IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

In re *Inter-Partes Review* of:	)	
	)	
U.S. Patent No. 9,788,853 B2	)	
	)	
Issued: October 17, 2017	)	Attorney Docket No. 68890-280124
	)	
Inventors: Paul Joseph Robinson et al.	)	
	)	
Application No. 14/155,549	)	
	)	
Filed: January 15, 2014	)	
	)	FILED ELECTRONICALLY
For: ATHERECTOMY DEVICES	)	PER 37 C.F.R. § 42.6(b)(1)
AND METHODS	)	

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PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,788,853 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104

Pursuant to 35 U.S.C. § 312 and 37 C.F.R. § 42.100 *et seq.*, Cardiovascular Systems, Inc. ("Petitioner") hereby request *inter partes* review of claims 1-15 of U.S. Patent No. 9,788,853 B2 ("the '853 patent," attached as Petition Exhibit 1001), now purportedly assigned to Cardio Flow, Inc. ("CFI").

An electronic payment in the amount of $30,500 for the *inter partes* review fee specified by 37 C.F.R. § 42.15(a)(1) and 42.15(a)(2)—comprising the $15,500.00 request fee, and $15,000.00 post-institution fee—is being paid at the time of filing this petition. If there are any additional fees due in connection with the filing of this paper, please charge the required fees to our deposit account no. 505196.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

LIST OF EXHIBITS

Exhibit 1001:	U.S. Patent No. 9,788,853
Exhibit 1002:	Declaration of Dr. Morten Olgaard Jensen
Exhibit 1003:	U.S. Patent No. 8,177,801
Exhibit 1004:	U.S. Patent No. 5,584,843
Exhibit 1005:	U.S. Patent No. 8,628,550
Exhibit 1006	U.S. Patent No. 9,289,230
Exhibit 1007	U.S. Patent No. 8,353,923
Exhibit 1008	U.S. Patent Appl. Publ. No. U.S. 2009/0069829
Exhibit 1009	U.S. Patent Appl. Publ. No. U.S. 2012/0178986
Exhibit 1010	U.S. Patent Appl. Publ. No. U.S. 2012/0035633
Exhibit 1011	U.S. Patent No. 4,445,509
Exhibit 1012	U.S. Patent No. 4,990,134
Exhibit 1013	U.S. Patent No. 6,132,444
Exhibit 1014	U.S. Patent No. 6,494,890
Exhibit 1015	U.S. Patent No. 5,314,438
Exhibit 1016	U.S. Patent No. 5,556,389
Exhibit 1017	File History for U.S. Patent No. 9,788,853
Exhibit 1018	WO 2008/006704
Exhibit 1019	WO 2008/006705
Exhibit 1020	WO 2008/006706
Exhibit 1021	WO 2008/006708
Exhibit 1022	WO 2008/062069

Exhibit 1023	WO 2006/126076
Exhibit 1024	WO 2006/126176
Exhibit 1025	U.S. Patent No. 7,507,245

I. MANDATORY NOTICES

A. Real Party-in-Interest

Cardiovascular Systems, Inc. ("CSI" and/or "Petitioner") is the real party-in-interest.

B. Related Matters

Petitioner is not aware of any judicial or administrative matter that would affect, or be affected by, a decision in the proceeding.

C. Lead and Back-Up Counsel and Service Information

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D. Certification Of Grounds For Standing

Petitioner certify pursuant to Rule 42.104(a) that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

II. RELIEF REQUESTED

Petitioner requests institution of an *inter partes* review and cancellation of claims 1-15, as unpatentable under 35 U.S.C. § 103.

III. OVERVIEW OF CHALLENGES

A. Identification of Challenges

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1-15 of U.S. Patent No. 9,788,853 ('853 patent) (Ex. 1001) as unpatentable in view of, the following patents and printed publications:

1. Kallok, et al, U.S. Patent No. 8,177,801, "Method And Apparatus For Increasing Rotational Amplitude Of Abrasive Element On High-Speed Rotational Atherectomy Device," filed March 17, 2009 ("Kallok") (Ex. 1003).

2. Wulfman, et al., U.S. Patent No. 5,584,843, "Shaped Wire Multi-Burr Rotational Ablation Device," filed December 20, 1994 ("Wulfman") (Ex. 1004).

3. Narveson, U.S. Patent No. 8,628,550, "Rotational Atherectomy Segmented Abrading Head And Method To Improve Abrading Efficiency," filed February 19, 2009 ("Narveson") (Ex. 1005).

4. Cambronne, U.S. Patent No. 9,289,230, "Rotational Atherectomy Device With A System Of Eccentric Abrading Heads," filed September 17, 2012 ("Cambronne") (Ex. 1006).

5. Campbell et al., U.S. Patent Appl. Publ. No. U.S. 2012/0178986, "Percutaneous Heart Pump," filed January 6, 2012 ("Campbell") (Ex. 1009).

6. Shturman et al., U.S. Patent Appl. Publ. No. U.S. 2012/0035633, "Rotational Atherectomy Device With Eccentric Abrasive Element and Method of Use," filed October 21, 2011 ("Shturman '633") (Ex. 1010).

7. Shturman, et al., U.S. Patent No. 6,132,444, "Eccentric Drive Shaft For Atherectomy Device And Method For Manufacture," filed August 8, 1997 ("Shturman '444") (Ex. 1013).

8. Liprie, U.S. Patent No. 5,556,389, "Method And Apparatus For Treating Stenosis Or Other Constriction In A Bodily Conduit," filed March 31, 1994 ("Liprie") (Ex. 1016).

According to their publications, each of Kallok, Wulfman, Narveson, Campbell, Shturman ‘633, and Shturman ‘444 is prior art under at least one of 35 U.S.C. §§ 102(a)(1) and (a)(2) as being published before the presumed effective filing date of the ‘853 patent (i.e., before the presumed effective filing date of January 15, 2014). Cambronne is prior art under at least 35 U.S.C. §§ 102(a)(2) as a U.S. patent applicant publication that was effectively filed, naming another inventor, before the presumed effective filing date of the ‘853 patent.

Cambronne was not made of record or cited by the examiner during prosecution of the ‘853 patent. Kallok was cited but was not applied during prosecution. Kallok’s late appearance on the record (appearing on the record on August 31, 2017 after an initial Notice of Allowance had been mailed on May 8, 2017, see Ex. 1017, pp. 4-33) together with its drawings which focus on alternative enlarged-coil configurations, may have left Kallok’s important teachings unappreciated at the time of examination. Shturman ‘633, Kallok, Wulfman, and Shturman ‘444 were made of record but were not applied by the examiner during the prosecution of the ‘853 patent. Although Narveson, Liprie and Campbell were previously applied by the examiner, the Office has not previously considered these reference applied as presented in Petitioner’s challenges, for example, in combination in the same manner and/or with the same prior art as presented herein. Additionally, Petitioner now presents testimony from Dr. Morten Jensen (Ex.

1002) establishing that all of the limitations recited in the challenged claims would have been obvious to POSITA in consideration of these prior art references.

