent Infringement**
Lead Docket: **None**
Other Docket: **USCA for the Federal Circuit, 14-01185**
Jurisdiction: **Federal Question**

Class Code: **CLOSED**
Closed: **08/11/2014**
Statute: **35:271**
Jury Demand: **Plaintiff**
Demand Amount: **$0**
NOS Description: **Patent**

Litigants	Attorneys
Vascular Solutions, Inc. Plaintiff	Forrest Tahdooahnippah LEAD ATTORNEY; ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA 612-492-6876 Fax: 612-486-8897 Email: Tahdooahnippah.F@dorsey.Com J Thomas Vitt LEAD ATTORNEY; ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA 612-340-2600 Fax: 612-340-8856 Email: Vitt.Thomas@dorsey.Com Shannon L Bjorklund LEAD ATTORNEY; ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA 612-492-6636 Fax: 612-677-3086 Email: Bjorklund.Shannon@dorsey.Com Heather D Redmond ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA 612-340-6343 Fax: 612-340-2868 Email: Redmond.Heather@dorsey.Com

Boston Scientific Corporation Defendant	Edward Han LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004 USA 202-942-5756 Email: Edward.Han@aporter.Com Jeffer Ali LEAD ATTORNEY; ATTORNEY TO BE NOTICED Carlson Caspers Vandenburgh Lindquist & Schuman PA 225 S 6th St Ste 4200 Mpls , MN 55402 USA 612-436-9600 Fax: 612-436-9605 Email: Jali@carlsoncaspers.Com John E Nilsson LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: John.Nilsson@aporter.Com Matthew M Wolf LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter 555 Twelfth Street Nw Washington , DC 20004 USA 202-942-5756 Email: Matthew.Wolf@aporter.Com Sara Zogg LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Sara.Zogg@aporter.Com Seth I Heller LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Seth.Heller@aporter.Com Tara Williamson LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Tara.Williamson@aporter.Com Sarah M Stensland ATTORNEY TO BE NOTICED Carlson Caspers Vandenburgh Lindquist & Schuman PA 225 S 6th St Ste 4200 Mpls , MN 55402 USA 612-436-9600 Fax: 612-436-9605 Email: Sstensland@carlsoncaspers.Com

Boston Scientific Corporation Counter Claimant	Edward Han LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004 USA 202-942-5756 Email: Edward.Han@aporter.Com Jeffer Ali LEAD ATTORNEY; ATTORNEY TO BE NOTICED Carlson Caspers Vandenburgh Lindquist & Schuman PA 225 S 6th St Ste 4200 Mpls , MN 55402 USA 612-436-9600 Fax: 612-436-9605 Email: Jali@carlsoncaspers.Com John E Nilsson LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: John.Nilsson@aporter.Com Matthew M Wolf LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter 555 Twelfth Street Nw Washington , DC 20004 USA 202-942-5756 Email: Matthew.Wolf@aporter.Com Sara Zogg LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Sara.Zogg@aporter.Com Seth I Heller LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Seth.Heller@aporter.Com Tara Williamson LEAD ATTORNEY; PRO HAC VICE; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Tara.Williamson@aporter.Com Sarah M Stensland ATTORNEY TO BE NOTICED Carlson Caspers Vandenburgh Lindquist & Schuman PA 225 S 6th St Ste 4200 Mpls , MN 55402 USA 612-436-9600 Fax: 612-436-9605

Email: Sstensland@carlsoncaspers.Com

Vascular Solutions, Inc.
Counter Defendant

J Thomas Vitt
LEAD ATTORNEY; ATTORNEY TO BE NOTICED
Dorsey & Whitney LLP
50 S 6th St Ste 1500
Mpls , MN 55402-1498
USA
612-340-2600
Fax: 612-340-8856
Email: Vitt.Thomas@dorsey.Com

Shannon L Bjorklund
LEAD ATTORNEY; ATTORNEY TO BE NOTICED
Dorsey & Whitney LLP
50 S 6th St Ste 1500
Mpls , MN 55402-1498
USA
612-492-6636
Fax: 612-677-3086
Email: Bjorklund.Shannon@dorsey.Com

Forrest Tahdooahnippah
ATTORNEY TO BE NOTICED
Dorsey & Whitney LLP
50 S 6th St Ste 1500
Mpls , MN 55402-1498
USA
612-492-6876
Fax: 612-486-8897
Email: Tahdooahnippah.F@dorsey.Com

Heather D Redmond
ATTORNEY TO BE NOTICED
Dorsey & Whitney LLP
50 S 6th St Ste 1500
Mpls , MN 55402-1498
USA
612-340-6343
Fax: 612-340-2868
Email: Redmond.Heather@dorsey.Com

Boston Scientific Corporation
Counter Claimant

Edward Han
LEAD ATTORNEY; ATTORNEY TO BE NOTICED
Arnold & Porter LLP
555 Twelfth Street Nw
Washington , DC 20004
USA
202-942-5756
Email: Edward.Han@aporter.Com

Jeffer Ali
LEAD ATTORNEY; ATTORNEY TO BE NOTICED
Carlson Caspers Vandenburgh Lindquist & Schuman PA
225 S 6th St Ste 4200
Mpls , MN 55402
USA
612-436-9600
Fax: 612-436-9605
Email: Jali@carlsoncaspers.Com

John E Nilsson
LEAD ATTORNEY; ATTORNEY TO BE NOTICED
Arnold & Porter LLP
555 Twelfth Street Nw
Washington , DC 20004-1206
USA
202-942-5000
Email: John.Nilsson@aporter.Com

	Matthew M Wolf LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter 555 Twelfth Street Nw Washington , DC 20004 USA 202-942-5756 Email: Matthew.Wolf@aporter.Com Sara Zogg LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Sara.Zogg@aporter.Com Seth I Heller LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Seth.Heller@aporter.Com Tara Williamson LEAD ATTORNEY; ATTORNEY TO BE NOTICED Arnold & Porter LLP 555 Twelfth Street Nw Washington , DC 20004-1206 USA 202-942-5000 Email: Tara.Williamson@aporter.Com Sarah M Stensland ATTORNEY TO BE NOTICED Carlson Caspers Vandenburgh Lindquist & Schuman PA 225 S 6th St Ste 4200 Mpls , MN 55402 USA 612-436-9600 Fax: 612-436-9605 Email: Sstensland@carlsoncaspers.Com
Vascular Solutions, Inc. Counter Defendant	Forrest Tahdooahnippah LEAD ATTORNEY; ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA 612-492-6876 Fax: 612-486-8897 Email: Tahdooahnippah.F@dorsey.Com J Thomas Vitt LEAD ATTORNEY; ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA 612-340-2600 Fax: 612-340-8856 Email: Vitt.Thomas@dorsey.Com Shannon L Bjorklund LEAD ATTORNEY; ATTORNEY TO BE NOTICED Dorsey & Whitney LLP 50 S 6th St Ste 1500 Mpls , MN 55402-1498 USA

612-492-6636
Fax: 612-677-3086
Email:Bjorklund.Shannon@dorsey.Com

Heather D Redmond
ATTORNEY TO BE NOTICED
Dorsey & Whitney LLP
50 S 6th St Ste 1500
Mpls , MN 55402-1498
USA
612-340-6343
Fax: 612-340-2868
Email:Redmond.Heather@dorsey.Com

