UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,048,032

Attorney Docket No. 0025216-00057

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

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

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

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

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

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

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

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

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

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

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

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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 '032 PATENT

A. Overview Of Interventional Cardiology Procedures

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. REQUIREMENTS FOR INTER PARTES REVIEW

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

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

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

B. Identification of Challenge and Relief Requested

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

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

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

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

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

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

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

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

V. Non-Redundancy of Proposed Alternative Grounds

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

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

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

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

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

VI. Level of Skill In the Art

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

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

A. Construction Of The Challenged Claims

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

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

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

1. "rail structure without a lumen"

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

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

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

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

2. "interventional cardiology device(s)"

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

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

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

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

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

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

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

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

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

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

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

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

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

B. The Prior Art References

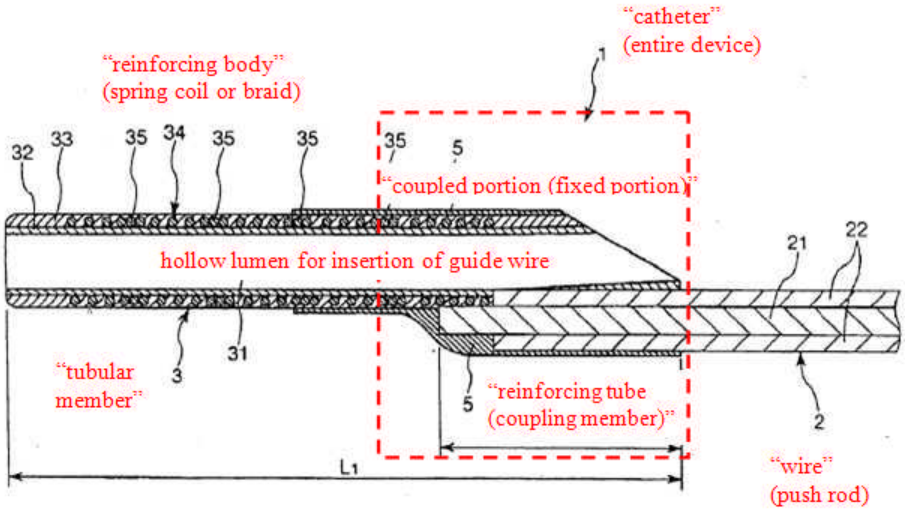
As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under at least §102(b).[2]

1. Mihara

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

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

FIG. 2



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

2. Takahashi

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

C. How The Construed Claim(s) Are Unpatentable

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

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

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

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

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

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

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

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

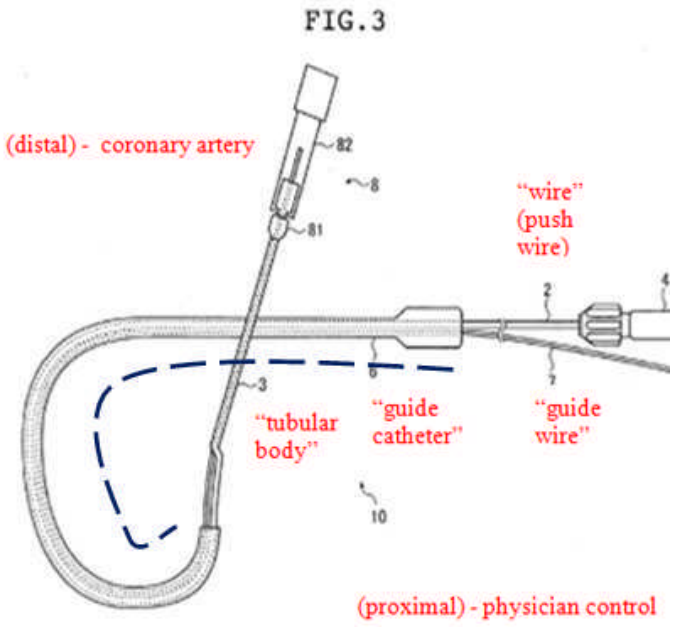
Claim 1 of the '032 patent discloses:

