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 8,292,850

Attorney Docket No. 0025216-00057

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

TABLE OF CONTENTS

Page

Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,292,850

Exhibit Description	Exhibit No.
U.S. Patent No. 8,292,850 B2 to Root, et al.	1001
File History for U.S. Patent No. 8,292,850	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. 8,142,413 to Root, et al.	1005
File History for U.S. Patent No. 8,048,032	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 '850 Patent	1008B
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. 2007/0260219 A1 to Root et al.	1012
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1013
U.S. Patent No. 6,638,268 to Niazi	1014
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1015
U.S. Publication No. 2004/0127927 to Adams	1016
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1017
U.S. Patent No. 5,776,141 to Klein et al.	1018
U.S. Patent No. 7,232,452 to Adams et al.	1019
U.S. Patent No. 5,328,472 to Steinke et al.	1020
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)	1021
U.S. Patent No. 5,690,613 to Verbeek	1022
U.S. Patent No. 5,156,594 to Keith	1023
U.S. Patent No. 5,102,403 to Alt	1024
Kucklick, Theodore R., The Medical Device R&D Handbook (2006)	1025
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)	1026
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).	1027

Exhibit Description	Exhibit No.
(June 10, 2013)	
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)	1028
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)	1029
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)	1030
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed December 27, 2013	1031
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	1032
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir). filed January 7, 2014	1033
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir). filed January 29, 2014	1034
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir). filed February 3, 2014	1035
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir).	1036
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1037
Joint Claim Construction Statement filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn). (February 21, 2014)	1038
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1039
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1040
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1041
U.S. Patent No. 5,267,958 to Buchbinder et al.	1042

Inter partes review is respectfully requested for claims 1-4, 8, 12, 14, 18 of U.S. Patent No. 8,292,850 ("the '850 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 '850 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 '850 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. 8,048,032 (the "'032 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 (Exh. 1005)) and apparatus ('032 patent (Exh. 1004)) versions of the system claims of the '850 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.

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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 '850 PATENT

A. Overview Of Interventional Cardiology Procedures

The claims of the '850 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. (*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 '850 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 '850 Patent

The '850 Patent (Exh. 1001) contains 24 system claims, including two independent claims (claims 1 and 12). The specification of the '850 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, 1:18-22).

The challenged claims of the '850 patent are not straightforward. Unlike typical system claims, the '850 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 '850 patent is representative of the independent claims:

> **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; 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 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 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.

(Exh. 1001, 10:35-11:4).

Dependent claim 2 of the ‘850 patent depends from independent claim 1 and requires that “the tubular structure includes a distal portion *adapted to be extended beyond* the distal end 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." (*Id*., 11:5-2).

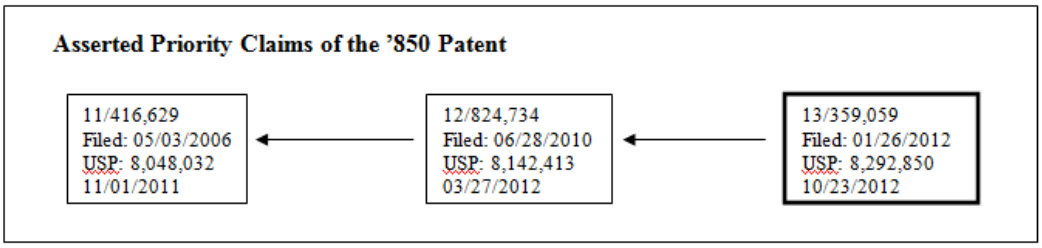
Dependent claim 3 (depending from independent claim 1 and dependent claim 2), is directed to a "proximal side opening" in a proximal portion of the tubular structure, where such opening "extend[s] for a distance along the longitudinal access" and is "transverse [*i.e*., at an angle] to the longitudinal axis." Dependent claim 14 (depending from independent claim 12) contains substantially similar limitation, except that the "partially cylindrical portion defining an opening extending for a distance along a side thereof" in the substantially rigid (as opposed to tubular) portion. (*Id*., 11:13-20).

Dependent claim 4 depends from claim 3 and requires a "structure defining a full circumference portion and structure defining a partially cylindrical portion," (*id*., 11:21-23) 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 '850 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle.