Date	#	Proceeding Text	Source
05/16/2013	1	COMPLAINT against Boston Scientific Corporation. (Filing fee $ 400 receipt number 0864-3558731.) Filed by Vascular Solutions, Inc.. Filer requests summons issued. (Attachments: # 1 Exhibit(s) A-C, # 2 Civil Cover Sheet) (Redmond, Heather) (Entered: 05/16/2013)	
05/16/2013	2	RULE 7.1 DISCLOSURE STATEMENT. There is no parent corporation, publicly held corporation or wholly-owned subsidiary to report for Plaintiff Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 05/16/2013)	
05/16/2013	3	TEXT-ONLY ENTRY. CLERK'S NOTICE OF INITIAL CASE ASSIGNMENT. Case assigned to Judge John R. Tunheim per Patent Deck referred to Magistrate Judge Steven E. Rau. Please use case number 13cv1172 (JRT/SER). (jz) (Entered: 05/16/2013)	
05/16/2013	4	Summons Issued as to Boston Scientific Corporation. (jz) (Entered: 05/16/2013)	
05/28/2013	5	SUMMONS Returned Executed by Vascular Solutions, Inc.. Boston Scientific Corporation served on 5/17/2013, answer due 6/7/2013. (Redmond, Heather) (Entered: 05/28/2013)	
05/28/2013	6	AMENDED COMPLAINT against Boston Scientific Corporation. Filed by Vascular Solutions, Inc.. No summons requested. (Attachments: # 1 Exhibit(s) A-E) (Redmond, Heather) (Entered: 05/28/2013)	
05/31/2013	7	AFFIDAVIT of Service by Vascular Solutions, Inc. re 6 Amended Complaint (Redmond, Heather) (Entered: 05/31/2013)	
06/10/2013	8	MOTION for Preliminary Injunction by Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 06/10/2013)	
06/10/2013	9	NOTICE OF HEARING ON MOTION 8 MOTION for Preliminary Injunction : at date and time to be determined. (Redmond, Heather) (Entered: 06/10/2013)	
06/10/2013	10	MEET and CONFER STATEMENT re 8 Motion for Preliminary Injunction filed by Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 06/10/2013)	
06/10/2013	11	MEMORANDUM in Support re 8 MOTION for Preliminary Injunction filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Redmond, Heather) (Entered: 06/10/2013)	
06/10/2013	12	Declaration of Howard Root in Support of 8 MOTION for Preliminary Injunction filed by Vascular Solutions, Inc.. (Attachments: # 1 Exhibit(s) 1-5, # 2 Exhibit(s) 6-7, # 3 Exhibit(s) 8, # 4 Exhibit(s) 9-13, # 5 Exhibit(s) 14-15, # 6 Exhibit(s) 16-22, # 7 Exhibit(s) 23-25, # 8 Exhibit(s) 26-29, # 9 Exhibit(s) 30-33, # 10 Exhibit(s) 34, # 11 Exhibit(s) 35-41)(Redmond, Heather) (Entered: 06/10/2013)	
06/10/2013	13	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 8 MOTION for Preliminary Injunction and Certificate of Service on Non-ECF Participant (Redmond, Heather) (Entered: 06/10/2013)	
06/11/2013	14	STIPULATION for Extension of Time to Answer or Otherwise Plead for Defendant Boston Scientific Corporation by Boston Scientific Corporation, Vascular Solutions, Inc.. (Stensland, Sarah) (Entered: 06/11/2013)	
06/11/2013	15	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Boston Scientific Corporation re 14 Stipulation for Extension of Time to Answer or Otherwise Plead for Defendant Boston Scientific Corporation (Stensland, Sarah) (Entered: 06/11/2013)	
06/13/2013	16	STIPULATION Regarding Schedule for Limited Discovery and Briefing Schedule for Plaintiff's Motion for Preliminary Injunction by Vascular Solutions, Inc.. (Bjorklund, Shannon) (Entered: 06/13/2013)	
06/13/2013	17	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 16 Stipulation (Bjorklund, Shannon) (Entered: 06/13/2013)	
06/14/2013	18	DOCUMENT FILED IN ERROR. Replaced by Document number 25. MOTION for Admission Pro Hac Vice for Attorney Matthew M. Wolf. Filing fee $ 100, receipt number 0864-3592676 by	

		Boston Scientific Corporation. (Ali, Jeffer) Modified on 6/18/2013 (MAP). Modified on 6/18/2013 (MAP). (Entered: 06/14/2013)
06/14/2013	19	MOTION for Admission Pro Hac Vice for Attorney Sara Zogg. Filing fee $ 100, receipt number 0864-3592686 by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 06/14/2013)
06/14/2013	20	MOTION for Admission Pro Hac Vice for Attorney Edward Han. Filing fee $ 100, receipt number 0864-3592691 by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 06/14/2013)
06/14/2013	21	Document Filed in Error. MOTION for Admission Pro Hac Vice for Attorney John E. Nilsson. Filing fee $ 100, receipt number 0864-3592694 by Boston Scientific Corporation. (Ali, Jeffer) Modified on 6/18/2013 (MAP). (Entered: 06/14/2013)
06/14/2013	22	TEXT ONLY ENTRY. ORDER granting 20 Motion for Admission Pro Hac Vice of Attorney Edward Han for Boston Scientific Corporation. Approved by Magistrate Judge Steven E. Rau on 6/14/2013. (MAP) (Entered: 06/14/2013)
06/14/2013	23	ORDER: Pursuant to the Joint Stipulation For Extension of Time to Answer or Otherwise Plead for Defendant Boston Scientific Corporation (ECF No. 14), Defendant Boston Scientific Corporation is hereby granted until July 11, 2013 to answer, or otherwise plead in response to, the Amended Complaint. Signed by Magistrate Judge Steven E. Rau on 06/14/2013. (MMP) (Entered: 06/14/2013)
06/17/2013	24	ORDER re 16 Stipulation Regarding Schedule for Limited Discovery and Briefing Schedule for Plaintiffs Motion for Preliminary Injunction. Signed by Judge John R. Tunheim on June 17, 2013. (HAM) (Entered: 06/17/2013)
06/18/2013	25	MOTION for Admission Pro Hac Vice for Attorney Matthew M. Wolf. Filing fee $ 100, receipt number 0864-3595236 by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 06/18/2013)
06/18/2013	26	TEXT ONLY ENTRY. ORDER granting 19 Motion for Admission Pro Hac Vice of Attorney Sara Zogg for Boston Scientific Corporation. Approved by Magistrate Judge Steven E. Rau on 6/18/2013. (MAP) (Entered: 06/18/2013)
06/18/2013	27	TEXT ONLY ENTRY. ORDER granting 25 Motion for Admission Pro Hac Vice of Attorney Matthew M Wolf for Boston Scientific Corporation. Approved by Magistrate Judge Steven E. Rau on 6/18/2013. (MAP) (Entered: 06/18/2013)
06/19/2013	28	RULE 7.1 DISCLOSURE STATEMENT. There is no parent corporation, publicly held corporation or wholly-owned subsidiary to report for Defendant Boston Scientific Corporation. (Stensland, Sarah) (Entered: 06/19/2013)
07/08/2013	29	RESPONSE in Opposition re 8 MOTION for Preliminary Injunction PLACEHOLDER filed by Boston Scientific Corporation. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Stensland, Sarah)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 7/8/13 LGL Modified on 7/9/2013 (LGL). (Entered: 07/08/2013)
07/08/2013	30	Declaration of Sarah M. Stensland in Support of 29 Response in Opposition to Motion filed by Boston Scientific Corporation. (Attachments: # 1 Exhibit(s) 1 and 3-9, # 2 Exhibit(s) 2 PLACEHOLDER)(Stensland, Sarah)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 7/8/13 LGL Modified on 7/9/2013 (LGL). (Entered: 07/08/2013)
07/08/2013	31	Declaration of Anthony C. Vrba in Support of 29 Response in Opposition to Motion filed by Boston Scientific Corporation. (Attachments: # 1 Exhibit(s) A-B, # 2 Exhibit(s) C-I) (Stensland, Sarah) (Entered: 07/08/2013)
07/08/2013	32	Declaration of Tony J. DeMartini, M.D. in Support of 29 Response in Opposition to Motion filed by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 07/08/2013)
07/08/2013	33	Declaration of Sam Rasmusen in Support of 29 Response in Opposition to Motion filed by Boston Scientific Corporation. (Stensland, Sarah)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 7/8/13 LGL Modified on 7/9/2013 (LGL). (Entered: 07/08/2013)
07/08/2013	34	CERTIFICATE OF SERVICE by Boston Scientific Corporation of UNDER SEAL documents (Stensland, Sarah) (Entered: 07/08/2013)
07/11/2013	35	ANSWER to Amended Complaint and, COUNTERCLAIM against Vascular Solutions, Inc.. by Boston Scientific Corporation. (Attachments: # 1 Exhibit(s) A) (Stensland, Sarah) (Entered: 07/11/2013)
07/11/2013	36	STIPULATION (Joint) Regarding Amended Limited Discovery and Briefing Schedule for Plaintiff's Motion for Preliminary Injunction by Boston Scientific Corporation, Vascular Solutions, Inc.. (Bjorklund, Shannon) (Entered: 07/11/2013)
07/11/2013	37	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 36 Stipulation (Bjorklund, Shannon) (Entered: 07/11/2013)
07/12/2013	38	TEXT ONLY ENTRY: Notice re: Non-Admitted AttorneyWe have received documents listing John Nilsson as counsel of record. If he or she wishes to be listed as an attorney of record in this case, he or she must be admitted to the bar of the U.S. District Court of Minnesota in accordance with Local Rule 83.5 (a), (b) and (c) or temporarily admitted pro hac vice in accordance with Local Rule 83.5 (d) or (e).For more admissions information and forms, please see the Attorney Forms Section of the courts website at