Ground	Reference(s)	Challenged Claims
1	§ 103 Shturman '633 in combination with Kallok and any one or more of Narveson, Cambronne, Shturman '444 and Wulfman	1-10, 12-14
2	§ 103 Shturman '633 in combination with Kallok and any one or more of Narveson, Cambronne, Shturman '444 and Wulfman, and Liprie	11
3	§103 Shturman '633 in combination with Kallok and any one or more of Narveson, Cambronne, Shturman '444 and Wulfman, and Campbell.	15

B. There is a Reasonable Likelihood that at least One Claim of the '853 Patent is Unpatentable under 35 U.S.C. § 103

The '853 patent is directed to wholly conventional system for a rotational atherectomy device for removing or reducing stenotic lesions in blood vessels. *See, e.g.,* '853 patent at Title; Abstract; 1:5-9 (Ex. 1001). In the described embodiment, abrasive elements and a stability element are attached to an elongated drive shaft. The center of mass of the abrasive element is offset to the longitudinal axis of the drive shaft, whereas the center of mass of the stability element is aligned with the longitudinal axis. When rotated at high speeds, the eccentric abrasive element rotates on an orbital path that is substantially larger in diameter than the outer diameter of the rotational atherectomy device at rest. The weighted stability elements control the rotary motion such that the rotation is stable and predictable. But before the alleged invention of the '853 patent, multiple others arrived at the same solution of attaching eccentric abrasive elements and centric stability elements on a drive shaft to provide the same function as disclosed in the '853 patent. *See, e.g.* Ex. 1010, Shturman '633; Ex. 1003, Kallok; Ex. 1005, Narveson; Ex. 1006, Cambronne; Ex. 1004, Wulfman; Ex. 1013, Shturman '444; Ex. 1009, Campbell; and Ex. 1016, Liprie.

Each of these references demonstrates the unpatentability of the challenged claims. As set forth in more detail below, and as supported by the Declaration of Dr. Morten Jensen, an Associate Professor of Biomedical Engineering at the University of Arkansas ("Jensen Decl.") (Ex. 1002), the cited patents and printed publications establish a reasonable likelihood that Petitioner will prevail with at least one of the challenged claims. *See* 35 U.S.C. § 314(a).

IV. THE '853 PATENT

A. Overview of the '853 Patent

The '853 patent is directed to a rotational atherectomy device for removing or reducing stenotic lesions in blood vessels. *See, e.g.*, '853 patent at Title; Abstract; 1:5-9 (Ex. 1001). Atherosclerosis is characterized by the buildup of fatty deposits in blood vessels. Over time, the fatty deposits harden into calcified atherosclerotic plaque. The plaque deposit restricts the flow of blood and is often referred to as stenotic lesions or stenoses and the blocking materials as stenotic material. The clogging of the arteries with plague is a cause of coronary heart disease or vascular disease.

A variety of techniques and medical devices have been developed to remove or shrink the stenotic material. One such technique is rotational atherectomy. Rotational atherectomy involve the use of an abrasive burr rotating at a high speed within the blood vessel to scrape against and removing or reducing the stenotic material and thereby improving blood flow through the vessel. The ‘853 patent recognizes numerous rotational atherectomy devices already exist and identifies 16 published patent applications and patents as some examples. The ‘853 patent does not identify any problems associated with these prior rotational atherectomy devices. Instead, the ‘853 patent offers routine design modifications to existing rotational atherectomy devices to achieve known and predictable results. The embodiments of the ‘853 patent include an elongated flexible drive shaft, an eccentric abrasive element fixed to the drive shaft, weighted stability elements attached to the drive shaft and at least one weighted stability element on each side of the abrasive element. *See, e.g., Id.* at 1:46-55; 2:1-18; 3:17-31; 3:52-4:1.

The claimed invention purportedly offers two advantages over earlier rotational atherectomy devices. First, the claimed invention provides a stable and predictable rotary motion profile because the eccentric abrasive element follows a predefined, consistent orbital path while the stability elements and other portions of the device remain on or near the axis of rotation for the drive shaft in a stable manner. *Id.* at 4:32-50. Second, the claimed invention can be used to treat a larger diameter vessels compared to the diameter of the device at rest. This is achieved by the eccentric abrasive element tracing a larger orbital path during rotation. *Id.* at 4:51-5:5. As discussed further herein, both of these purported advantages were known.

B. Claim Construction

Claim terms are given their ordinary and accustomed meaning as understood by one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*). A claim in an unexpired patent subject to *inter partes* review receives the "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). This standard is broad, but takes into account the guidance of the specification. *Id.* Any construction under this standard – like the district court standard – should cover the preferred embodiments of the invention because a construction that excludes the preferred embodiments is rarely, if ever, correct. *See, e.g., Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1326 (Fed. Cir. 2013).

A person of ordinary skill in the art at the time of the alleged invention of the '853 patent (a "POSITA") would have had a range of knowledge roughly equivalent to the knowledge and/or training of a person holding the degree of Bachelor of Science in Mechanical Engineering, Biomedical Engineering or equivalent, and at least two years of practical experience (or comparable and/or equivalent education or training), including familiarity with rotational atherectomy. Ex. 1002, ¶¶ 19-23.

Petitioner believes that the all of the terms and phrases from the claims of the '853 patent are well understood to a POSITA. Accordingly, it is not necessary to provide a construction for every term or phrase from the claims of the '853 patent. Nevertheless, Petitioner proposed claim construction for select terms and phrases for this proceeding are set forth below. The broadest reasonable interpretation should be applied to any claim terms or phrases not addressed below.

1. "spherical"

A POSITA would understand the broadest reasonable interpretation of "spherical" to mean "relating to or having properties of a sphere." Ex. 1002, ¶ 32. The term "spherical" is a description of a shape for the claimed "abrasive element." *See, e.g.*, '853 patent, claim 1 (". . . at least three spherical abrasive elements. . ."); 10:26-29 ("In alternative embodiments, one or more of the segments [referring to the segmented eccentric abrasive element] may have a different shape such as, but not limited to, spherical, cylindrical, conical, frustro conical, polyhedral, and the like.”).[1] It is understood to POSITA that relating to or having properties of a sphere is not limited to a sphere (*e.g.* a three dimensional representation of a two dimensional circle), but would include shapes that are sphere-like. *Id.*

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[1] Although not a ground for unpatentability in this Petition, it should be noted that the specification of the ‘853 patent does not disclose a rotational atherectomy device having more than one abrasive element. The specification discloses that a segmented abrasive element may include “multiple side by side abrasive segments” (13:1-24) (Emphasis supplied) and those segments may have different shapes, such as the claimed “spherical” shape. Nowhere in the specification does it disclose a device having multiple abrasive elements, as opposed to an abrasive element having multiple segments. Moreover, the specification uses the terms abrasive “elements” separately from “segments” and thus those terms are not interchangeable. Not surprisingly, consistent with the specification, the claims as filed in the Preliminary Amendment recited “the abrasive element comprises at least three segments. . . .” Ex. 1017 at pp. 255-258, Oct. 8, 2015 Preliminary Amendment, Claim 35. This concept of an abrasive element comprising at least three segments continued throughout the prosecution until the April 14, 2017 Amendment when Claim 35 was amended as “The system of claim 16, wherein ~~the abrasive elements comprises at least three segments,~~ each spherical abrasive element ~~segment~~ of the at least three spherical abrasive elements has ~~segments having~~ an abrasive outer surface, and wherein a middle spherical abrasive element ~~segment~~ of the at least three spherical abrasive elements ~~segments~~ has a larger outer diameter than a proximal spherical abrasive element ~~segment~~ of the at least three spherical abrasive elements ~~segments~~ and a larger outer diameter than a distal spherical abrasive element ~~segment~~ of the at least three spherical abrasive elements ~~segments~~.” Claim 16 was similarly amended to add “an array of at least three spherical [[an]] abrasive elements . . . .” Ex. 1017 at pp. 75-79, Apr. 14, 2017 Amendment, Claim 35 and 16. There is no written description support for a device having multiple abrasive elements, as opposed to a single abrasive element having multiple segments.