Dependent claim 8 (depending from independent claim 1) and 18 (depending from independent claim 12) 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."

C. Effective Filing Date of the Contested Patent

As depicted below, the '850 patent asserts priority back to May 3, 2006 through a chain of two applications: (1) U.S. Patent Application No. 11/416,629 (filed May 3, 2006 and issued as U.S. Patent No. 8,048,032 (the "'032 patent"), and (2) U.S. Patent Application No. 12/824,734 (filed June 28, 2010 and issued as U.S. Patent No. 8,142,413 (the "'413 patent")).[1]



D. Summary of the Prosecution History of the '850 Patent

[1] Petitioner's depiction of the asserted priority claims of the '850 patent is for illustrative purposes only. Petitioner notes that it is contesting the asserted priority date of the '850 patent in a concurrently filed parallel Petition, "Petition B," challenging the claims of the '850 patent on different grounds. (*See* Exh. 1008). Since the prior art relied upon for purposes of this Petition has an effective prior art date well before Patent Owner's asserted priority date of May 3, 2006, Petitioner applies this as the presumed effective date of the '850 patent exclusively for purposes of its analysis herein.

The ‘850 Patent was filed as U.S. App. Serial No. 13/359,059 on January 26, 2012 (Exh. 1002, paper 1). The prosecution of the ‘032 patent, to which the ‘850 claims priority, spanned five years and three months. During that time, the Examiner issued numerous rejections of claims which are nearly identical to the system claims of the ‘850 patent challenged herein. Ultimately, however, following at least six rejections and eight amendments, the Examiner conditioned patentability of the claims on the addition of a “rail structure without a lumen” limitation within the substantially rigid portion.

The claims of the ‘850 patent issued following an amendment by the same Examiner of independent claims 1 and 12 moving the location of the “rail structure without a lumen” limitation from the tubular structure of the flexible tip portion (where the Patent Owner had sought to include it), to the substantially rigid portion, where it had been included in the ‘032 patent. The Examiner’s stated reasons for allowance were that, “just as in the parent applications, the examiner did not find any teaching or suggestion for the claimed arrangement. Specifically, adding a guide catheter to the claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.” A Notice of Allowance was mailed August 22, 2012, and the ‘850 Patent issued on October 23, 2012. (Exh. 1002 at 16).

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 '850 Patent is satisfied.

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

Petitioner certifies that the '850 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, 12, 14, and 18 of the '850 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, 8, 12, 14, and 18 of the '850 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 37 years of academic and industry experience in the field of interventional cardiology devices, has reviewed the claim charts submitted in the '850 Petition and is in agreement with the grounds of invalidity and the evidentiary

support set forth therein. (*See* Exh. 1003 ¶ 82). *Inter partes* review is requested in view of the following references and specific grounds for rejection.

No.	Grounds
1	Claims 1-2, and 12 are anticipated by US 5,527,292 ("Adams '292")
2	Claims 1-4, 12 and 14 are obvious over Adams '292 in view of US 5,776,141 ("Klein")
3	Claims 1-4, 12 and 14 are obvious over Adams '292 in view of US 7,232,452 ("Adams '452'")
4	Claims 1-4, 12 and 14 are obvious over Adams '292 in view of US 5,328,472 ("Steinke")
5	Claims 1-2, 8, 12 and 18 are obvious over Adams '292 in view of Knowledge of One of Skill in the Art
6	Claims 1-2, 8, 12 and 18 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.

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, 12, 14 and 18 of the '850 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 '850 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 (Mihara) in

parallel Petition B differs from the primary prior art reference raised herein (Adams ‘292). Mihara anticipates a different set of dependent claims (claims 3, 4, and 14) 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 18). 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.

Petitioner’s asserted ground of unpatentability in Petition B based on Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the‘032 patent), is not redundant of the other grounds of

unpatentability raised herein because it renders obvious all challenged claims only if the ‘850 patent is denied the benefit of its claimed May 3, 2006 priority date.

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 ‘850 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 ¶¶ 28-31).

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[]." 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.[2]

1. "rail structure without a lumen"

Because the '850 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 '850 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, 2:65). *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 meaning for "rail" in the claim term "rail structure without a lumen." (Exh. 1003 ¶ 64). 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,"

[2] 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.