		href=http://www.mnd.uscourts.gov/FORMS/court_forms.shtml#attorneyforms. (jz) (Entered: 07/12/2013)
07/16/2013	39	ORDER adopting 36 the Joint Stipulation Regarding Amended Limited Discovery and Briefing Schedule. The Court hereby orders: 1. Vascular Solutions, Inc. will take the depositions of Boston's declarants by July 18, 2013. 2. Vascular Solutions, Inc.s reply brief shall be due on July 24, 2013. 3. The other deadlines and requirements in the Courts order dated June 17, 2013 shall remain in effect. Signed by Judge John R. Tunheim on July 16, 2013. (haz) (Entered: 07/16/2013)
07/19/2013	40	LETTER to Request Permission to Exceed Word/Line Limits for filing Due July 24. (Bjorklund, Shannon) (Entered: 07/19/2013)
07/22/2013	41	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation . (Attachments: # 1 Exhibit(s) A, # 2 Exhibit(s) B)(Ali, Jeffer) (Entered: 07/22/2013)
07/23/2013	42	ORDER granting in part 40 the Request to Exceed Word/Line Limits filed by Vascular Solutions, Inc. Signed by Judge John R. Tunheim on July 23, 2013. (haz) (Entered: 07/23/2013)
07/24/2013	43	REPLY re 8 MOTION for Preliminary Injunction filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate, # 2 Placeholder for Filed Under Seal Version of Plaintiff's Reply Memorandum)(Redmond, Heather) SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 7/24/13 LGL Modified on 7/25/2013 (LGL). (Entered: 07/24/2013)
07/24/2013	44	Second Declaration of Howard Root in Support of 8 MOTION for Preliminary Injunction filed by Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 07/24/2013)
07/24/2013	45	Declaration of Heather D. Redmond in Support of 8 MOTION for Preliminary Injunction filed by Vascular Solutions, Inc.. (Attachments: # 1 Exhibit(s) A-G)(Redmond, Heather)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 7/24/13 LGL Modified on 7/25/2013 (LGL). (Entered: 07/24/2013)
07/24/2013	46	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 8 MOTION for Preliminary Injunction (Redmond, Heather) (Entered: 07/24/2013)
07/26/2013	47	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation . (Ali, Jeffer) (Entered: 07/26/2013)
07/30/2013	48	AMENDED NOTICE of Hearing on Motion: 8 MOTION for Preliminary Injunction : Motion Hearing set for 8/27/2013 02:00 PM in Courtroom 13E (MPLS) before Judge John R. Tunheim. (Bjorklund, Shannon) (Entered: 07/30/2013)
07/31/2013	49	STIPULATION to Extend Time to Respond to Counterclaims by Boston Scientific Corporation, Vascular Solutions, Inc.. (Bjorklund, Shannon) (Entered: 07/31/2013)
07/31/2013	50	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 49 Stipulation to Extend Time to Respond to Counterclaims (Bjorklund, Shannon) (Entered: 07/31/2013)
08/05/2013	51	ORDER re 49 Stipulation filed by Boston Scientific Corporation, Vascular Solutions, Inc. Plaintiff/Counterclaim-Defendant Vascular Solutions, Inc. is hereby granted until August 22, 2013, to answer or otherwise respond to the counterclaims brought by Boston Scientific Corporation. Signed by Magistrate Judge Steven E. Rau on 8/5/13. (GMW) (Entered: 08/05/2013)
08/07/2013	52	MOTION for Admission Pro Hac Vice for Attorney John E. Nilsson. Filing fee $ 100, receipt number 0864-3653985 by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 08/07/2013)
08/08/2013	53	TEXT ONLY ENTRY: ORDER granting 52 Motion for Admission Pro Hac Vice of Attorney John E Nilsson for Boston Scientific Corporation. Approved by Magistrate Judge Steven E. Rau on 08/08/2013. (KMM) (Entered: 08/08/2013)
08/22/2013	54	REPLY to Counterclaim by Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 08/22/2013)
08/26/2013	55	STIPULATION for Protective Order by Boston Scientific Corporation, Vascular Solutions, Inc.. (Bjorklund, Shannon) (Entered: 08/26/2013)
08/26/2013	56	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 55 Stipulation (Bjorklund, Shannon) (Entered: 08/26/2013)
08/27/2013	57	ORDER/NOTICE OF PRETRIAL CONFERENCE: A Pretrial Conference set for 9/18/2013 11:00 AM in Judge's Chambers, Suite 334 (STP) before Magistrate Judge Steven E. Rau. Signed by Magistrate Judge Steven E. Rau on 08/27/2013. (Attachments: # 1 Consent Form)(las) (Entered: 08/27/2013)
08/27/2013	58	Minute Entry for proceedings held before Judge John R. Tunheim: Motion Hearing held on 8/27/2013 re 8 MOTION for Preliminary Injunction filed by Vascular Solutions, Inc. Motion taken under advisement. Written order forthcoming. (Court Reporter Kristine Mousseau) (HAZ) (Entered: 08/28/2013)
09/05/2013	59	STIPULATION for Protective Order by Boston Scientific Corporation, Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 09/05/2013)