2. "abrasive elements"

A POSITA would understand the broadest reasonable interpretation of "abrasive element" to mean "a component of a device capable of removing material by grinding or rubbing." Ex. 1002, ¶ 33; *see, e.g.*, '853 patent, 8:47-67 ("the eccentric abrasive element 140, which may also be referred to as a burr, can comprise a biocompatiable material that is coated with an abrasive media such as diamond grit, diamond particles, silicon carbide, and the like . . . Therefore, as the eccentric abrasive element 140 is rotated in an orbital path, at least a portion of the abrasive surface 142 of the eccentric abrasive element 140 can make contact with surrounding stenotic lesion material.")

3. "stability element"

A POSITA would understand the broadest reasonable interpretation of "stability element" to mean "a component of a device capable of exerting opposing force to provide a stable and predictable motion." Ex. 1002, ¶ 34. Indeed, the specification of the '853 patent discloses that the stability elements "enhance the stability and predictability of rotary motion" when the drive shaft is rotated a high speed. *see, e.g.*, '853 patent 4:32-42.

4. "cylindrical"

A POSITA would understand the broadest reasonable interpretation of "cylindrical" to mean "relating to or having similarity to a cylinder" which would include having generally straight parallel sides and a circular or ovular cross-section." Ex. 1002, ¶ 35. As discussed above with the claim term "spherical," the claim term "cylindrical" is also refers to a shape. '853 patent, 13:27-29 (describing cylindrical as one of multiple shapes). It is understood to POSITA that "cylindrical" is not limited to a cylinder, but includes formations similar in nature to a cylinder. *Id*.

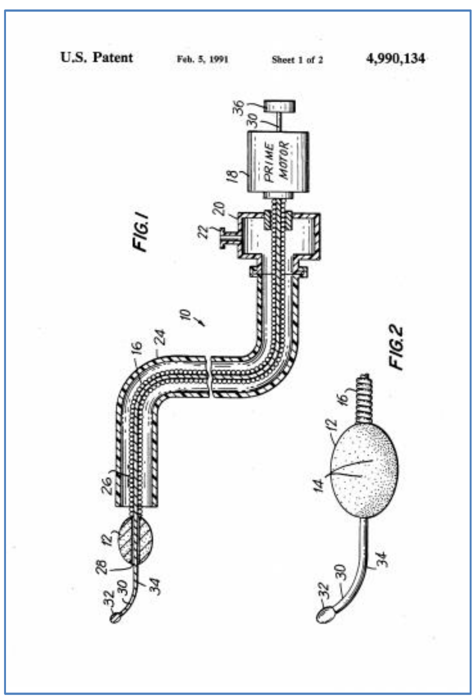
V. CLAIMS 1-15 OF THE '853 PATENT ARE UNPATENTABLE

Each challenged claim and where each portion of the claim is taught or suggested in the cited prior art, as well as where each portion of the claim is further analyzed in the declaration of Dr. Morten Jensen is discussed in greater detail below for each claim portion. In addition, each claim portion is annotated, e.g., "1[a]," for descriptive convenience in the sections that follow.

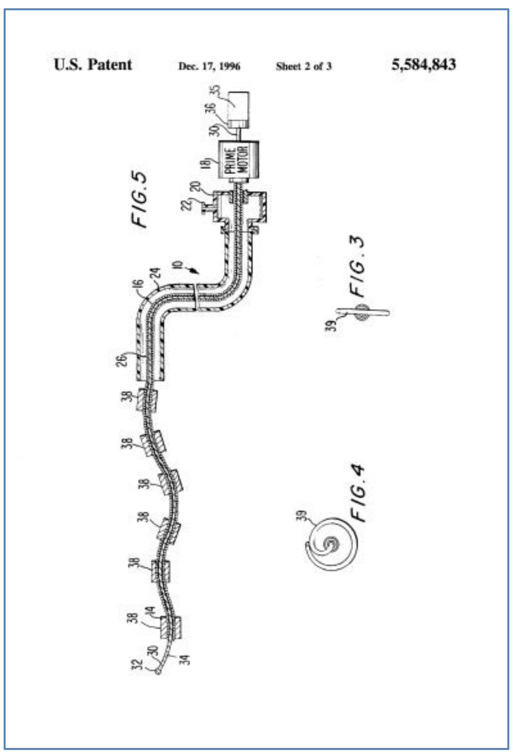
A. There Is Nothing New About A Rotational Atherectomy Device Having An Elongated Drive Shaft, Abrasive Element, And Stability Elements To Provide A Stable And Predictable Rotary Motion And Larger Orbital Path Than The Diameter Of The Device At Rest

The '853 patent claims focus on the simple concept of attaching abrasive elements and stability element(s) on a drive shaft. The center of mass of the abrasive stability element is offset to the longitudinal axis of the drive shaft, whereas the center of mass of the stability element(s) is/are aligned with the longitudinal axis. The relationship of the eccentric abrasive element and the stability element(s) relative to the longitudinal axis of the drive shaft provide a stable and predictable rotary motion and larger orbital path of the abrasive element when rotated at high speeds compared to the outer diameter of the device at rest.

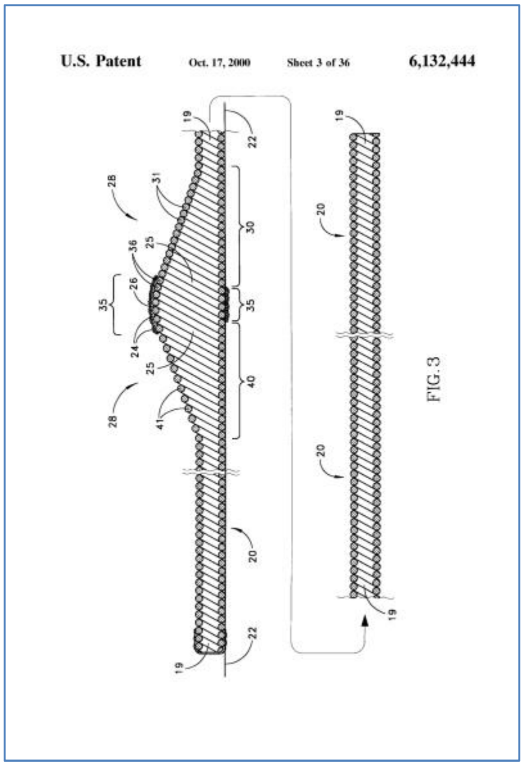
This simple concept and the associated advantages, however, long pre-dates the '853 patent. In fact, this concept was the result of a natural evolution of rotational atherectomy devices that began at least as early as the early 1980's. Early rotational atherectomy devices cleared an occlusion with a device having an orbital path during high speed rotation that is roughly equivalent to the resting diameter. For example, U.S. Patent Nos. 4,445,509 (Ex. 1011) and 4,990,134 (Ex. 1012) (both to Auth) taught a concentric burr mounted at the distal end of a rotational drive shaft with the center of mass of the concentric burr located on the rotational axis of the drive shaft.