"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 12 under 35 U.S.C. §§ 102 and 103, and claims 2, 3, 4, 8, 14, and 18 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; this cannot be the "rail structure" for purposes of the claim, however, because the claimed structure must be "without a lumen." (Exh. 1003 ¶¶ 64-66). 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*). 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 or narrowing in the arteries due to atherosclerotic plaques or other lesions. (Exh. 1003 ¶ 67). The specification of the '850 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001, 1:28-31) ("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 to which the claim is directed is "to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." Dependent claim 14 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…." 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"). Accordingly,

such language should not be read as positive limitations on apparatus claims 3 or 14 of the '850 patent. To the extent that there is doubt, the BRI of the claims suggests that only the structural limitation(s) of claims 3 and 14 (namely, a skived proximal opening) be 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 '850 patent claims are system claims, the requisite invalidity analysis turns on a direct comparison of the claimed ***structures*** to prior art ***structures***. *See In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) *Carolina Mktg. Int'l*, 289 F.3d at 810 ("To hold otherwise would effectively impose a method limitation on an apparatus claim without justification"). The functional statements in claims 3 and 14 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 14 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 14, 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 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***." (Exh. 1001, claim 2). 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.,* 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.

B. 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. 1011) matured from an application filed on September 9, 1994, prior to the earliest filing date the benefit of which is claimed by the '850 patent and is therefore available as prior art to the '850 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. 1002 4:35-38; Exh. 1003 ¶¶ 69-70), 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

[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.

> 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.

(*Id.* 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 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, 9:12-24; *see* Exh. 1003 ¶¶ 32, 69-70).

2. Klein

U.S. Patent No. 5,776,141 to Klein ("Klein") matured from an application filed on August 26, 1996, prior to the earliest filing date the benefit of which is claimed by the '850 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 ¶ 35).

3. Adams '452

U.S. Patent No. 7,232,452 to Adams ("Adams '452") matured from an application filed on July 12, 2002, prior to the earliest filing date the benefit of which is claimed by the '850 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. 1011, 8:47-50; Exh. 1003 ¶ 36). Adams '452 further discloses "A proximal wire or other control means…." (Exh. 1011, 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 ¶ 36). 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. (Exh. 1011, Figs 2A-C).

4. Steinke

U.S. Patent No. 5,328,472 to Steinke ("Steinke") (Ex. 1020) matured from an application filed on July 27, 1992, prior to the earliest filing date the benefit of which is claimed by the '850 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.1020, 3:1-2; Exh. 1003 ¶ 37).

5. Takahashi

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions Exh. 1021, 452-456 ("Takahashi") is an article that was published in 2004 and, thus, qualifies as prior art under § 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 ¶ 38). 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 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, 12, 14, and 18 of the '850 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 (Exh. 1003).

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 in the corresponding claim charts.

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 '850 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

A. Claims 1, 2, 8, 12, And 18 Are Anticipated Under 35 U.S.C. §102(b) By Adams'292

As shown below, each element recited in claims 1, 2, 8, 12, And 18 is anticipated by Adams '292, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '850 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." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

1. Claim 1

Claim 1 of the '850 patent discloses a "system comprising: a guide catheter …"; Adams '292 similarly teaches "The invention is directed to the

structure and use of a distal extension (intravascular device) for a guide catheter." (Exh. 1011, 4:36-37). Claim 1 of the 850 patent recites "a flexible tip portion defining a tubular structure having a circular cross-section" (Exh. 1001, ; Adams discloses that "The intravascular device includes a relatively flexible tube 45…." (Exh. 1011, 2:44-51). Claim 1 of the '850 patent further recites "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 …"; Adams discloses that "The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the 65 guide catheter 12 so that it may be slidably disposed therethrough and to permit insertion of the tube 32 …" (Exh. 1011, 5:64-67). Claim 1 of the '850 patent further recites "a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion …" (Exh. 1001, claim 1); Adams 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." (Exh. 1011, 7:13-26). Finally, claim 1 of the '850 patent recites "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 …"

(Exh. 1001, claim 1); Adams '292 similarly discloses that "The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches" (Exh. 1011, 15:49-53), which is longer than a standard guide catheter—approximately 40 inches. (Exh. 1003 ¶ 98). Thus, the Adams '292 discloses every element of claim 1 of the '850 patent.