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

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

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

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

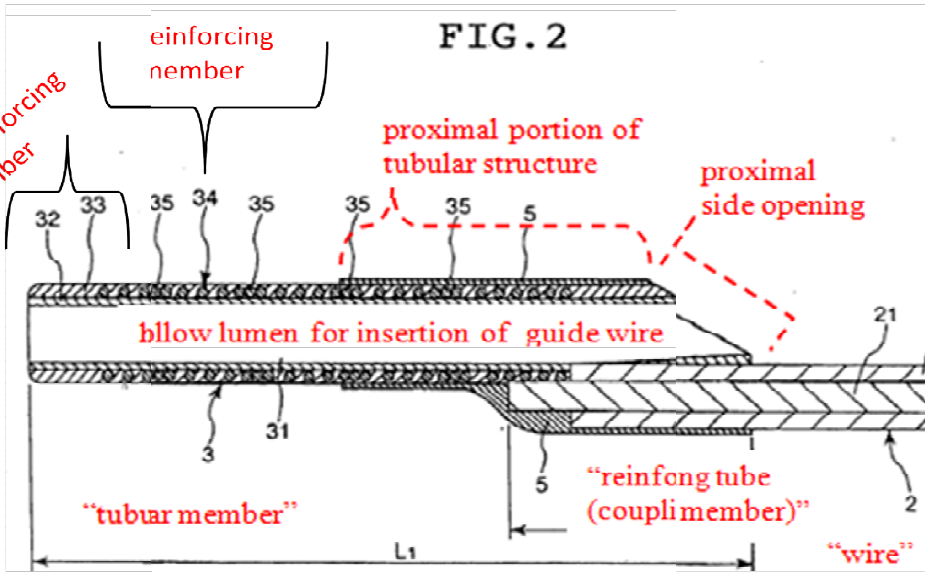


Mihara also discloses that the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Claim 2

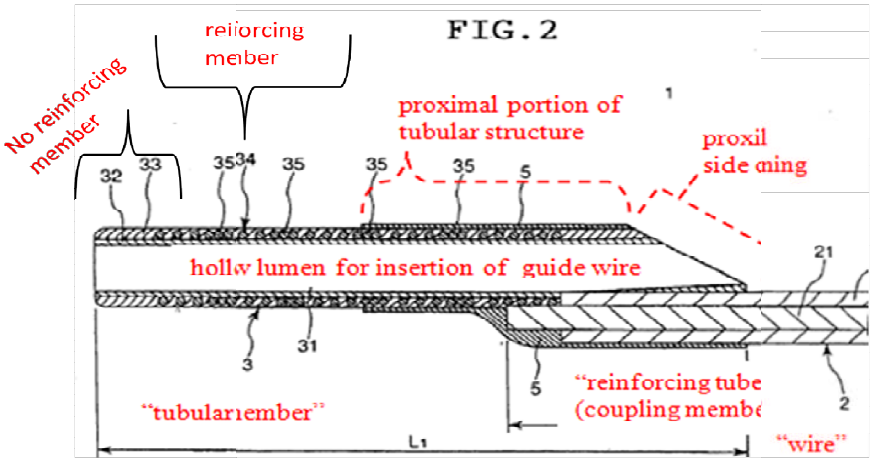
Regarding dependent claim 2, both the '032 patent and Mihara are directed to a catheters that provide strong backup support or "pushabililty" for deep intubation beyond the ostium, providing a counter-force to the force/resistance created by the advancement of a guidewire into a tight or substantially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

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

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

2. Claims 3, 4, and 13

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



Specifically:

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

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

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

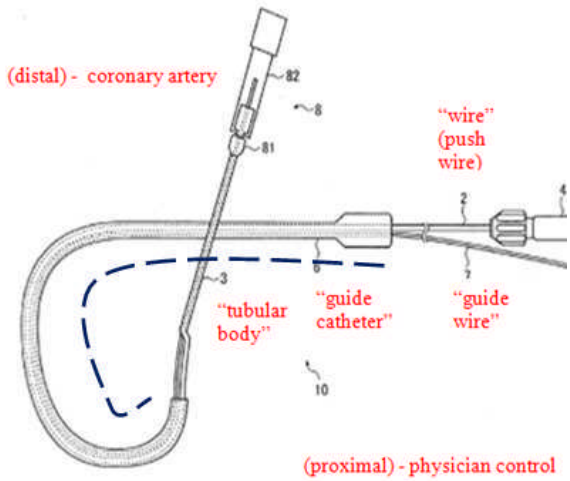
This disclosure satisfies the structural limitations of dependent claim 3 (which depends from claims 1 and 2) requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible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

