UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,142,413 B2

Attorney Docket No. 0025216-00057

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

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

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

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

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

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

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

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

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

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

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

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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 ‘413 PATENT

A. Overview Of Interventional Cardiology Procedures

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. REQUIREMENTS FOR INTER PARTES REVIEW

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

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

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

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

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

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

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

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

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

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

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

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

E. Construction Of The Challenged Claims

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

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

1. "rail structure without a lumen"

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

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

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

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

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

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

2. "interventional cardiology device(s)"

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

F. The Prior Art References

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

1. Adams '292

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

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

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

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

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

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

2. Klein

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

3. Adams '452

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

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

4. Mihara

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

5. Steinke

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

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

6. Takahashi

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

G. How The Construed Claim(s) Are Unpatentable

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

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

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

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

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

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

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

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

1. Claim 1

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

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

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

2. Claim 13

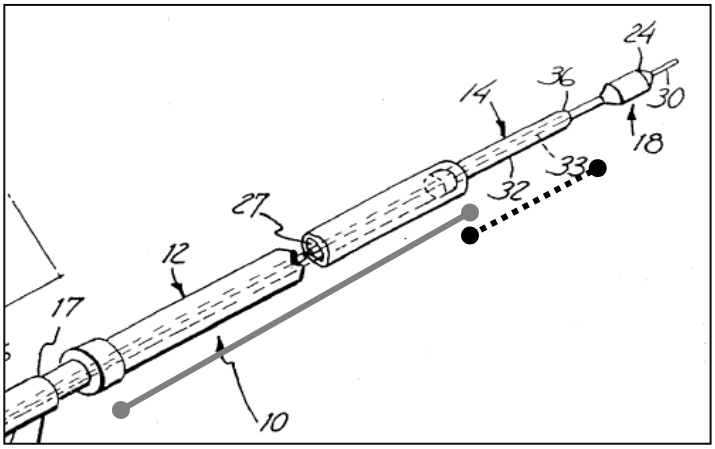
Claim 13 (depending from claim 1) of the '413 patent requires "selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter." The Adams '292 patent discloses that the outer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

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

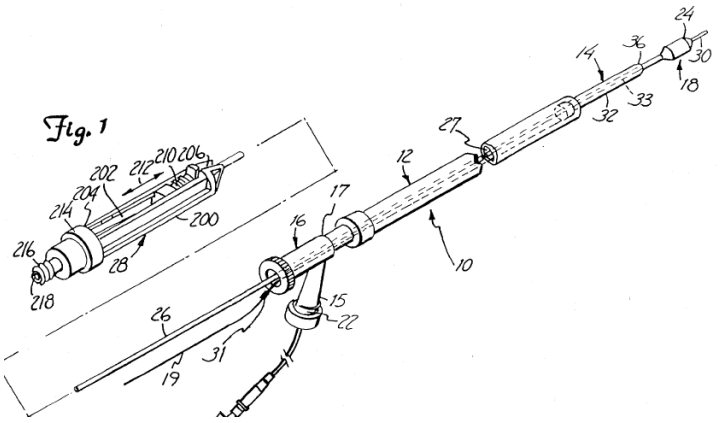
The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
interventional cardiology device for use in the coronary vasculature, **[2]** the interventional cardiology device being adapted to be passed through a standard guide catheter, **[3]** the standard guide catheter having a continuous lumen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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

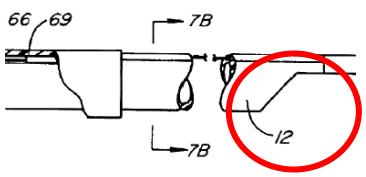
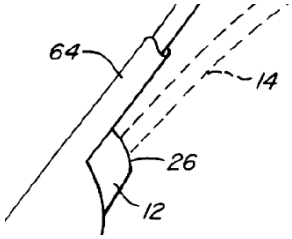
Dependent claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening" in the tubular structure while claim 10 (which depends from claim 9) requires "advancing" such device through the "full circumference" and the "partially cylindrical" portions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

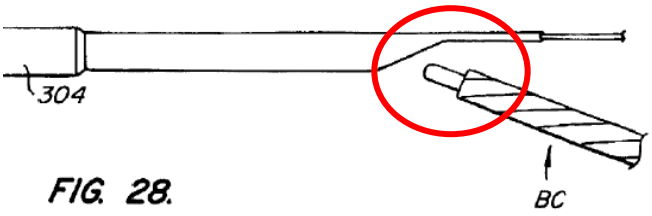
Adams ‘292 discloses the function of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003, ¶ 105). Klein discloses the claimed structure of a proximal side opening extending for a distance along a proximal portion of the tubular structure, defining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

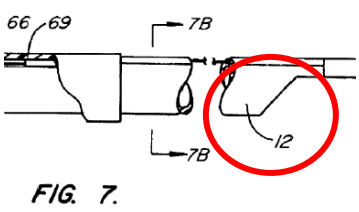
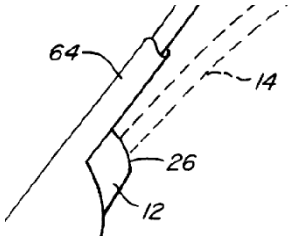
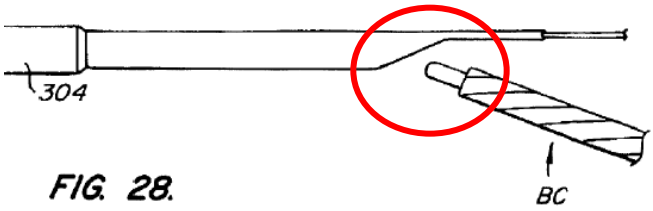
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 112-114), a POSA would have found it obvious to modify the proximal opening of the Adams ‘292 device in view of Klein to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters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