2. Claim 2

Both the '850 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, claim 2 *with* Ex. 1011, 16:49-58; *see* Exh. 1003 ¶¶ 102-07).

3. Claim 12

As discussed above, claim 12 of the '850 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. Adams '292 also disclosed the "reinforced portion" of claim 12, as shown in the claim chart below. (Exh. 1003 ¶¶ 100-01).

4. Claims 8 and 18

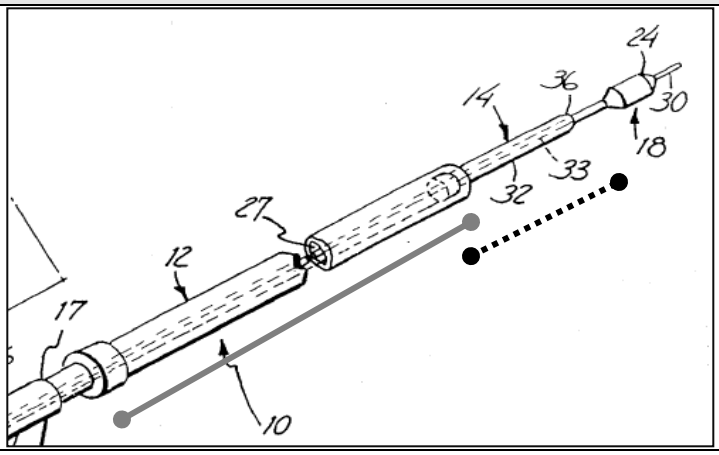
Dependent claims 8 (depending from claim 1) and 18 (depending from claim 12) require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner

diameter of the guide catheter." 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; Exh 1003 ¶ 121-24) 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).

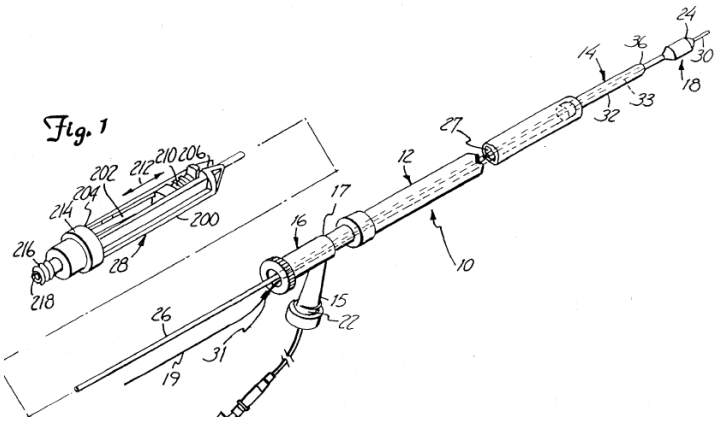
The '850 Patent	**Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length 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	**[1]** To the extent that the preamble is a limitation, Adams discloses a system for use with interventional cardiology devices adapted to be insertable 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 hemostasic valve. 5:16-29 ("The

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
insertable into and through the continuous lumen of the guide catheter; a device adapted for use with the guide catheter, including:	guide catheter manifold 16 is mounted at the 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 hemostasis valve (not shown) on channel leg 17 provides hemostatic control for the guide catheter system 10 of the present invention"); 11:20-30 ("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. 6:29-31 ("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 '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	("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"); 16:39-44 ("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 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. 2:44-50 ("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 '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 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 defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	**[1]** Adams 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 65 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. 8:57-61 ("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

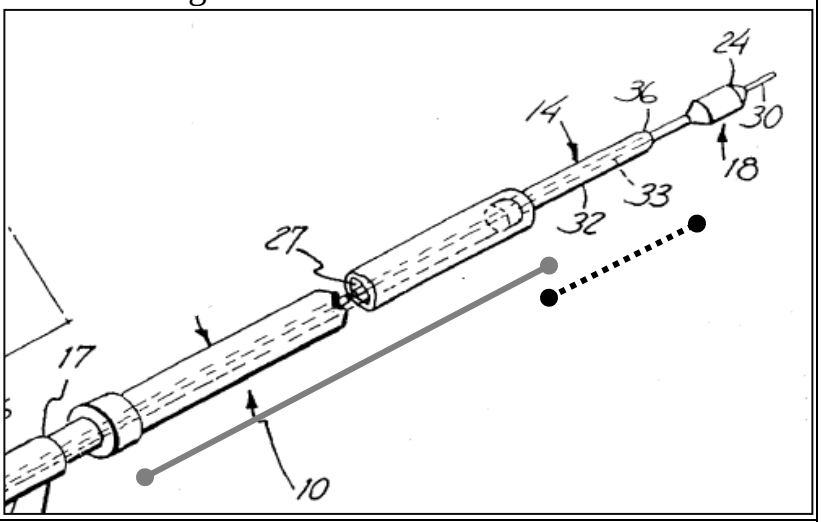
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	anchoring device comprising: a relatively flexible tube sized for insertion through the central lumen of the guide catheter into the coronary vessel, the flexible tube being concentrically aligned with the guide 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 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." 7:13-26; *see* 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 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 ("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