09/05/2013	60	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 59 Stipulation (Redmond, Heather) (Entered: 09/05/2013)
09/06/2013	61	PROTECTIVE ORDER. Signed by Magistrate Judge Steven E. Rau on 9/6/13. (jam) (Entered: 09/06/2013)
09/09/2013	62	TEXT ONLY ENTRY: NOTICE of RESCHEDULING of Hearing: 57 ORDER/NOTICE OF PRETRIAL CONFERENCE: A Pretrial Conference set for 9/18/2013 11:00 AM has been RESCHEDULED to 10/2/2013 11:30 AM in Judge's Chambers, Suite 334 (STP) before Magistrate Judge Steven E. Rau. (MME) (Entered: 09/09/2013)
09/09/2013	63	EXHIBIT 41 re 12 Declaration in Support, of Plaintiff's Motion for Preliminary Injunction by Vascular Solutions, Inc.. (Redmond, Heather)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 9/9/13 LGL Modified on 9/10/2013 (LGL). Modified on 9/10/2013 (kt). (Entered: 09/09/2013)
09/09/2013	64	CERTIFICATE OF SERVICE by Vascular Solutions, Inc. re 63 Exhibit (Redmond, Heather) (Entered: 09/09/2013)
09/10/2013	65	DOCUMENT FILED IN ERROR--MOTION for Admission Pro Hac Vice for Attorney Tara Williamson. Filing fee $ 100, receipt number 0864-3690406 by Boston Scientific Corporation. (Ali, Jeffer) Modified on 9/18/2013 (MAP). (Entered: 09/10/2013)
09/20/2013	66	MOTION for Admission Pro Hac Vice for Attorney Seth I. Heller. Filing fee $ 100, receipt number 0864-3703840 by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 09/20/2013)
09/25/2013	67	TEXT ONLY ENTRY: NOTICE of Resetting of Hearing: 62 TEXT ONLY ENTRY: NOTICE of RESCHEDULING of Hearing: Pretrial Conference set for 10/2/2013 11:30 AM has been RESCHEDULED to 10/3/2013 08:30 AM in Judge's Chambers, Suite 334 (STP) before Magistrate Judge Steven E. Rau. (MME) (Entered: 09/25/2013)
09/25/2013	68	REPORT of Rule 26(f) Planning Meeting by Boston Scientific Corporation, Vascular Solutions, Inc..(Redmond, Heather) (Entered: 09/25/2013)
09/26/2013	69	TEXT ONLY ENTRY: ORDER granting 66 Motion for Admission Pro Hac Vice of Attorney Seth I Heller for Boston Scientific Corporation. Approved by Magistrate Judge Steven E. Rau on 09/26/2013. (MAP) (Entered: 09/26/2013)
10/03/2013	70	Minute Entry for proceedings held before Magistrate Judge Steven E. Rau: Pretrial Scheduling Conference held on 10/3/2013. Scheduling order will be issued. (GMW) (Entered: 10/03/2013)
10/09/2013	71	PRETRIAL SCHEDULING ORDER: Amended Pleadings due by 3/28/2014. Discovery due by 7/15/2014. Motions (non-disp) due 7/29/2014. Motions (disp) due by 11/14/2014. Ready for trial due by 3/16/2014. Signed by Magistrate Judge Steven E. Rau on 10/09/2013. (MMP) (Entered: 10/09/2013)
10/15/2013	72	LETTER TO MAGISTRATE JUDGE by Boston Scientific Corporation, Vascular Solutions, Inc. proposing revisions to Pretrial Scheduling Order. (Attachments: # 1 Exhibit(s) A, # 2 Exhibit (s) B)(Ali, Jeffer) (Entered: 10/15/2013)
10/16/2013	73	MOTION for Admission Pro Hac Vice for Attorney Tara Williamson. Filing fee $ 100, receipt number 0864-3732267 by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 10/16/2013)
10/16/2013	74	TEXT ONLY ENTRY: ORDER granting 73 Motion for Admission Pro Hac Vice of Attorney Tara Williamson for Boston Scientific Corporation. Approved by Magistrate Judge Steven E. Rau on 10/16/2013. (MAP) (Entered: 10/16/2013)
10/17/2013	75	AMENDED PRETRIAL SCHEDULING ORDER: Amended Pleadings due by 3/28/2014. Discovery due by 7/15/2014. Motions (non-disp) due 7/29/2014. Motions (disp) due by 11/14/2014. Ready for trial due by 3/16/2015. Signed by Magistrate Judge Steven E. Rau on 10/16/2013. (MMP) (Entered: 10/17/2013)
12/09/2013	76	SEALED ORDER. Signed by Judge John R. Tunheim on 12/9/13. (kt) CC: Counsel of record. (kt) (Entered: 12/09/2013)
12/11/2013	77	NOTICE by Vascular Solutions, Inc. of Posting Bond (Attachments: # 1 Exhibit(s) A) (Redmond, Heather) (Entered: 12/11/2013)
12/11/2013	78	LETTER TO DISTRICT JUDGE by Vascular Solutions, Inc. Regarding Unsealing Order. (Redmond, Heather) (Entered: 12/11/2013)
12/12/2013	79	LETTER to Request Permission to File Motion to Reconsider . (Ali, Jeffer) (Entered: 12/12/2013)
12/12/2013	80	SEALED ORDER. Signed by Judge John R. Tunheim on 12/12/13. (kt) CC: Counsel of record. (Entered: 12/12/2013)
12/13/2013	81	LETTER RESPONSE re 79 Letter to Request Permission to File Motion to Reconsider. (Redmond, Heather) (Entered: 12/13/2013)
12/19/2013	82	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation . (Attachments: # 1 Exhibit(s) A)

		(Ali, Jeffer) (Entered: 12/19/2013)
12/23/2013	83	ORDER denying Request for Permission to File Motion to Reconsider filed by Boston Scientific Corporation (Written Opinion). Signed by Judge John R. Tunheim on December 23, 2013. (HAZ) (Entered: 12/23/2013)
12/26/2013	84	NOTICE OF APPEAL TO FEDERAL CIRCUIT as to 76 Order on Motion for Preliminary Injunction by Boston Scientific Corporation. Filing fee $ 505, receipt number 0864-3813341. (Williamson, Tara) (Entered: 12/26/2013)
12/27/2013	85	NOTICE OF FEDERAL APPEAL TRANSMITTAL re 84 Notice of Appeal to Federal Circuit. (Attachments: # 1 Listed Attorneys)(jam) (Entered: 12/27/2013)
12/27/2013	86	Federal Circuit Case Number 14-1185 for 84 Notice of Appeal to Federal Circuit filed by Boston Scientific Corporation. (akl) (Entered: 01/02/2014)
01/08/2014	87	STATUS REPORT Joint by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 01/08/2014)
01/08/2014	88	DOCUMENT FILED IN ERROR. NOTICE of Filing of Official Transcript. This filing has 1 transcript (s) associated with it. (KM) Modified on 1/9/2014 (GMW). (Entered: 01/08/2014)
01/08/2014	89	TRANSCRIPT of Motions Hearing held on 08/27/2013 before Judge John R. Tunheim. (88 pages). Court Reporter: Kristine Mousseau (E-mail: Kristine_Mousseau@mnd.uscourts.gov. Telephone: (612) 664-5106). Redaction Request due 1/29/2014. Redacted Transcript Deadline set for 2/10/2014. Release of Transcript Restriction set for 4/8/2014. For information on redaction procedures, please review Local Rule 5.5. (KM) (Entered: 01/08/2014)
01/08/2014	91	ORDER from the United States Court of Appeals for the Federal Circuit: Boston Scientific's motion for an "interim stay" is denied. The motion for a stay pending appeal shall be considered in due course. (akl) (Entered: 01/09/2014)
01/09/2014	90	NOTICE of Filing of Official Transcript (re 89 Transcript). This filing has 1 transcript(s) associated with it. (KM) Modified on 1/9/2014 (GMW). (Entered: 01/09/2014)
01/09/2014	92	NOTICE by Boston Scientific Corporation of Transcript Purchase Order (Stensland, Sarah) (Entered: 01/09/2014)
02/03/2014	93	MOTION for Bond to Modify by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 02/03/2014)
02/03/2014	94	NOTICE OF HEARING ON MOTION 93 MOTION for Bond to Modify : at date and time to be determined. (Ali, Jeffer) (Entered: 02/03/2014)
02/03/2014	95	MEMORANDUM in Support re 93 MOTION for Bond to Modify , PLACEHOLDER filed by Boston Scientific Corporation. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate) (Ali, Jeffer)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 2/3/14LGL Modified on 2/4/2014 (LGL). (Entered: 02/03/2014)
02/03/2014	96	Declaration of Seth I. Heller in Support of 93 MOTION for Bond to Modify filed by Boston Scientific Corporation. (Attachments: # 1 Exhibit(s) 1 PLACEHOLDER)(Ali, Jeffer)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 2/3/14LGL Modified on 2/4/2014 (LGL). (Entered: 02/03/2014)
02/03/2014	97	Declaration of Todd Bethel in Support of 93 MOTION for Bond to Modify filed by Boston Scientific Corporation. (Ali, Jeffer)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 2/3/14LGL Modified on 2/4/2014 (LGL). (Entered: 02/03/2014)
02/03/2014	98	MEET and CONFER STATEMENT re 93 Motion for Bond filed by Boston Scientific Corporation. (Ali, Jeffer) (Entered: 02/03/2014)
02/03/2014	99	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Boston Scientific Corporation re 93 MOTION for Bond to Modify (Ali, Jeffer) (Entered: 02/03/2014)
02/03/2014	100	CERTIFICATE OF SERVICE by Boston Scientific Corporation re 93 MOTION for Bond to Modify of Sealed Documents (Ali, Jeffer) (Entered: 02/03/2014)
02/07/2014	101	STIPULATION For Extension of Time to Respond to Motion to Modify Bond by Vascular Solutions, Inc.. Jointly Signed by Vascular Solutions, Inc. and Boston Scientific Corporation. (Attachments: # 1 Certificate of Service)(Tahdooahnippah, Forrest) (Entered: 02/07/2014)
02/07/2014	102	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 101 Stipulation, for Extension of Time to Respond to Motion to Modify Bond (Tahdooahnippah, Forrest) (Entered: 02/07/2014)
02/07/2014	103	ORDER granting 101 Stipulation, filed by Vascular Solutions, Inc.. Signed by Judge John R. Tunheim on February 7, 2014. (HAZ) (Entered: 02/07/2014)
02/11/2014	104	STIPULATION to Extend Time for Filing Joint Claim Construction Statement by Vascular Solutions, Inc.. Jointly Signed by Boston Scientific Corporation and Boston Scientific Scimed, Inc.. (Redmond, Heather) (Entered: 02/11/2014)
02/11/2014	105	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 104 Stipulation (Redmond, Heather) (Entered: 02/11/2014)