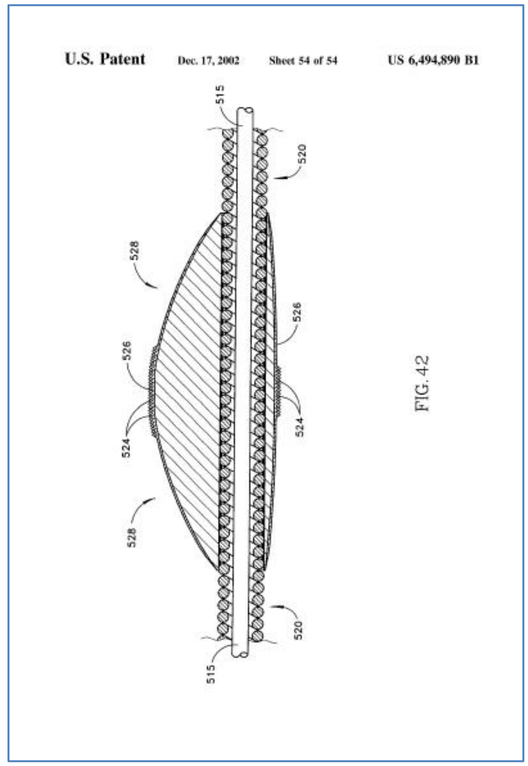


By mid-1990's, researchers were pursuing methods to generate orbital paths that were larger than the resting diameter of the abrasive elements. Wulfman (Ex. 1004) taught a series of spaced-apart abrasive cylinders mounted on the drive shaft, wherein the proximal abrasive cylinder may be dimensioned to ease entry into occlusion. When the shaped guide wire is translated along drive shaft lumen, the centers of mass of the affected cylinders are spaced radially away from the nominal rotational axis of the drive shaft. When rotated, the working diameter traced by the spaced-apart cylinders is larger than the resting diameter of the spaced-apart cylinders and provides extended length of abrasion as well as control over the working diameter.



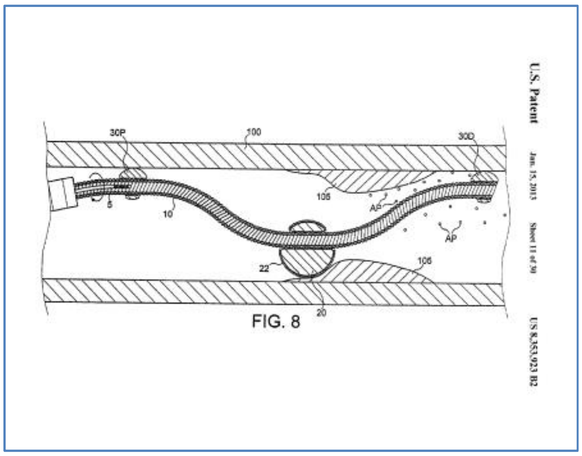
By the late 1990's, it was known that the use of an abrasive element with a center of mass radially offset from the drive shaft's nominal rotational longitudinal axis during high-speed rotation results in a working diameter that is greater than the resting diameter of the abrasive element. *See, e.g.*, U.S. Patent No. 6,132,444 (Ex. 1013) (teaching an eccentric enlarged section formed by the wire turns of a drive shaft consisting of strands of metal wire helically wound to form the drive shaft with a central lumen. The eccentric enlarged section is formed proximal to the distal end of the drive shaft. The eccentric enlarged section of the drive shaft having a shaping achieved by stretching the filars of the wire turns of the drive shaft over a mandrel having the desired shape, then removing the mandrel by described means.); and U.S. Patent No. 6,494,890 (Ex. 1014) (disclosing a solid burr mounted proximal to the distal end of a helically coiled drive shaft, wherein the burr's center of mass is radially spaced away from the nominal rotational axis of the drive shaft).

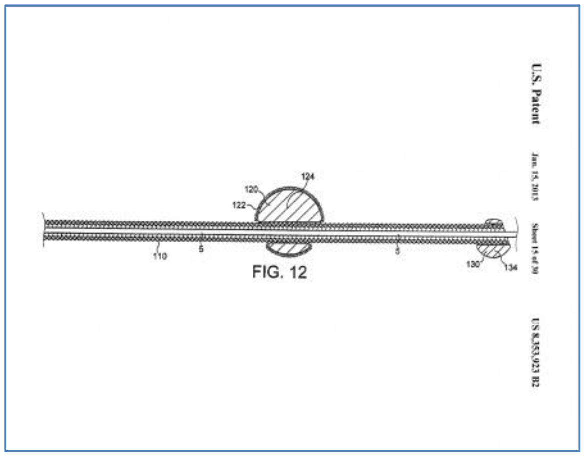


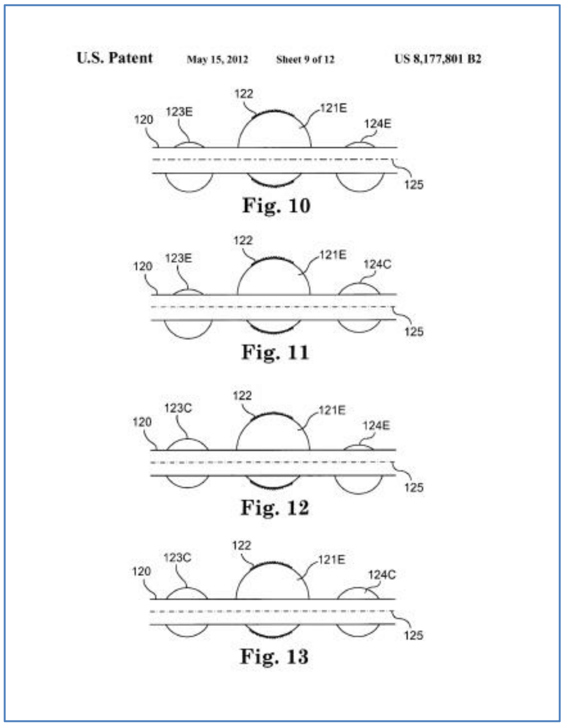


By the early 2000's, control over the orbital rotary motion was achieved by the use of stability elements positioned on the drive shaft proximally and distally from the abrasive element. The use of stability elements with eccentric abrasive elements provided a working diameter traced by the abrasive element during high-speed rotation that is larger than the resting diameter of the abrasive element, and control of the working diameter to provide greater stability and predictability of the abrasive element. *See, e.g.*, U.S. Patent No. 8,353,923 (Ex. 1007) (disclosing a central eccentric abrasive element with a proximal and/or distal eccentric element spaced away proximally and distally from the eccentric abrasive element with location of centers of mass to stimulate and control the orbital motion induced in the central eccentric abrasive element during high-speed rotation.); and U.S. Patent

No. 8,177,801 (Ex. 1003) (teaching a central abrasive element with one or more proximal and/or one or more distal counterweights spaced away from the central abrasive element. The spacing distance of the one or more counterweights may, or may not, be equidistant from the central abrasive element. The abrasive element may be eccentric (center of mass spaced away from the axis of rotation of the drive shaft), with concentric (center of mass on the axis of rotation of the drive shaft) counterweights.).







Accordingly, for many years prior to the effective filing date of the '853 patent, it was known that an eccentric abrasive element traces an orbital path having a larger diameter than the outer diameter of the rotational atherectomy device in the non-rotating state and the use of certain design features, such as placement and mass of stability elements on the drive shaft, can be used to control the orbital motion.