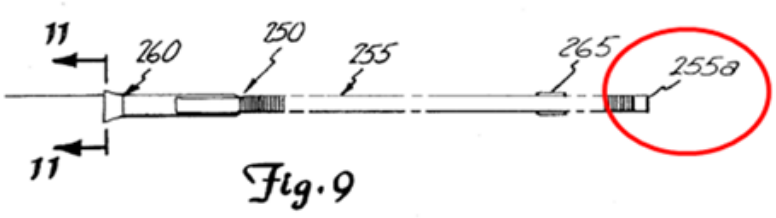
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	inch distal tubular opening …").
and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than 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 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

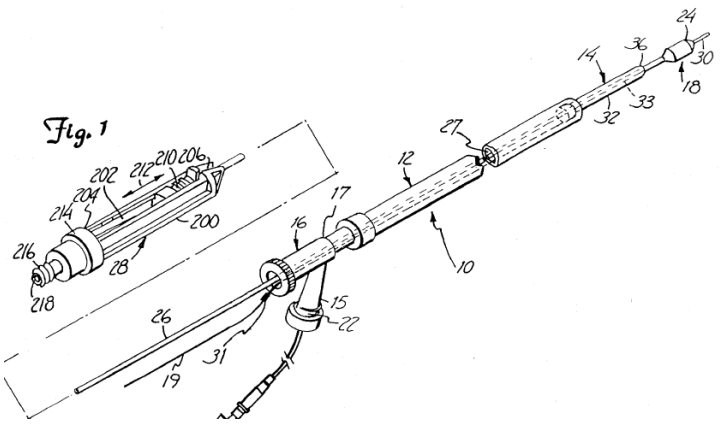
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. 17:3-7 ("The total length of the extension 250 permits the flexible tube 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 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,	The Adams '292 patent 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 within a coronary artery." (Abstract); 9:17-22 ("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 the 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 to the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	4:63-67 ("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

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	defines an anchoring device for securing the guide catheter 12 for operation…. [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…."); 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 system of claim 1	Adams '292 discloses the system 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).
12. A system for use with interventional cardiology	**[1]** To the extent that the preamble is a limitation, Adams discloses a system for use with interventional

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
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	cardiology devices for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract and 4:36-37. **[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.
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,	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 and having a circular cross-section that is smaller than the	**[1]** Adams discloses a flexible tip portion defining a tubular structure in the form of a "relatively flexible tube" **[2]** having an inner and outer diameter. 2:44-50 and 23:36-37.

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
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,	**[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 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;	**[1]** Adams 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

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	coil 40A." 7:4-7.  Fig. 9
a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis rail than the flexible tip portion defining a structure without a lumen	Adams 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." 7:13-26; see also Abstract; 2:47-48; 6:1-2; 6:13-15; 15:8-12; 22:51-52; and 23- 44-45.
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 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	Adams 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:

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	 "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 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 guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient." 17:3-7.
18. The system of claim 12,	Adams '292 discloses the system of claim 12 (*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).

VIII. Obviousness of Challenged Claims

The below challenged claims of the '850 patent are rendered obvious under §103(a) in view of the prior art references set forth below,[4] either in view of the knowledge of one of ordinary skill in the art, or in the combinations expressly 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).

A. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Klein

Klein (Exh. 1018) was cited during prosecution of the '032 Patent but was not considered in combination with Adams '292 (Exh. 1011), nor was it considered during prosecution of the '850 Patent. As shown below, each element recited in claims 1-4, 8, 12, 14 And 18 is obvious over Adams '292 in view of Klein. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above.