02/13/2014	106	ORDER GRANTING EXTENSION OF TIME TO FILE JOINT CLAIM CONSTRUCTION STATEMENT: Based on the Stipulation of the Parties, IT IS HEREBY ORDERED THAT Plaintiff/Counter-Defendant Vascular Solutions, Inc., Defendant/Counterclaim- Plaintiff Boston Scientific Corporation and Counter-Plaintiff Boston Scientific Scimed, Inc., shall have until February 21, 2014 to file their Joint Claim Construction Statement. Signed by Magistrate Judge Steven E. Rau on 02/13/2014. (MMP) (Entered: 02/13/2014)
02/18/2014	107	MEMORANDUM in Opposition re 93 MOTION for Bond to Modify filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Tahdooahnippah, Forrest)SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 2/18/14LGL Modified on 2/18/2014 (LGL). (Entered: 02/18/2014)
02/18/2014	108	DECLARATION of J. Thomas Vitt in Opposition to 107 Memorandum in Opposition to Motion filed by Vascular Solutions, Inc.. (Attachments: # 1 Exhibit 1)(Tahdooahnippah, Forrest) Modified on 2/18/2014 (jz). (Entered: 02/18/2014)
02/18/2014	109	EXHIBIT re 108 Declaration in Opposition, 107 Memorandum in Opposition to Motion to Modify Bond by Vascular Solutions, Inc. filed by Vascular Solutions, Inc.. (Tahdooahnippah, Forrest) SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 2/18/14LGL Modified on 2/18/2014 (LGL). (Entered: 02/18/2014)
02/19/2014	110	CERTIFICATE OF SERVICE by Vascular Solutions, Inc. re 107 Memorandum in Opposition to Motion, 109 Exhibit, (Tahdooahnippah, Forrest) (Entered: 02/19/2014)
02/20/2014	111	LETTER TO MAGISTRATE JUDGE by Vascular Solutions, Inc. Requesting IDR. (Redmond, Heather) (Entered: 02/20/2014)
02/21/2014	112	DOCUMENT FILED IN ERROR: LETTER TO DISTRICT JUDGE by Boston Scientific Corporation Requesting Permission to File Reply Brief. (Attachments: # 1 Exhibit(s))(Heller, Seth) DOCUMENT FILED IN ERROR-DOCUMENT RESTRICTED AS DOCUMENT SHOULD HAVE BEEN FILED UNDER SEAL. Modified on 2/24/2014 (TSS). (Entered: 02/21/2014)
02/21/2014	113	Joint Claim Construction Statement by Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 02/21/2014)
02/24/2014	114	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation . (Stensland, Sarah) (Entered: 02/24/2014)
02/27/2014	115	ORDER re 114 Letter to District Judge filed by Boston Scientific Corporation granting permission to file reply. Signed by Judge John R. Tunheim on February 27, 2014. (HAZ) (Entered: 02/27/2014)
02/27/2014	116	REPLY re 93 MOTION for Bond to Modify PLACEHOLDER filed by Boston Scientific Corporation. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Stensland, Sarah) SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 2/27/14LGL Modified on 2/28/2014 (LGL). (Entered: 02/27/2014)
02/27/2014	117	CERTIFICATE OF SERVICE by Boston Scientific Corporation re 116 Reply of Sealed Document (Stensland, Sarah) (Entered: 02/27/2014)
04/14/2014	118	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation Requesting Leave to Amend Its Prior Art Statement. (Heller, Seth) (Entered: 04/14/2014)
04/15/2014	119	Opinion of USCA as to 84 Notice of Appeal to Federal Circuit(Judge Moore, Judge Plager, Judge Chen): For these reasons, we vacate the preliminary injunction. (AKL) (Entered: 04/15/2014)
04/15/2014	120	USCA JUDGMENT as to 84 Notice of Appeal to Federal Circuit (received electronically from COA) (AKL) (Entered: 04/15/2014)
04/24/2014	121	ORDER re 118 Letter to District Judge filed by Boston Scientific Corporation. Signed by Judge John R. Tunheim on April 23, 2014. (HAZ) (Entered: 04/24/2014)
05/02/2014	122	Amended MOTION for Bond to Modify by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	123	NOTICE OF HEARING ON MOTION 122 Amended MOTION for Bond to Modify : at date and time to be determined. (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	124	MEMORANDUM in Support re 122 Amended MOTION for Bond to Modify PLACEHOLDER filed by Boston Scientific Corporation. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate) SEALED DOCUMENT RECEIVED IN CLERKS OFFICE ON 5/2/14. (Stensland, Sarah) Modified on 5/5/2014 (AKL). (Entered: 05/02/2014)
05/02/2014	125	MEET and CONFER STATEMENT re 122 Motion for Bond filed by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	126	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Boston Scientific Corporation re 122 Amended MOTION for Bond to Modify (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	127	CERTIFICATE OF SERVICE by Boston Scientific Corporation re 122 Amended MOTION for Bond to Modify for Under Seal document (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	128	MOTION to Alter/Amend/Supplement Pleadings 35 Answer to Amended Complaint,