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

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

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

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

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

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

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

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

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

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

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

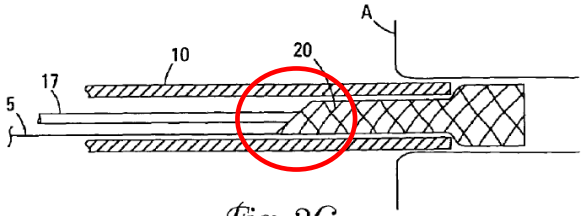
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 116-118), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon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

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

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

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

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

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

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

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

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

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

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

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

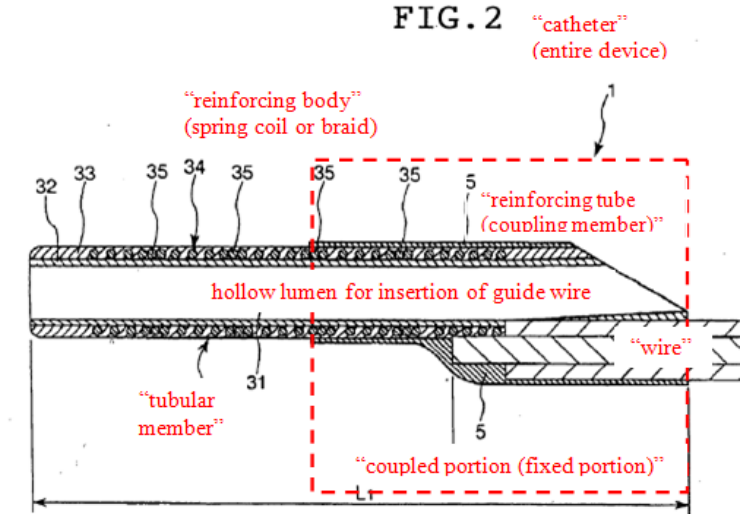
the "full circumference" and the "partially cylindrical" portions of such opening. Adams '292 discloses the functions of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003 ¶ 105). Mihara discloses the claimed structure of a proximal side opening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

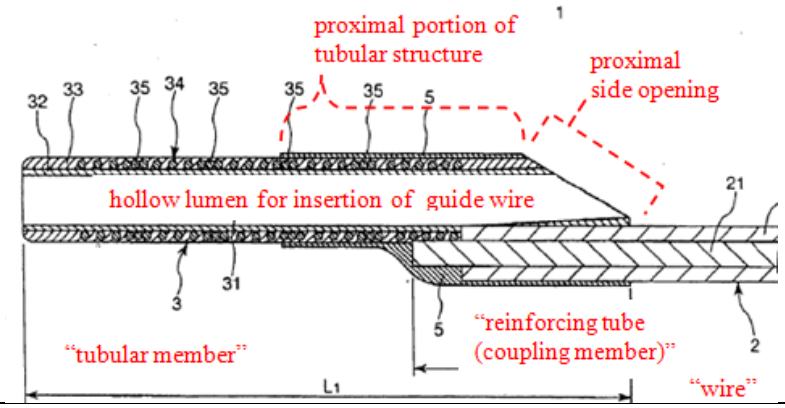
As confirmed by the Solar Declaration (Exh. 1003, ¶¶ 120-21), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Mihara to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters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

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

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

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

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

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

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

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

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

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

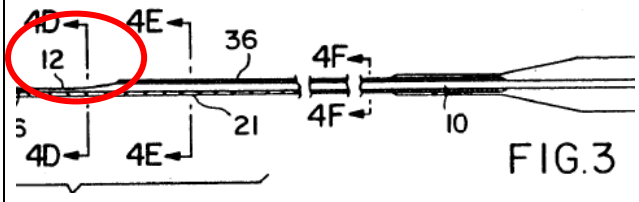
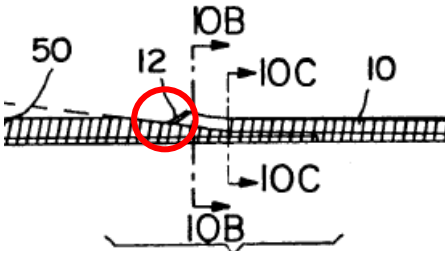
an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires "selecting the substantially rigid portion of the coaxial guide catheter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

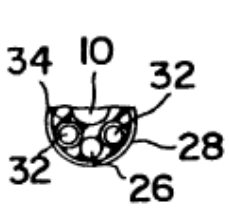
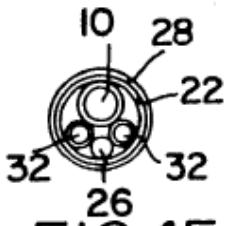
Dependent claim 9 of the '413 patent requires "extending the interventional cardiology device through a proximal side opening" in the tubular structure while claim 10 (which depends from claim 9) requires "advancing" such device through the "full circumference" and the "partially cylindrical" portions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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Claim Chart A-6: Cl. 13

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

VI. CONCLUSION

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

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

Respectfully submitted,

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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 15, 2014, to the USPTO correspondence address of record listed below:

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