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

As set forth in section VII above, Adams ‘292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107, 120-124). 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 and Klein. (*See* Exh. 1003 ¶¶ 108-111).

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,” 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 14 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.”

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams ‘292 expressly discloses such functions. (*See, e.g.*, 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 reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ..."). *See* (Exh. 1011, 16:11-14).

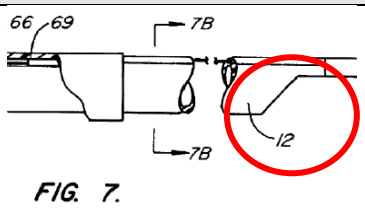
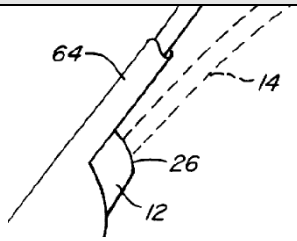
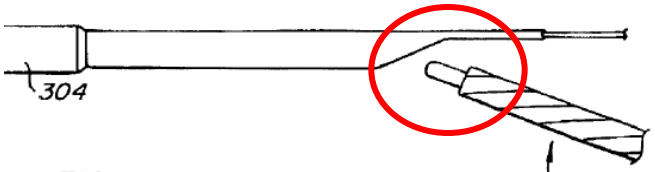
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86, 108-111), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Klein to meet the limitations of the challenged claims. Adams '292 and Klein are both analogous to the '850 patent as they are directed 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 '850 patent. (Exh. 1003 ¶¶ 71-74). As such, one of skill in the art would have been aware of these references and would have referred to Adams '850 and Klein in addressing the problem addressed by the '850 patent.

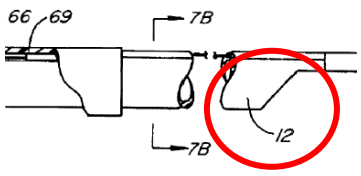
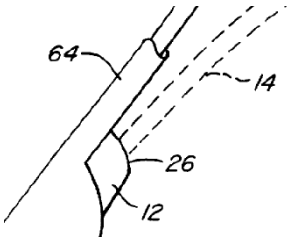
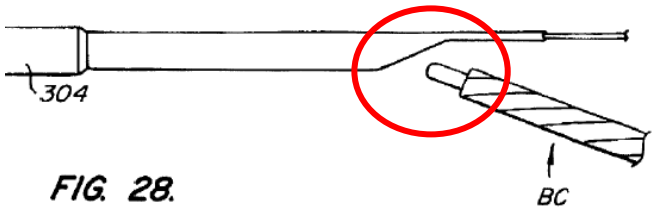
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the device disclosed by Adams '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 device 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. (Exh. 1003 ¶¶ 84-86, 108-111).

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 ‘850 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 ¶¶ 108-11).

Claim Chart A-2: Cl. 3-4, 14	
The ‘850 Patent	**Adams ‘292 in view of Klein**
3. The system of claim 2,	Adams ‘292 discloses the system 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	“Tubular catheter body 16 includes an internal lumen 24 which extends from a 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 the balloon catheter 14.” 9:17-23. 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, 14	
The '850 Patent	**Adams '292 in view of Klein**
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).
to receive the interventional cardiology devices 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 system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical	(*See, e.g.*, Klein, Figs. 7, 28)., *see also above*.

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	**Adams '292 in view of Klein**
portion.	
14. The system of claim 12,	Adams '292 discloses the system of claim 12 (*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	"Tubular catheter body 16 includes an internal lumen 24 which extends from a 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 the balloon catheter 14." 9:17-23. 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).
that is adapted to receive an interventional cardiology device	Adams '292 is "directed to the structure and use of a distal extension … for a guide catheter" (Adams '292, 4:36-37 (Exh. 100_)), wherein "[g]uide catheter 52 is an elongated, flexible tubular member defining a first guide cathter lumen 53

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	**Adams '292 in view of Klein**
passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	through which an angioplasty balloon catheter 60 or some other angioplasty device is disposed and guided to a stenosis or obstruction." (*Id*., 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 the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into 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.	(*See, e.g*., Klein, Figs. 7, 28)., *see also above*.