B. Claim 1 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[1a]. *A system for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient, the system comprising:*

Shturman '633 discloses a system for performing rotational atherectomy to remove stenotic lesion material from a blood vessel of a patient. *See e.g.,* Ex. 1010, Title, abstract, ¶1 ("The present invention relates to a rotational atherectomy device for removing a stenotic lesion from within a vessel of a patient."). Shturman '633's "device" can equally be referred to as a system, as a group of component parts and/or as a device for use with other components, such as guidewires, power sources and/or pressure sources, as an operable system. *Id.* at ¶¶13, 30, 44, 51, 54-56, 66; Jensen Decl. (Ex. 1002) ¶ 43. Although the preamble does not appear to limit the claim, Shturman '633 discloses this feature. *Id.*

[1b] an *elongate flush tube defining a first lumen and a second lumen; and*

Shturman '633 discloses the claimed flush tube at least at sheath 41,43. Shturman '633 teaches that its sheath 41 provides flush fluid received from tube 42 to encourage removal of abraded particles. Ex. 1010 at ¶¶46-57. Shturman '633 further teaches that sheath 43 drains the flush fluid from the artery to the side branch 45. Under the broadest reasonable interpretation, Shturman '633's sheaths 41,43 is an elongate flush tube providing flush fluid to corral abrasion particles. Jensen Decl. (Ex. 1002) ¶ 44. The sheaths 41,43 define first and second lumens according to the flow paths for the flush fluid provided within the sheaths 41,43. *Id*.

[1c] *a rotational atherectomy device comprising*:

Shturman ‘633 discloses a rotational atherectomy device. *See, e.g.,* Ex. 1010, Title, Abstract (“The present invention relates to a rotational atherectomy device for removing a stenotic lesion from within a vessel of a patient.”). Jensen Decl. (Ex. 1002) ¶ 45.

[1d] *an elongate flexible drive shaft comprising helically wound metallic filars that form a coil having a constant outer diameter, the drive shaft defining a longitudinal axis, the drive shaft configured for rotation about the longitudinal axis, the drive shaft configured to be at least partially disposed within the second lumen when the system is used for performing the rotational atherectomy;*

Shturman ‘633 discloses that its rotational atherectomy device includes the claimed drive shaft as at least drive shaft 10,11,14. *See e.g.*, Ex. 1010 at Figs. 1-5, 7, 8; ¶¶3-7, 10-30, 31, 33, 43-45, 49-51, 53-55, 58, 62-66, claims 1-45. For example, Shturman ‘633 discloses its drive shaft 10 including elongated portions 11,14 to be a flexible drive shaft *(e.g.,* ¶¶28, 58); defining a longitudinal axis for rotation (*e.g.,* ¶36, claim 26); and disposed within the second lumen (*e.g.,* sheaths 41,43); Jensen Decl. (Ex. 1002) ¶ 46.

To the extent that Shturman ‘633 does not expressly discuss its shaft as comprising commonly known helically wound metallic filars, Shturman ‘633 implies such construction of its drive shaft 10 at least by reference to U.S. Patent No. 4,990,134 disclosing a shaft of helically wound filars (*e.g.*, Ex. 1012 at 3:5-10), and U.S. Patent No. 6,132,444 (*e.g.* Ex. 1013 at 10:1-19), according to the understanding of the POSITA. Moreover, the POSITA would have understood that rotational drive shafts of helically wound metallic filars forming a coil are commonly known and applied in atherectomy devices as a routine design choice of materials, obvious to try as a selection from a finite number of predetermine choice with reasonable expectation of success, as an implementation of a known element to yield predictable results, and/or for strength, density, flexibility, hygiene, availability, manufacturing, and/or commercial advantages. Jensen Decl. (Ex. 1002) ¶¶ 47-53.

To the extent that Shturman '633 does not expressly discuss its shaft as comprising commonly known helically wound metallic filars, Shturman '633 implies such construction of its drive shaft 10 at least by reference to the rotational atherectomy device commercially produced by Cardiovascular Systems, Inc., the instant petitioner at ¶ 0004. Cardiovascular Systems, Inc. has used a drive shaft of helically wound metallic filar construction in its atherectomy products for over 15 years.

[1e] *an array of at least three spherical abrasive elements positioned adjacent to one another along the coil, the spherical abrasive elements*

being fixed to the drive shaft such that a center of mass of each abrasive element is offset from the longitudinal axis, each abrasive elements being spaced apart from an adjacent abrasive element by an element spacing distance;

Shturman '633 also discloses using spherical abrasive elements at least as abrasive element 16, and that its abrasive element is fixed to its drive shaft offset to the axis (eccentric). *See, e.g.*, Ex. 1012 at ¶¶9-12, 26-29, 32-33, 36 (mass spaced apart from longitudinal axis), ¶¶ 43-44, 46, 49, 53, 55 ("eccentric abrasive element is mounted to the drive shaft 10"), ¶ 58; claim 26; and Figs. 1-6, 7-8. To the extent that Shturman does not expressly disclose at least three adjacent abrasive elements, such a change is no more than routine design choice. Jensen Decl. (Ex. 1002) ¶ 54.

The recitation of "at least three" abrasive elements represents no patentable distinction absent unexpected results. *Lexion Med., LLC*, IPR2017-00518, 2018 WL 3216551, at *14 (June 29, 2018) (*citing In re Harza*, 274 F.2d 669 (CCPA 1960) ("It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced, and we are of the opinion that such is not the case here."). As indicated above, Shturman discloses this claim element, except, it is silent as to the interrelated aspects of the "at least three" elements and their "element spacing distance." However, the recited "element spacing distance" fails to elevate the difference beyond mere duplication of parts at least because under the broadest reasonable interpretation this would include any spacing choice made by the POSITA, indeed even a distance near zero. Jensen Decl. (Ex. 1002) ¶ 55-58.

Moreover, the POSITA in routinely duplicating Shturman '633's abrasive elements would have implemented them adjacent to one another to maintain the abrasive elements between stability elements. Jensen Decl. (Ex. 1002) ¶ 56. Placing the abrasion elements in spaced-apart longitudinal relationship with each other would be expected to maintain the precision of the orbital movement of the abrasive elements—as opposed to interspersing the abrasive and stability elements. *Id*. Indeed, interspersing the abrasive and stability elements would expectedly create dissimilar orbital rotations for the different abrasive elements, effectively canceling the usefulness of the additional abrasives, imposing unnecessary rotating mass away from the stenotic lesion (a potential hazard), and degrading the effectiveness of the stability elements. *Id*. Therefore, it would have been obvious to modify Shturman '633 to have at least three of its abrasive elements 16 adjacent to one another along the shaft as routine design choice, duplication of parts, implemented to maintain precision orbital motion and having merely expected results. *Id.*

Further, the POSITA will, as specifically taught by Narveson (Ex. 1005 at 11:30-54) readily understand the following fundamental principles relating to generating and controlling the working path of an abrasive element attached to a drive shaft during high-speed rotation, wherein the working path traces out a diameter that is larger than the resting diameter of the abrasive element, i.e., achieving "orbital motion", and how to influence same:

> "[A]pplicants believe that offsetting the center of mass 32 from the axis of rotation 21 of the drive shaft 20 produces an "orbital" movement of the eccentric abrading head 100, *the diameter of the "orbit" being controllable by varying, inter alia, the rotational speed of the drive shaft 20 and the number of at least one cylindrical segments 102 employed and the mass, and mass distribution, thereof.* Applicants have empirically demonstrated that by varying the rotational speed of the drive shaft 20 and/or the number of cylindrical segment(s) 102, one can control the centrifugal force urging the abrasive surface 26 on the outer surface 104 of the cylindrical segment(s) 102 of the eccentric abrading head 100 against the surface of the stenosis. The centrifugal force can be determined according to the formula:
>
> $$Fc=m\Delta x(\pi n/30)2$$
>
> where *Fc* is the centrifugal force, *m* is the mass of the eccentric abrading head 100, Δx is the distance between the center of mass 32 of the eccentric abrading head 100 and the rotational axis 21 of the drive shaft 20, and *n* is the rotational speed in revolutions per minute (rpm). Controlling this force

> *Fc* provides control over the rapidity with which tissue is removed, control over the maximum diameter to which the device will open a stenosis, and improved control over the particle size of the tissue being removed."