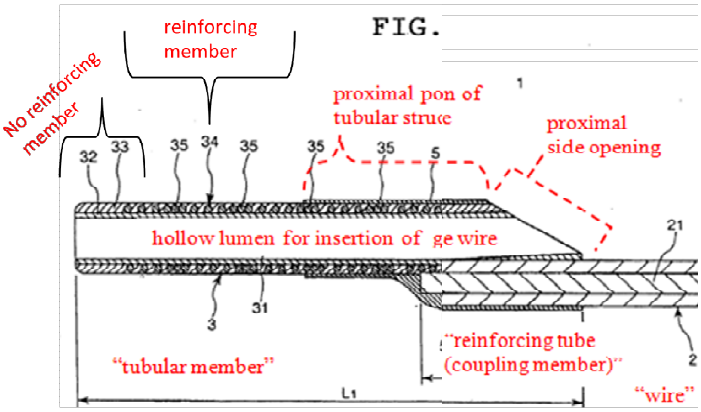
3. Claim 11

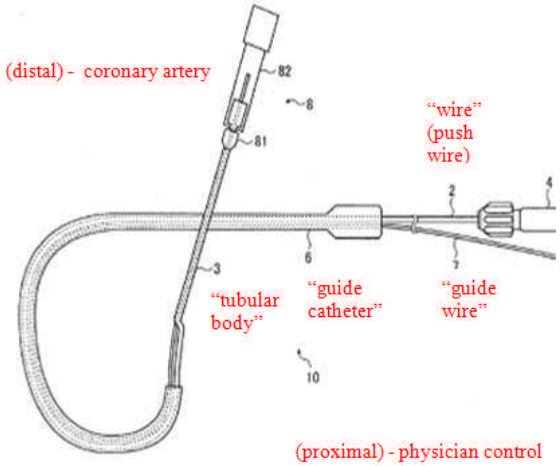
a reinforced portion proximal to the flexible tip portion;

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

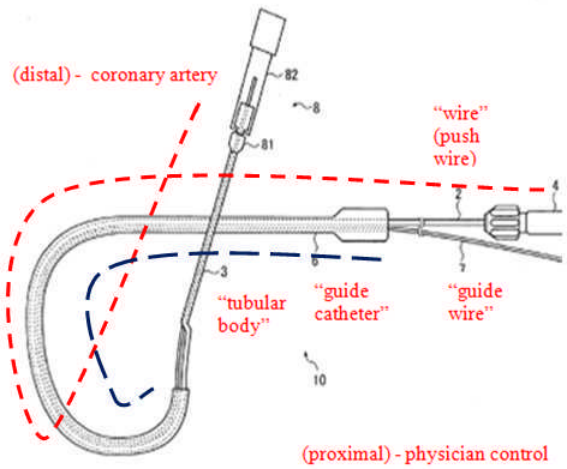
The '032 Patent	**Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)**

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

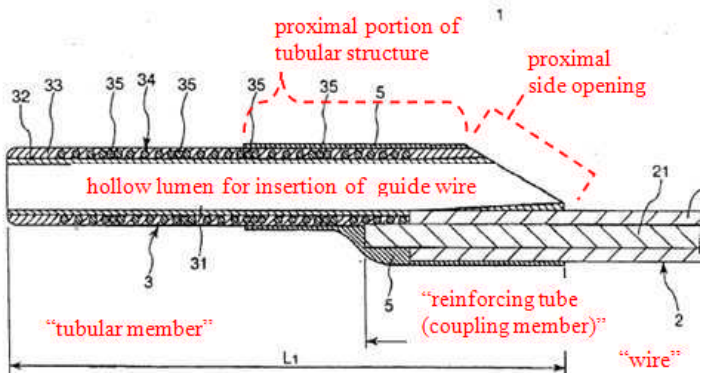
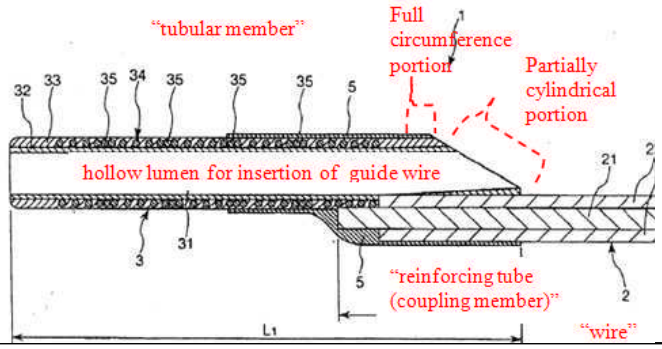
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	the coronary artery. Then, the guide wire 7…was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the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