B. Claims 1-4, 8, 12, 14 And 18 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, 12, 14 And 18 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 '850 Patent. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above. As set forth in section VII above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107 and 120-124). 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 and Adams ‘452. *See* (Exh. 1003 ¶¶ 84-86, 112-15).

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. 1011, 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 and which is accessible from a side transverse to the longitudinal axis. (*See* Exh. 1003 ¶ 36). 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*).

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 14 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. 1003 ¶¶ 112-15).

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.*, Exh. 1003 ¶¶ 112-115; 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 reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...")).

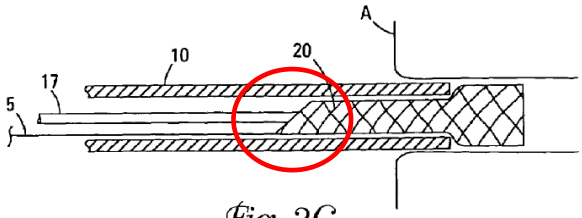
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86 and 112-15), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims. Adams '292 and Adams '452 are both analogous to the '850 patent as 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 '850 patent. (*See* Exh. 1003 ¶¶ 71, 75-76). 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 '850 patent. (*See id*. ¶¶ 84-86, 112-115).

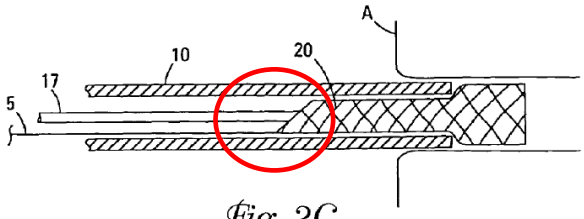
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id*., 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the disclosure of Adams '292 with the teaching in Adams '452 of the advantages of a skived proximal

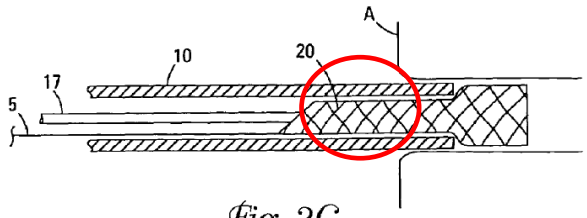
opening to the device lumen of a cardiovascular treatment device for facilitating a smoother withdrawal of the device from the guide catheter. (*See* Exh. 1003 ¶¶ 84-86, 112-115). This is particularly true given that the devices of Adams '452 and Adams '292 are both directed to the receipt of interventional cardiology devices through a proximal opening of the device while a proximal portion of the device is within the standard guide catheter. (*Id.* ¶¶ 32, 36, 71 and 75-76). 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 '850 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 ¶¶ 112-15).

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**
3. The system of claim 2,	Adams '292 discloses the system 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." 8:47-50. "A proximal wire … extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter." 8:47-50. 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 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.
to receive the interventional cardiology devices into the coaxial lumen while the proximal	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

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**
portion remains within the lumen of the guide catheter.	to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57- 16:13.
4.. The system of claim 3,	As shown above, Adams '292 in combination with Adams '452 discloses the system 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.
14. The system of claim 12,	Adams '292 discloses the system of claim 12 (*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." 8:47-50. 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 longitudinal axis:  *Fig. 2C* The proximal portion of the guide seal 20 remains

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**
	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 the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into 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, Fig. 2C; 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:  *Fig. 2C*

C. Claims 1-4, 8, 12, 14 and 18 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, 12, 14 and 18 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 '850 Patent. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set

forth above. As set forth above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107 and 120-124). 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 and Steinke. *See* (Exh. 1003 ¶¶ 108-111).

Steinke discloses "a catheter which allows rapid exchange" (Exh. 1020, 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. 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. (Ex. 1003 ¶¶ 35 and 72). 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 14 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."

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.*; 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 reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...")).