Ex. 1005 (Emphasis supplied) (*See also* Figs. 5 and 6).

Accordingly, Narveson teaches with known and predictable mathematical precision, the effects of modifying a single abrasive element into more than one abrasive element along the drive shaft, where each abrasive element comprises a center of mass that is radially spaced away from the longitudinal axis of the drive shaft to which the abrasive elements are attached. *See* Narveson (Ex. 1005) at Figs 5 and 6. Moreover, Narveson teaches the specific variables available for modification in order to gain control over the orbital motion of the abrasive elements, including, *inter alia*:

- The rotational speed of the abrasive elements;
- The number of the abrasive elements with a radially offset center of mass attached to the drive shaft;
- The mass of the abrasive elements; and
- The distribution of that mass relative to the drive shaft's longitudinal axis.

Jensen Decl. (Ex. 1002) ¶ 59-60.

Narveson further teaches an orbital atherectomy device including multiple adjacent abrasive elements 130, 135, (102, 104), 140. Narveson teaches its use of multiple abrasive elements can encourage flexibility in the drive shaft while maintaining precise control of the orbital rotation. *See* Ex. 1005, ¶¶7-10. Narveson's flexibility can promote ease in insertion and withdrawal of the device. *Id*., at 46. Narveson also teaches a variety of other advantages of its multiple abrasive elements including disrupting hydraulic wedge effect, increasing abrasion efficiency and lessening trauma, increasing surface area, the use of different abrasive grits providing, for example, optimized surfaces for hard and soft tissue. Jensen Decl. (Ex. 1002) ¶ 61.

The POSITA would recognize that Narveson's abrasive elements are suggested to be spaced apart from each other as a substitution for a continuous solid abrasive element. Narveson's spacing would likewise encourage placing the elements adjacent one another while allowing the potential to vary their attributes. Jensen Decl. (Ex. 1002) ¶ 62. Accordingly, the spherical abrasive element of Shturman '633would be predictably split into more than one spherical abrasive element or duplicated to achieve the claimed three spherical abrasive elements following modification by Narveson and without unexpected results. *Id.*

Similarly, Cambronne teaches an orbital atherectomy device having two or more eccentric abrading heads in spaced-apart longitudinal distribution along a flexible, elongated, rotational drive shaft. *See* Ex. 1006, Cambronne, Abstract; 4:20-22; claim 1; Figs 2, 4A-4B; Jensen Decl. (Ex. 1002) ¶ 63. Each of Cambronne's spaced-apart eccentric abrading heads comprises a geometric center and a center of mass, wherein the center of mass for each of the eccentric abrading heads is radially offset from the drive shaft's axis. *See Id.* at Figs 3, 4A-4B; claim 1.

Further, Cambronne's spaced-apart eccentric abrading heads comprise the centers of mass thereof to be offset from the drive shaft axis in the same direction and plane. *See Id.* at Figs 2, 3A; 4:57-5:1. This arrangement will "tend to result in centrifugal forces generated during high speed rotation of the drive shaft 20 and orbital motion of the abrading heads. . . ." *Id.* at 5:35-37.

Alternatively, Cambronne's spaced-apart eccentric abrading heads may be arranged such that the centers of mass are provided along the same plane, but in opposing directions. *See Id.* at 5:1-6.

Still more alternatively, Cambronne's spaced-apart eccentric abrading heads may be arranged so that the centers of mass of adjacent eccentric abrading heads are all radially spaced away from the drive shaft axis and rotationally spaced apart from each other. *See Id.* at 5:7-16; Figs. 3B, 4A.

Accordingly, in addition to the knowledge described *supra*, the POSITA also possesses the teachings from Cambronne for manipulating and controlling the orbital pathing achieved during high-speed rotation using an eccentric abrasive element and/or a system of spaced-apart eccentric abrasive elements. This is not surprising in view of Cambronne, like Narveson, discloses and relies on the application of the formula for centrifugal force and manipulation of the relevant variable described in Narveson. *Id.* at 10:30-60; Jensen Decl. (Ex. 1002) ¶ 63-65.

Cambronne further teaches the definition of "eccentric" as used in combination with its spaced-apart eccentric abrading heads. "Eccentric" has two meanings according to Cambronne: "(1) a difference between a geometric center of an abrading head and the rotational axis of the drive shaft; or (2) a difference in location between the center of mass of system components [such as the] exemplary enlarged abrading head 28S and/or eccentric abrading head 28A and the rotational axis of the drive shaft 20." Ex. 1006 at 9:24-43. Accordingly, Cambronne directly addresses the effects of a multi-head system of eccentric abrading heads. Jensen Decl. (Ex. 1002) ¶ 66.

Cambronne also discusses the concept of "geometric center" for eccentric abrading heads of non-regular geometric shaping. 9:36-43. Accordingly, the POSITA will readily understand that regular geometric shapes may also be employed in the system of eccentric abrading heads, including but not limited to, *e.g.,* spherical eccentric abrasive heads. Jensen Decl. (Ex. 1002) ¶ 67.

Accordingly, based on the teachings in Cambronne alone, or in combination with the teachings of the preceding references, the POSITA will understand that the principles that apply to a single eccentric abrading head also apply to more than one eccentric abrading head, for example, three or more eccentric abrading heads, and would enable the POSITA to consider modifying the single spherical abrading head from Shturman '633 to create a system of at least three spherical abrading heads with offset centers of mass from the drive shaft axis. Further, it will be well within the POSITA's abilities to modify and control the orbital pathing of the system of eccentric abrading heads during high-speed rotation. Jensen Decl. (Ex. 1002) ¶ 63-68.

Wulfman also teaches a rotational atherectomy device with multiple adjacent and spaced-apart abrasive heads attached to a trifilar helically wound drive shaft. Ex. 1004, 2:54-56. Wulfman expressly teaches multiple burrs to "enlarge the cutting area." Ex. 1004, 4:21-22. Wulfman evidences that multiple abrasives provide a technology neutral advantage and emphasizes the routine nature of the modification to Shturman to multiply its abrasive elements. Jensen Decl. (Ex. 1002) ¶ 69.

Further, Wulfman teaches "cuffs" 38 which are symmetrically attached around and to the drive shaft at spaced-apart intervals therealong. See Ex. 1004 Fig. 5. These "cuffs" are cylinders, comprising straight parallel sides and a circular radial cross section, with a central lumen through which the drive shaft 26 is attached. *Id*. The cylindrical cuffs 38 wrap around and are fixed to the outer portion of the drive shaft 26, and appear to be symmetrically disposed around the drive shaft 26. This arrangement implies that the center of mass is on the drive shaft's longitudinal axis for each cylindrical cuff 38. Although each individual cylindrical cuff is aligned with the longitudinal axis of the drive shaft, the introduction of a shaped guidewire creates the radially offset center of mass for at least some of the cylindrical cuffs 38 by translating a shaped guide wire 30 with a preformed portion 34 through the lumen of the drive shaft 26, thus moving the centers of mass of the affected cylindrical cuffs 38 off of the drive shaft's longitudinal axis. Jensen Decl. (Ex. 1002) ¶ 70.