		Counterclaim by Boston Scientific Corporation. (Attachments: # 1 Exhibit(s) 1, # 2 Exhibit(s) 2)(Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	129	NOTICE OF HEARING ON MOTION 128 MOTION to Alter/Amend/Supplement Pleadings 35 Answer to Amended Complaint, Counterclaim : Motion Hearing set for 5/22/2014 09:00 AM in Courtroom 3C (STP) before Magistrate Judge Steven E. Rau. (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	130	MEMORANDUM in Support re 128 MOTION to Alter/Amend/Supplement Pleadings 35 Answer to Amended Complaint, Counterclaim filed by Boston Scientific Corporation. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	131	MEET and CONFER STATEMENT re 128 Motion to Alter/Amend/Supplement Pleadings filed by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 05/02/2014)
05/02/2014	132	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Boston Scientific Corporation re 128 MOTION to Alter/Amend/Supplement Pleadings 35 Answer to Amended Complaint, Counterclaim (Stensland, Sarah) (Entered: 05/02/2014)
05/12/2014	133	MEMORANDUM in Opposition re 122 Amended MOTION for Bond to Modify filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate) (Redmond, Heather) (Entered: 05/12/2014)
05/12/2014	134	MEMORANDUM in Opposition re 128 MOTION to Alter/Amend/Supplement Pleadings 35 Answer to Amended Complaint, Counterclaim filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Redmond, Heather) (Entered: 05/12/2014)
05/19/2014	135	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation Requesting Permission to File a Reply Brief. (Stensland, Sarah) (Entered: 05/19/2014)
05/19/2014	136	LETTER TO MAGISTRATE JUDGE by Vascular Solutions, Inc. in Response to Request for Reply. (Redmond, Heather) (Entered: 05/19/2014)
05/20/2014	137	TEXT ONLY ENTRY: Defendant Boston Scientific Corporation's request to file a reply brief [Doc. No. 135] is DENIED. The issue of additional briefing will be discussed at the May 22, 2014 hearing on the Motion to Amend [Doc. No. 128].(EKP) (Entered: 05/20/2014)
05/22/2014	138	Minute Entry: for proceedings held before Magistrate Judge Steven E. Rau: Motion Hearing held on 5/22/2014. Hearing on Defendant's Motion to Amend the Pleadings. Doc. No. 128 . A written order will be issued. (MMP) (Entered: 05/22/2014)
05/22/2014	139	MANDATE of USCA as to 84 Notice of Appeal to Federal Circuit filed by Boston Scientific Corporation (received electronically from COA) (AKL) (Entered: 05/22/2014)
05/27/2014	140	ORDER granting 128 Motion to Alter/Amend/Supplement Pleadings. Signed by Magistrate Judge Steven E. Rau on 5/27/14. (AKL) (Entered: 05/27/2014)
05/27/2014	141	AMENDED ANSWER with Jury Demand to 6 Amended Complaint and, COUNTERCLAIM against Vascular Solutions, Inc.. by Boston Scientific Corporation. (Stensland, Sarah) (Entered: 05/27/2014)
06/10/2014	142	APPEAL/OBJECTION OF MAGISTRATE JUDGE DECISION to District Judge re 140 Order on Motion to Alter/Amend/Supplement Pleadings (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Redmond, Heather) (Entered: 06/10/2014)
06/10/2014	143	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 142 APPEAL/OBJECTION OF MAGISTRATE JUDGE DECISION to District Judge re 140 Order on Motion to Alter/Amend/Supplement Pleadings (Redmond, Heather) (Entered: 06/10/2014)
06/13/2014	144	Vascular Solution Inc's REPLY to Counterclaim of Boston Scientific Corporation by Vascular Solutions, Inc.. (Tahdooahnippah, Forrest) (Entered: 06/13/2014)
06/13/2014	145	MOTION for Judgment on the Pleadings by Vascular Solutions, Inc.. (Tahdooahnippah, Forrest) (Entered: 06/13/2014)
06/13/2014	146	NOTICE OF HEARING ON MOTION 145 MOTION for Judgment on the Pleadings : at date and time to be determined. (Tahdooahnippah, Forrest) (Entered: 06/13/2014)
06/13/2014	147	MEMORANDUM in Support re 145 MOTION for Judgment on the Pleadings filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate) (Tahdooahnippah, Forrest) (Entered: 06/13/2014)
06/13/2014	148	MEET and CONFER STATEMENT re 145 Motion for Judgment on the Pleadings filed by Vascular Solutions, Inc.. (Tahdooahnippah, Forrest) (Entered: 06/13/2014)
06/13/2014	149	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 145 MOTION for Judgment on the Pleadings (Tahdooahnippah, Forrest) (Entered: 06/13/2014)
06/24/2014	150	MEMORANDUM in Opposition re 142 APPEAL/OBJECTION OF MAGISTRATE JUDGE DECISION to District Judge re 140 Order on Motion to Alter/Amend/Supplement Pleadings filed by Boston Scientific Corporation. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate) (Ali, Jeffer) (Entered: 06/24/2014)

06/25/2014	151	Joint MOTION to Alter/Amend/Correct Other Orders 75 Scheduling Order, by Vascular Solutions, Inc. and Boston Scientific Corporation. (Redmond, Heather) Modified text on 6/26/2014 (LPH). (Entered: 06/25/2014)
06/25/2014	152	MEET and CONFER STATEMENT re 151 Motion to Alter/Amend/Correct Other Orders filed by Vascular Solutions, Inc.. (Redmond, Heather) (Entered: 06/25/2014)
06/25/2014	153	NOTICE OF HEARING ON MOTION 151 Joint MOTION to Alter/Amend/Correct Other Orders 75 Scheduling Order at date and time to be determined. (Redmond, Heather) Modified text on 6/26/2014 (LPH). (Entered: 06/25/2014)
06/25/2014	154	MEMORANDUM in Support re 151 Joint MOTION to Alter/Amend/Correct Other Orders 75 Scheduling Order, filed by Vascular Solutions, Inc.. (Attachments: # 1 LR7.1/LR72.2 Word Count Compliance Certificate)(Redmond, Heather) (Entered: 06/25/2014)
06/25/2014	155	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Vascular Solutions, Inc. re 151 Joint MOTION to Alter/Amend/Correct Other Orders 75 Scheduling Order, (Redmond, Heather) (Entered: 06/25/2014)
06/27/2014	156	SECOND AMENDED PRETRIAL SCHEDULING ORDER: Discovery due by 9/1/2014. Motions (non-disp) due 9/15/2014. Signed by Magistrate Judge Steven E. Rau on 6/27/2014. See Order further details.(las) Modified text on 6/30/2014 (LPH). (Entered: 06/27/2014)
07/08/2014	157	LETTER TO DISTRICT JUDGE by Boston Scientific Corporation . (Ali, Jeffer) (Entered: 07/08/2014)
07/15/2014	158	THIRD AMENDED PRETRIAL SCHEDULING ORDER: (Discovery due by 10/1/2014, Motions (non-disp) due 10/15/2014). Signed by Magistrate Judge Steven E. Rau on 7/15/14. (AKL) (Entered: 07/16/2014)
08/08/2014	159	STIPULATION of Dismissal by Boston Scientific Corporation. Jointly Signed by Vascular Solutions, Inc.. (Stensland, Sarah) (Entered: 08/08/2014)
08/08/2014	160	CERTIFICATE OF SERVICE ON PROPOSED ORDER by Boston Scientific Corporation re 159 Stipulation of Dismissal (Stensland, Sarah) (Entered: 08/08/2014)
08/11/2014	161	ORDER DISMISSING CASE. Signed by Judge John R. Tunheim on August 11, 2014. (HAZ) (Entered: 08/11/2014)
08/12/2014	162	JUDGMENT (Attachments: # 1 Civil Notice - appeal)(AKL) (Entered: 08/12/2014)

Coaxial guide catheter for interventional cardiology procedures

Assignee: Vascular Solutions, Inc

Inventor: Root, Howard Sutton, Gregg Welch, Jeffrey M Garrity, Jason M

Publication info: Root, Howard; Sutton, Gregg; Welch, Jeffrey M; Garrity, Jason M (Inventors). Vascular Solutions, Inc (Assignee). US 8048032 . (Published 01 Nov 2011).
ProQuest document link

Publication number: US 8048032 (01 November 2011, Utility)

Related patent: US 8142413 US 8292850

US classification: 604/16.401: Surgery

Plaintiff: VASCULAR SOLUTIONS, INC

Defendant: BOSTON SCIENTIFIC CORPORATION

Court and docket number: Minnesota(Docket: 0:13CV01172)

Court filing date: 16 May 2013

Subsequent action date: 16 May 2013

Action: COMPLAINT AGAINST BOSTON SCIENTIFIC CORPORATION FILING FEE $ 400 RECEIPT NUMBER 0864-3558731 FILED BY VASCULAR SOLUTIONS, INC FILER REQUESTS SUMMONS ISSUED (ATTACHMENTS #1EXHIBIT(S) A-C, #2 CIVIL COVER SHEET REDMOND, HEATHER

Language: English

Document type: Patent

Source attribution: LitAlert, © Publisher specific

Accession number: P2014-15-01

First available: 2014-04-14

Database: LitAlert® (1973 - current)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	2005.86USREI3

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		Defendant, Boston Scientific Corporation's Prior Art Statement, Dated December 20, 2013, cited in Civil No. 0:13-cv-01172-JRT-SER.	
		Defendant, Boston Scientific Corporation's First Amended Prior Art Statement, Dated April 25, 2014, cited in Civil No. 0:13-cv-01172-JRT-SER	
		Plaintiff, Vascular Solutions, Inc.'s Response to Defendant Boston Scientific Corporation's Prior Art Statement, Dated January 23, 2014, Civil No. 0:13-cv-01172-JRT-SER.	
		Plaintiff, Vascular Solutions, Inc.'s Response to Defendant Boston Scientific Corporation's First Amended Prior Art Statement, Dated July 1, 2014, Civil No. 0:13-cv-01172-JRT-SER.	