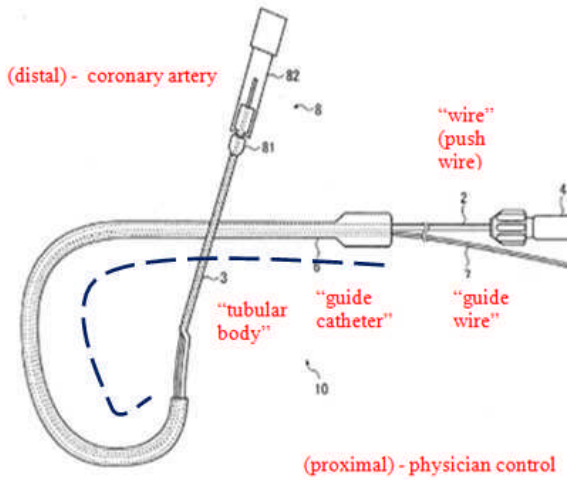
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	[3] "Although the length of the tubular body 3…is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm." (Exh. 1009, [0057].)
the tubular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

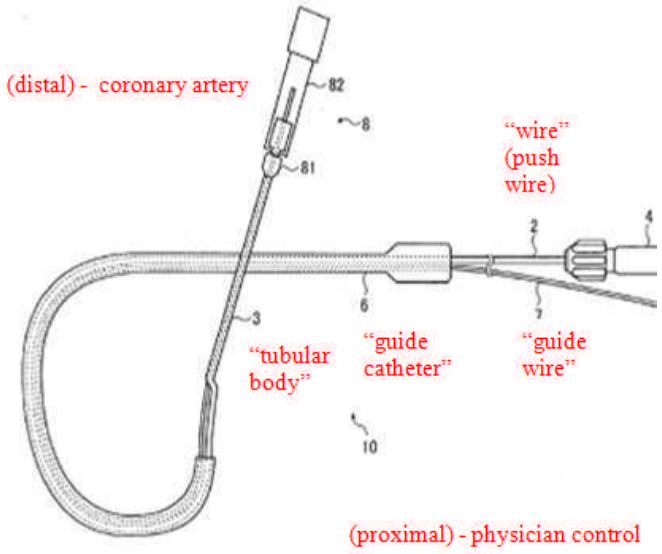
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	(holding portion) 4 placed on a proximal end of the wire 2" (Exh. 1009, [0033].) "The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3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

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

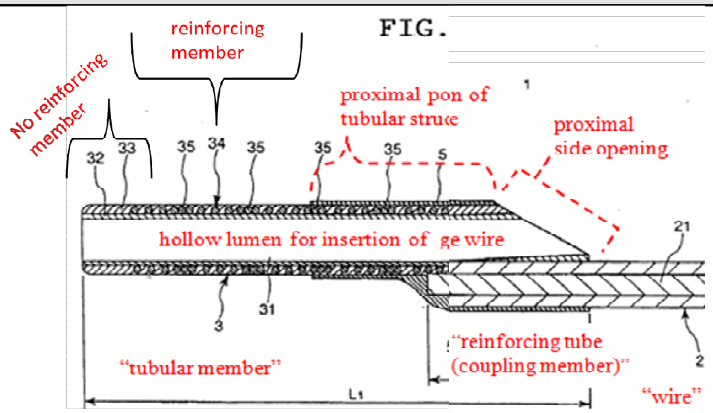
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,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

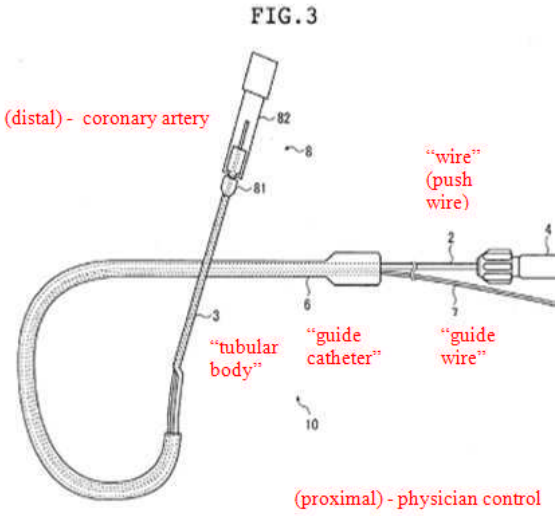
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	FIG. 2 
to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	"The hollow portion 31 of the tubular body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