POSITA could easily modify Shturman '633 to multiply its abrasive elements to have at least three elements, as routine design choice having no patentable distinction, and/or as taught by at least one of Cambronne, Wulfman, and Narveson as routine design choice, mere duplication of parts, to enlarge the abrasive working surface, to enhance flexibility of the shaft, to provide variety in the abrasive grit, to disrupt hydraulic wedge effect, and/or to increase abrasive efficiency and lessen trauma. Jensen Decl. (Ex. 1002) ¶ 70-71. More particularly, it is evident that at the time of alleged invention of the challenged claims, Shturman '633 would have been obvious to modify in the manner discussed above based on the knowledge of the POSITA alone, and/or based on the teaching of Cambronne, Wulfman, and/or Narveson individually as evidenced and/or motivated by the POSITA's knowledge and the teachings of the individual references. *Id.* Additionally and/or alternatively, such modification of Shturman '633 would have also been obvious to POSITA over the collective teachings of any two or more of Cambronne, Wulfman, and/or Narveson as evidenced and/or motivated by the POSITA's knowledge and the teachings of the references. *Id.*

[1f] *a metallic stability element having a cylindrical shape defining an inner diameter, the metallic stability element being fixed along the inner diameter to the helically wound metallic filars of the drive shaft, the metallic stability element having a center of mass aligned with the longitudinal axis, the stability element being distally spaced apart from a distal-most abrasive element of the spherical abrasive elements by a distal separation distance, the distal separation distance being greater than the element spacing distance*;

A POSITA understand that the terms "stability element" and "counterweight" may be used interchangeably. Jensen Decl. (Ex. 1002) ¶ 72. In fact, Shturman '633 uses the term "counterweight" interchangeably with the term "support element" which are synonymous with "stability element." Ex. 1010 at ¶ 0005. Indeed, the broadest reasonable interpretation of the term "stability element" includes "counterweight". *Id.* and *supra* IV(B)(4). Shturman '633 discloses stability elements 18 (proximal), 19 (distal) spaced apart from its abrasive element 16 by separation distances.[2] Ex. 1010, Figs. 1-6, 7, 8. While Shturman '633 does not specify the stability elements 18 and 19 as metallic, surgical metals are commonly known and would be applied to the stability elements by the POSITA as routine design choice, as an implementation of a known element to yield predictable results, and/or for strength, density, flexibility, hygiene, availability, manufacturing, and/or commercial advantages. Jensen Decl. (Ex. 1002) ¶ 72.

Shturman '633 discloses stability elements, as discussed above, but may not expressly disclose stability elements having a center of mass aligned with the longitudinal axis and further may not explicitly disclose a cylindrical shape.

However, as discussed above, Kallok discloses an atherectomy device having eccentric abrasive elements and various eccentric (center of mass radially spaced away from drive shaft axis 125) and concentric (center of mass on drive shaft axis 125) arrangements of counterweights spaced proximally and distally from the abrasive element 121C (concentric or center of mass on drive shaft axis 125), and 121E (eccentric with center of mass radially spaced from drive shaft axis 125). *See* Ex. 1003 (Figs. 10-17). Jensen Decl. (Ex. 1002) ¶ 73.

[2] Claim limitation [1f] only requires a one stability element being distally spaced from a distal most abrasive element. Shturman '633 and Kallok both disclose this distal stability element, in addition to other stability elements, including a stability element being proximately spaced from a proximal most abrasive element.

Kallok explicitly teaches an arrangement in Figure 13 comprising a spherical abrasive element 121E with an eccentric attachment to the drive shaft 125. This implies to the POSITA that the center of mass of the spherical abrasive element 121E is radially offset from the drive shaft's axis 125 by virtue of the eccentric mounting thereon. The distal counterweight element 124C is spaced distally from the spherical eccentric abrasive element and further comprises a center of mass on the drive shaft's nominal rotational axis 125 as claimed. Jensen Decl. (Ex. 1002) ¶ 74-75.

The POSITA will recognize that the term counterweight, as used in Kallok, applies to the range of embodiments shown in the Figures, including exemplary Figure 17 where all centers of masses are on the drive shaft axis 17 and Fig. 13 where the counterweights have centers of mass on axis 125 while the abrasive element is offset from the axis 125. Jensen Decl. (Ex. 1002) ¶ 75.

Further, Kallok also teaches the possibility of a single "counterweight" to "increase stability."

> "An improvement over simply increasing the mass of a single element is to provide *one or more counterweights* to the element, longitudinally separated from the element along the drive shaft. Taken as a whole, the increase in mass does increase stability during operation, but *having the mass increased at locations proximally and/or distally, with respect to the single element,*

may increase the stability without deteriorating the orbital motion of the single element."

Ex. 1003, Kallok, 11: 64- 12: 4 (Emphasis supplied).

Thus, POSITA will recognize that an element positioned distal to the eccentric abrading element may help stabilize the rotation. Jensen Decl. (Ex. 1002) ¶ 74-76.

Moreover, Kallok teaches that the elements, e.g., the distal element 124C, analogous to the claimed cylindrical shaped distal stability element, though shown as "merely circular," may comprise a variety of configurations, including "an abrasive burr, a mass, a weight, a counterweight, . . . or anything else that is distinguishable from the generally featureless drive shaft." Ex. 1003, Kallok 11:33-37.

Kallok's element, e.g., the distal element 124C may be "concentric" as defined: "an element that has its center of mass coincident with the rotational axis of the drive shaft." *Id.* at 11:18-21. A POSITA will recognize that a symmetrical shape, such as a circle, will likely, absent explicit teaching of modifications to the contrary such as materials with different densities, have its center of mass at its center. Jensen Decl. (Ex. 1002) ¶ 78-79.

Given these teachings of Kallok, the POSITA will recognize that the distal element 124C may be a concentric element attached to the drive shaft and given the array of possible configurations described above, that concentric element may be, in the most likely case, a geometrically concentric element disposed around the drive shaft, e.g., a spherical element or, significantly, a cylindrical element. Thus, it is readily apparent that the center of mass is on the drive shaft axis and POSITA would have implemented Shturman '633 in such a manner as routine, to adjust the movement of the device and/or its components, to adjust the "feel" for the user, and/or as obvious to try. Jensen Decl. (Ex. 1002) ¶ 79-83.

Kallok's multiple embodiments evidence the nature of concentric versus eccentric counterweights and/or eccentric elements, and the combinations thereof, to be routine design choice, and/or as obvious to try as a choice from a finite number of identified, predictable solutions, with a reasonable expectation of success. Jensen Decl. (Ex. 1002) ¶ 81-83. Similarly, the POSITA would know that the distance between the abrasive element and spaced-away proximal and distal elements need not be equal and is yet another variable that may be adjusted when modifying and/or controlling the rotational path and centrifugal forces delivered by an eccentric abrasive element, or a system thereof, during high-speed rotation. *See KSR, Int'l Co. v. Teleflex, Inc.*, 550 US 398, 416 (2012); Jensen Decl. (Ex. 1002) ¶ 81-83.

Moreover, the POSITA would have recognized that the coincidence of the center of mass of the stability element with the rotational axis of the drive shaft, and the relative spacing thereof from the eccentric abrading head or system of eccentric abrading heads, has a mathematically predictable effect on the operation of the device under rotation, including the movement of the drive shaft, abrasive elements, stability elements themselves. Jensen Decl. (Ex. 1002) ¶ 82.