EXAMINER SIGNATURE	/Bradley Osinski/ (10/27/2014)	DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14070161	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY OSINSKI	3763

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
604	103.04, 103.09,160-162,164.01,164.02,164.09-164.11,525	7/7/2014	bjo

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search	7/7/2014	bjo
Search from parent apps	7/7/2014	bjo

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
604	164.01,525	7/7/2014	bjo

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14070161	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY OSINSKI	3763

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/07/2014								
1	1	✓								
2	2	✓								
3	3	✓								
4	4	✓								
5	5	✓								
6	6	✓								
7	7	✓								
8	8	✓								
9	9	✓								
10	10	✓								
11	11	✓								
12	12	✓								
13	13	✓								
14	14	✓								
15	15	✓								
16	16	✓								
17	17	✓								
18	18	✓								
19	19	✓								
20	20	✓								
21	21	✓								
22	22	✓								
23	23	✓								
24	24	✓								
25	25	✓								
26	26	✓								
27	27	✓								
28	28	✓								
29	29	✓								
30	30	✓								
31	31	✓								
32	32	✓								
34	33	✓								
	34	-								
	35	-								
	36	-								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14070161	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY OSINSKI	3763

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	07/07/2014								
	37	-								
	38	-								
	39	-								
	40	-								
	41	-								
	42	-								
	43	-								
	44	-								
35	45	✓								
36	46	✓								
37	47	✓								
38	48	✓								
39	49	✓								
33	50	✓								
40	51	✓								
41	52	✓								
42	53	✓								

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 8790

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
14/070,161	11/01/2013 RULE	604	3763	2005.86USREI3

APPLICANTS

VASCULAR SOLUTIONS, INC., Minneapolis, MN, Assignee (with 37 CFR 1.172 Interest);

INVENTORS

Howard Root, Tonka Bay, MN;
Gregg Sutton, Plymouth, MN;
Jeffrey M. Welch, Maple Grove, MN;
Jason M. Garrity, Lima, NY;

**** CONTINUING DATA ***************************

This application is a REI of 13/359,059 01/26/2012 PAT 8292850
which is a DIV of 12/824,734 06/28/2010 PAT 8142413
which is a DIV of 11/416,629 05/03/2006 PAT 8048032

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
11/18/2013

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No		MN	13	44	4
Verified and Acknowledged	/BRADLEY JAMES OSINSKI/ Examiner's Signature	Initials				

ADDRESS

PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100
UNITED STATES

TITLE

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

FILING FEE RECEIVED		
3550	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14070161	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3763

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

/BRADLEY OSINSKI/ Examiner.Art Unit 3763	7/4/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	41	
/AARTI B BERDICHEVSKY/ Primary Examiner.Art Unit 3763	07/07/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	25	3 and 4

U.S. Patent and Trademark Office

Part of Paper No. 20140706

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14070161	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3763

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION												
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED							
604	164.01	A	6	1	M	5 / 178 (2006.0)								
CROSS REFERENCE(S)		A	6	1	M	25 / 00 (2006.0)								
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)													
604	525													

/BRADLEY OSINSKI/ Examiner.Art Unit 3763 (Assistant Examiner)	7/4/2014 (Date)	**Total Claims Allowed:** 41	
/AARTI B BERDICHEVSKY/ Primary Examiner.Art Unit 3763 (Primary Examiner)	07/07/2014 (Date)	O.G. Print Claim(s) 25	O.G. Print Figure 3 and 4

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14070161	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3763

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17	33	50										
2	2	18	18	34	33										
3	3	19	19	35	45										
4	4	20	20	36	46										
5	5	21	21	37	47										
6	6	22	22	38	48										
7	7	23	23	39	49										
8	8	24	24	40	51										
9	9	25	25	41	52										
10	10	26	26	42	53										
11	11	27	27												
12	12	28	28												
13	13	29	29												
14	14	30	30												
15	15	31	31												
16	16	32	32												

/BRADLEY OSINSKI/ Examiner.Art Unit 3763 (Assistant Examiner)	7/4/2014 (Date)	**Total Claims Allowed:** 41	
/AARTI B BERDICHEVSKY/ Primary Examiner.Art Unit 3763 (Primary Examiner)	07/07/2014 (Date)	O.G. Print Claim(s) 25	O.G. Print Figure 3 and 4

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root Et Al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: Bradley Osinski
Filed: November 1, 2013	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

TELEPHONE INTERVIEW SUMMARY

Mail Stop REISSUE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

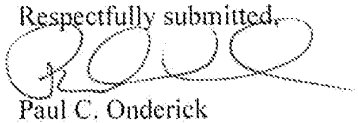
Commissioner:

Applicant thanks the Examiner for the courtesy extended to its undersigned representative in a telephone interview on July 3, 2014.

During the telephone interview an Examiner's Amendment was discussed. The authorized Examiner's Amendment is substantively as in the Notice of Allowance issued December 1, 2014.

Applicant thanks the Examiner for his attention to the claims and for the subsequent Notice of Allowance.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5766

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

Electronic Acknowledgement Receipt	
EFS ID:	20843628
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	02-DEC-2014
Filing Date:	01-NOV-2013
Time Stamp:	16:07:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	2005_86USREI3_TeleIntrvSumm.pdf	227194 8b8297d1fb72de4cb86d2acc3ea2888a7b89fc3e	no	1
Warnings:					
Information:					

Total Files Size (in bytes):	227194

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7590 12/01/2014
PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/070,161	11/01/2013	Howard Root	2005.86USREI3	8790

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	03/02/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
OSINSKI, BRADLEY JAMES	3763	604-527000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Patterson Thuente Pedersen P.A.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: VASCULAR SOLUTIONS, INC.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Minneapolis, Minnesota

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 16-0631 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date 12-4-2014
Typed or printed name Paul C. Onderick Registration No. 45354

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	14070161
Filing Date:	01-Nov-2013
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Paul C. Onderick/Mary Granger
Attorney Docket Number:	2005.86USREI3

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	2501	1	480	480
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**480**

Electronic Acknowledgement Receipt	
EFS ID:	20862442
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	04-DEC-2014
Filing Date:	01-NOV-2013
Time Stamp:	11:10:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$480
RAM confirmation Number	10650
Deposit Account	160631
Authorized User	ONDERICK, PAUL C
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)	
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2005_86USREI3_IssueFees.pdf	517343 ee74915aa913a0673b3964476663ceddc65b86d4	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30506 8770e3fb1aca866b6997555fc60fd69af33c5b45	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	547849		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI3

Howard Root Et Al. Confirmation No.: 8790

Application No.: 14/070,161 Examiner: Unassigned

Filed: November 1, 2013 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

CORRECTIVE TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

The applicant, Vascular Solutions, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior U.S. Patent Nos. 8,048,032, 8,142,413, 8,292,850, and Reissue Application Nos. 14/195,413, 14/195,435 and 14/195,385** as the term of said **prior patents and reissue applications** is presently shortened by any disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patents and reissue applications** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patents and reissue applications**, "as the term of said **prior patents and**

reissue applications is presently shortened by any terminal disclaimer," in the event that said **prior patents and reissue applications** later:

expire for failure to pay a maintenance fee;

are held unenforceable;

are found invalid by a court of competent jurisdiction;

are statutorily disclaimed in whole or terminally disclaimed under 37 CFR § 1.321;

have all claims canceled by a reexamination certificate;

are reissued; or

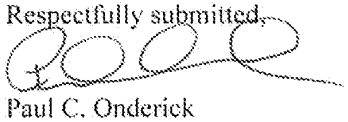
are in any manner terminated prior to the expiration of their full statutory term as presently shortened by any terminal disclaimer.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Electronic payment is submitted by credit card in payment of the fee required under 37 CFR § 1.321(b) and § 1.20(d). The Commissioner is hereby authorized to grant any extension of time necessary for consideration of this paper, and/or to charge any fee or credit any overpayment to Deposit Account No. 16-0631.