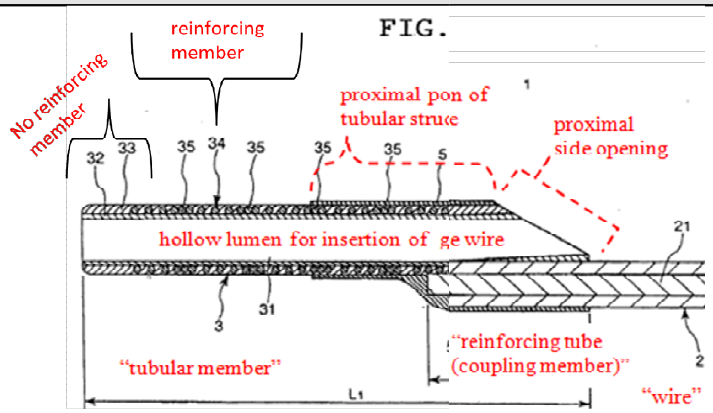
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous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

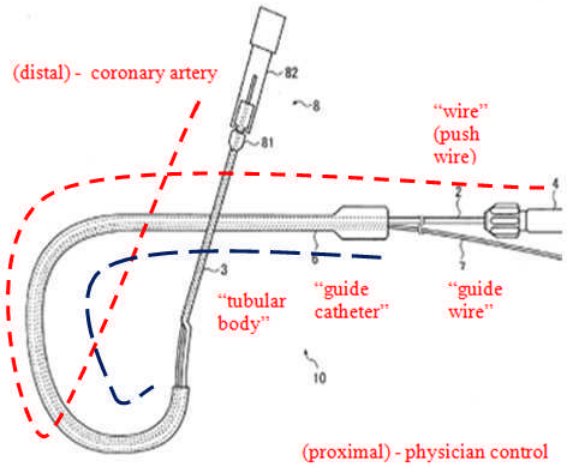
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093].) "First,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

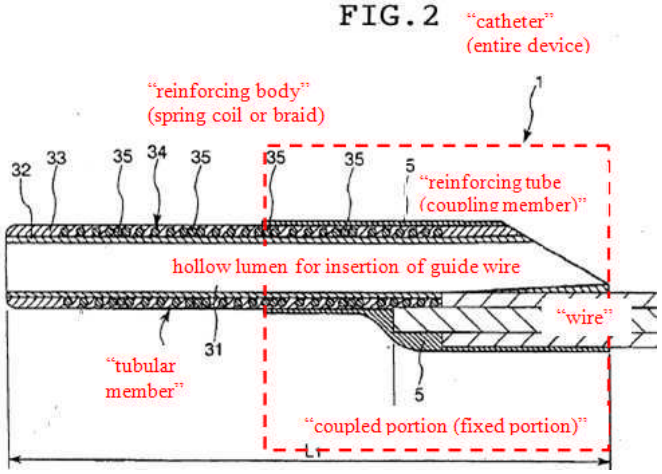
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	diameter of 1.8 mm…was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an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

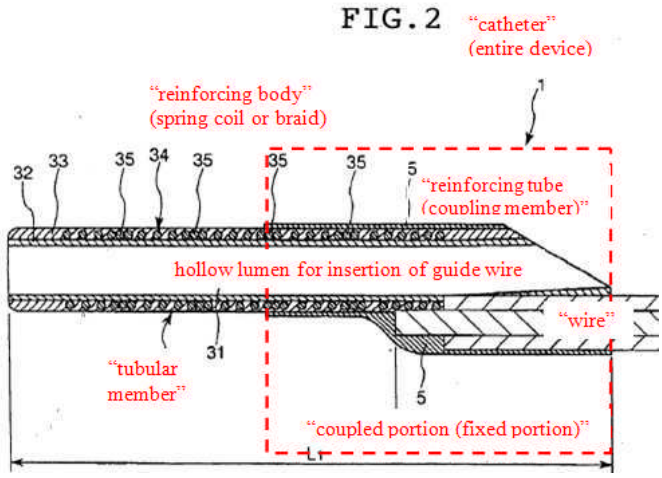
The '032 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 11, 13 US Pub. No. 2004/0236215 ("Mihara") (Exh. 1009)
	 **[2]** The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VIII. CONCLUSION

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

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

Respectfully submitted,

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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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