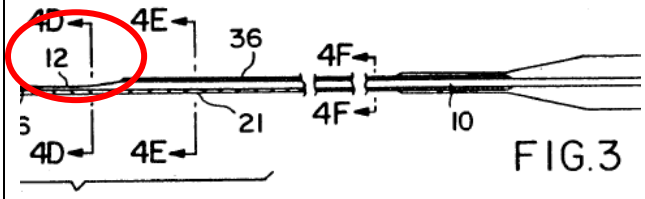
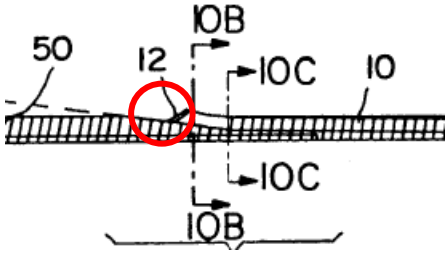
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86 and 116-119), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Steinke to meet the limitations of the challenged claims. Adams '292 and Steinke are both in the same field of endeavor as the '850 patent and are pertinent to the problem faced by the inventor of the '850 patent. (*Id*., 77-78). 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 '850 patent. (*Id*., 116-119).

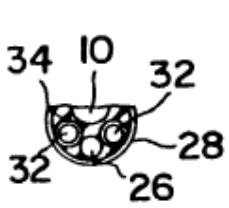
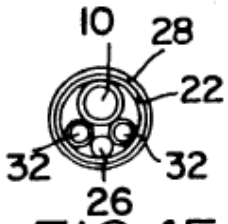
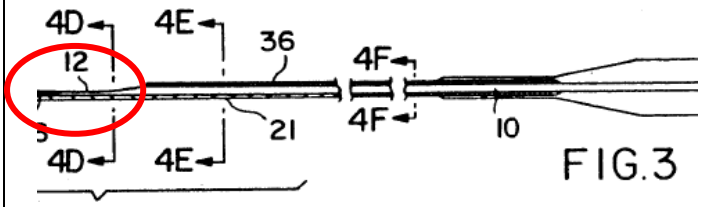
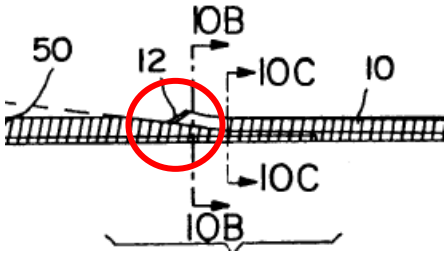
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34

(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. 1020, 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. (Exh. 1003 ¶¶ 32-34, 37 and 84-86).

In sum, Steinke shows that using skived proximal openings with rapid exchange catheters was well known by the time of the '850 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. (*Id.* ¶ 116-19).

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
3. The system of claim 2,	Adams discloses the system of claim 2 (*See* A-1, above).
wherein the proximal portion of the tubular structure further comprises structure	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

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
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,	and which is accessible from a side transverse to the longitudinal axis as depicted in Fig. 3:  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 the interventional cardiology devices 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 system of claim 3,	(*See* claim 3 above).
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical	Steinke discloses skived side port entry depicted in Figs. 4D, 4E defines a full circumference portion and a partially cylindrical portion:

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
portion.	 FIG.4D  FIG.4E
14. The system of claim 12,	Adams discloses the system of claim 12 (*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," 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.
that is adapted to receive an interventional cardiology device passed through continuous lumen of the	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 ...."

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	15:57-16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	Steinke 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.

D. Claims 1, 2, 8, 12 And 18 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 18 (depending from claim 12) 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." 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 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 ¶¶ 125-26).

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 '850 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. (*Id).*

E. Claims 1, 2. 8, 12 And 18 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 18 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 of either the '032 Patent or the '850 Patent, or considered in combination with Adams '292. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above. As set forth in section above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107, 120-124). 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 and the Takahashi article. *See* (Exh. 1003 ¶¶ 127-29).

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 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 ¶ 122, 127-29).

Claim Chart A-6: Cl. 8, 18	
The ‘850 Patent	**Adams ‘292 (Exh. 1011) in view of Takahashi (Exh. 1021)**
8. The system of claim 1,	Adams ‘292 discloses the system of claim 1 (*See* A-1, above).
wherein the cross-sectional inner diameter of the	“The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a

Claim Chart A-6: Cl. 8, 18	
The '850 Patent	**Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1021)**
coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	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*). "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).
18. The system of claim 12	Adams discloses the system of claim 12 (*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).

IX. CONCLUSION

Based on the foregoing, it is clear that claims 1, 2, 8, 12, and 18 of the '850 Patent define subject matter that is anticipated in view of Adams '292 and that the claims 1-4, 8, 12, 14, and 18 of the '850 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 '850 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

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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:

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