The undersigned is an attorney or agent of record.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5766

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

Electronic Acknowledgement Receipt	
EFS ID:	21021154
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	19-DEC-2014
Filing Date:	01-NOV-2013
Time Stamp:	15:48:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86USREI3_Ltr_TermDisc.pdf	435681 ade169ac96d9408333d953e5cf08469341d8f664	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Miscellaneous Incoming Letter	1	2
	Terminal Disclaimer Filed	3	4
Warnings:			
Information:			
	Total Files Size (in bytes):	435681	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root Et Al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: Unassigned
Filed: November 1, 2013	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

LETTER

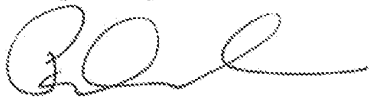
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

A Corrected Terminal Disclaimer is submitted herewith. The Corrected Terminal Disclaimer is being submitted because a typographical error in the Terminal Disclaimer filed on March 25, 2015, identified the wrong target patent as one of the patents over which the Terminal Disclaimer was filed. The typographical error is corrected in the Corrected Terminal Disclaimer. According to MPEP 1490(VI)(C) "the second terminal disclaimer replaces the first terminal

disclaimer, and the first terminal disclaimer is thus void" and "a second terminal disclaimer fee should not be assessed/charged." Accordingly, Applicants understand that no fee should be required.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5766

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	14/070,161	ROOT ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 12/19/14	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Lawana Hixon

U.S. Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/070,161	02/17/2015	RE45380	2005.86USREI3	8790

24113 7590 01/27/2015

PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

VASCULAR SOLUTIONS, INC., Minneapolis, MN, Assignee (with 37 CFR 1.172 Interest);
Howard Root, Tonka Bay, MN;
Gregg Sutton, Plymouth, MN;
Jeffrey M. Welch, Maple Grove, MN;
Jason M. Garrity, Lima, NY;

IR103 (Rev. 10/09)

Docket: VSI-1010-USRE1 (2005.86USREI3)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE			
First Named Inventor:	Howard Root		
Appln. No.:	14/070,161	Confirmation No.:	8790
Filing Date:	November 1, 2013	Examiner:	Osinski, Bradley James
Title:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	Group Art Unit:	3763

COMMUNICATION REGARDING CHANGE OF ENTITY STATUS

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

To the Commissioner:

Small entity status is no longer appropriate in the above-identified application. In accordance with the duty set forth in 37 C.F.R. §1.27, the entitlement to small entity status is hereby withdrawn.

If there are any questions relating to this matter, please contact Applicant's representative at the below-listed number. The Office is authorized to charge any deficiency in fees associated with this communication to Deposit Account 506636.

Respectfully submitted,

VASCULAR SOLUTIONS, INC.

Date: August 10, 2016

By: /Gregory W. Smock/
Gregory W. Smock, Reg. No. 60,208
Patent Counsel for Vascular Solutions, Inc.
(763) 656-4328

Electronic Acknowledgement Receipt

EFS ID:	26597287
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Gregory W. Smock/Julie Wang
Filer Authorized By:	Gregory W. Smock
Attorney Docket Number:	2005.86USREI3
Receipt Date:	10-AUG-2016
Filing Date:	01-NOV-2013
Time Stamp:	09:19:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notification of loss of entitlement to small entity status	1010USRE1-LossofSE.pdf	90439 d4982acef35130ba478da3f614442996794 2ffb8	no	1

Warnings:

Information:	
Total Files Size (in bytes):	90439

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DATE: May 13, 2018
TO: Certificates of Correction Branch
FROM: Gay Ann Spahn
Supervisory Patent Reexamination Specialist, Art Unit 3993
SUBJECT: REQUEST FOR CERTIFICATE OF CORRECTION

Please issue a Certificate of Correction in U. S. Letters Patent No. RE45,380 E as specified on the attached Certificate.

/Gay Ann Spahn/

GAY ANN SPAHN
Supervisory Patent Reexamination Specialist
Art Unit 3993

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : RE45,380 E
APPLICATION NO. : 14/070,161
DATED : February 17, 2015
INVENTOR(S) : Root et al.

The present reissue patent issued from an application that is one of a family of continuing reissue applications resulting from Patent No. 8,292,850**.** The present reissue patent has issued without the "notice" of all of the other reissue application(s) of the family which is required pursuant to 37 CFR 1.177(a). Accordingly, in column 1 of the specification, replace the heading "RELATED APPLICATIONS" and the paragraph thereunder, with the following:

Notice: More than one reissue application has been filed for the reissue of U.S. Patent No. 8,292,850. The reissue applications are U.S. Reissue Patent Application Serial No. 14/984,273, filed December 30, 2015, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 14/195,435, filed on March 3, 2014, now U.S. Reissue Patent No. RE46,116 E, issued August 23, 2016, which together with U.S. Reissue Patent Application Serial No. 14/195,413, filed March 3, 2014, now U.S. Reissue Patent No. RE45,776, issued October 27, 2015, and U.S. Reissue Patent Application Serial No. 14/195,385, filed March 3, 2014, now U.S. Reissue Patent No. RE45,760, issued October 20, 2015, are all a continuation reissue application of U.S. Reissue Patent Application Serial No. 14/070,16 (the present application)1, filed on November 1, 2013, now U.S. Reissue Patent No. RE45,380 E, issued February 17, 2015.

RELATED APPLICATIONS

[This] *U.S. Patent A*[a]pplication *Serial No. 13/359,059, filed January 26, 2012, now U.S. Patent No. 8,292,850, issued October 23, 2012,* is a divisional *application* of *U.S. Patent A*[a]pplication Ser[.]*ial* No. 12/824,734, filed Jun[.]*e* 28, 2010, now U.S. Pat[.]*ent* No. 8,142,413, *issued March 27, 2012,* entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures,"[,] which is a divisional *application* of *U.S. Patent A*[a]pplication Ser[.]*ial* No. 11/416,629, filed May 3, 2006, now U.S. Pat[.]*ent* No. 8,048,032, *issued November 1, 2011,* entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures."[.]

/Gay Ann Spahn/

GAY ANN SPAHN
Supervisory Patent Reexamination Specialist
Art Unit 3993

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE45,380 E
APPLICATION NO. : 14/070161
DATED : February 17, 2015
INVENTOR(S) : Root et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

Column 1, Line 12 (approx.), replace the heading "RELATED APPLICATIONS" and the paragraph thereunder, with the following:

Notice: More than one reissue application has been filed for the reissue of U.S. Patent No. 8,292,850. The reissue applications are U.S. Reissue Patent Application Serial No. 14/984,273, filed December 30, 2015, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 14/195,435, filed on March 3, 2014, now U.S. Reissue Patent No. RE46,116 E, issued August 23, 2016, which together with U.S. Reissue Patent Application Serial No. 14/195,413, filed March 3, 2014, now U.S. Reissue Patent No. RE45,776, issued October 27, 2015, and U.S. Reissue Patent Application Serial No. 14/195,385, filed March 3, 2014, now U.S. Reissue Patent No. RE45,760, issued October 20, 2015, are all a continuation reissue application of U.S. Reissue Patent Application Serial No. 14/070,16 (the present application) 1, filed on November 1, 2013, now U.S. Reissue Patent No. RE45,380 E, issued February 17, 2015.

RELATED APPLICATIONS
U.S. Patent Application Serial No. 13/359,059, filed January 26, 2012, now U.S. Patent No. 8,292,850, issued October 23, 2012, is a divisional application of U.S. Patent Application Serial No. 12/824,734, filed June 28, 2010, now U.S. Patent No. 8,142,413, issued March 27, 2012, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," which is a divisional application of U.S. Patent Application Serial No. 11/416,629, filed May 3, 2006, now U.S. Patent No. 8,048,032, issued November 1, 2011, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures."

Signed and Sealed this
Tenth Day of July, 2018

Andrei Iancu
Director of the United States Patent and Trademark Office