The POSITA would have implemented Shturman '633 with its distal stability element having a center of mass aligned with the longitudinal axis as taught by Kallok, in combination with an eccentric abrasive head, or a system of eccentric abrading heads as in Narveson, Cambronne and/or Wulfman, as routine design choice having no patentable distinction; to customize and/or refine the movement of any one or more of the drive shaft, abrasive elements, stability elements themselves; to customize and/or refine the feel to the surgeon; and/or as obvious to try as a choice from a finite number of identified, predictable solutions with a reasonable expectation of success. *See KSR*, 550 U.S. at 416; Jensen Decl. (Ex. 1002) ¶ 83.

Moreover, Kallok discloses a drive shaft of an elongate flexible drive shaft comprising helically wound metallic filars that form a coil having a constant outer diameter. *See* Ex. 1003, ¶¶9 (incorporating U.S. Patent No. 6,132,444 (Ex. 1013) disclosing metal coil shafts, 10:10-20), 40, 62 (incorporating U.S. Patent No. 5,314,438 (Ex. 1015) disclosing metal coil shafts, 14:10-33 "metallic wire turns"), 77, 93, Figs. 10-17. Assuming *arguendo* that Shturman '633 does not explicitly disclose helically wound metallic filars, the POSITA would have modified Shturman '633 to include such as drive shaft as routine design choice for flexible rotational shaft construction and/or as an implementation of known elements for their predictable results. Jensen Decl. (Ex. 1002) ¶ 84.

The POSITA in combining the prior art as discussed above, would have achieved an atherectomy device having a distal separation distance greater than the element spacing distance. Jensen Decl. (Ex. 1002) ¶ 42-82. The POSITA would have understood the relative spacing of the stability elements and abrasive elements to have effect on the orbital path, stability, momentum at each abrasive surface, and feel of the device in operation. *Id.*, ¶ 82. For example, Kallok evidences that the distance between a distal stability element 124 and the abrasive element is a choice of ordinary design. *See* Kallok, 12:10-14. Kallok also teaches customizing the distance D2 between its abrasive element 121 and distal stability element 124. *See* Kallok 14:11-12; Jensen Decl. (Ex. 1002) ¶ 82. Accordingly, the POSITA implementing the combinations discussed above would have achieved the distal separation distance greater than the element spacing distance as routine design choice and/or as obvious to try as a choice from a finite number of predetermined solutions (larger, equal, or smaller) with reasonable expectation of success. *Id.*

Additionally, Shturman '444 teaches a rotational atherectomy device (see Figs 1 and 31) comprising an elongate flexible drive shaft (20) comprising a torque transmitting coil (18) defining a central lumen and a longitudinal axis of the flexible drive shaft (20) defining an eccentric enlarged diameter abrasive section (28) with a center of mass (29) radially spaced from the drive shaft's rotational axis (21), the eccentric abrasive section (28) capable of generating a working diameter larger than its resting diameter during high-speed rotation. *See* Ex. 1013 Figs. 4A-4C; 7:14-41; Figs 11A-12B; 15A-16B; 19A-20B; Jensen Decl. (Ex. 1002) ¶¶ 86-90. Shturman '444 further teaches radiopaque markers 27 placed distal to, and proximal to, the eccentric enlarged diameter section (28). *Id.* at Fig. 31; 13:1-7. These markers 27 are explicitly metallic, "made from gold, platinum, iridium, alloys of these metals. . .[and function in part] "to secure several turns of the drive shaft to each other just distal and just proximal to the enlarged diameter section of the drive shaft." *Id*. Further, as shown in Figure 31, the metallic markers 27 are shown in a symmetrical shape that may be reasonably construed as a cylinder or cylindrical shape. The POSITA will readily understand that, absent any modifications to such a symmetric shaped element that is concentrically disposed about the drive shaft 21, the center of mass of the markers 27 is reasonably construed as coincident with the drive shaft's rotational longitudinal axis. Jensen Decl., (Ex. 1002) ¶ 86-87.

Given these teachings of Shturman ‘444, and viewed in combination with Kallok, Narveson, and/or Cambronne, the POSITA will readily recognize that the markers 27 of Shturman ‘444 will add mass to the drive shaft at their respective attachment points, distal and proximal to the eccentric abrasive element and will, therefore, have an effect on the diameter of the working diameter achieved by the eccentric abrasive section 28 during high-speed rotation. Jensen Decl. (Ex. 1002) ¶ 88.

Moreover, the POSITA will recognize that by tying together the wire turns of drive shaft 21, as shown in Fig. 31 and described at 13:1-7, the markers 27 will provide a stabilization function, because the other wire turns of the drive shaft are free to flex and move relative to each other whereas the tied-together wire turns of the drive shaft 21 in the region of the markers 27 will resist flexion. Jensen Decl. (Ex. 1002) ¶ 89.

Thus, Shturman ’444 further evidences that shape and materials of stability elements as recited in claim 1 are merely routine design changes without patentable significance in light of the prior art and knowledge of POSITA. Accordingly, modification to have cylindrical shape would have been achieved as routine, and/or to provide appropriate surfaces in case of incidental contact. Jensen Decl. (Ex. 1002) ¶ 90.

[1g] *wherein the drive shaft includes a distal extension portion extending distally beyond a distal end of the metallic stability element;*

Shturman '633 discloses the claimed distal extension portion as the portion of its drive shaft 10,14 from the element 19 proceeding away from the abrasive element 16. For example, Shturman discloses a portion of its drive shaft 10 to be arranged between the element 19 and the advancement mechanism 80 in figures 2-6. Figure 8 also indicates this feature as the portion of drive shaft 10 to the right of the element 19. Further, Shturman '633 discloses this feature by its description pertaining to the length of the drive shaft 10 beside the element 19 proceeding away from the abrasive element 16. *See*, *e.g.*, Ex. 1010, ¶¶ 12, 17, 29, 43-45, 54, 55 (Fig. 2, "another elongated drive shaft sheath 43 has been advanced over the elongate distal portion 14 of the drive shaft 10 … the sheaths 41,43 are spaced away from the [stability elements 18,19]); claims 1-2. Indeed, Shturman '633 insists that some portion of the drive shaft 10 extend distally beyond its stability elements to create its "back and forth" movement under tension. *Id.*, ¶¶ 9, 10, 18, 22 (alternately pulling), 24, 44, 46, 49, 55, 58 ("instead of pushing"), 62; claims 12, 14; Jensen Decl. (Ex. 1002) ¶ 91.

Moreover, Kallok teaches a number of embodiments in Figs. 10-17 comprising a drive shaft portion extending distally beyond the distal-most element attached to the drive shaft. Accordingly, to the extent that it could be argued that

Shturman '633 itself does not expressly teach this feature, the POSITA would have at least modified Shturman '633 to include an extension of the helically coiled drive shaft to extend beyond the distal stability element.

[1h] *wherein the drive shaft, the abrasive elements, and the metallic stability element rotate together about the longitudinal axis*.

Shturman '633, as modified by Kallok, and one or more of Narveson, Cambronne, Shturman '444 and Wulfman discloses these features as rotating together about the longitudinal axis. *See e.g.*, Ex. 1010, Abstract; ¶¶1, 8-10, 11 ("the eccentric abrasive element and the counterweights being configured for rapid rotation together with the drive shaft"), 28-29, 36, 46, 55, 58-60; Figs. 4-5; claims 1-2, 5, 7, 9, 11, 13, 15-19, 21, 22, 26, 33, 39-40; Jensen Decl. (Ex. 1002) ¶¶ 92-93. Thus, the POSITA will have readily understood that the drive shaft and abrasive elements and metallic stability element will rotate together about the longitudinal axis in a controlled pathway with a controlled working diameter. *Id.*

Accordingly, claim 1 is obvious in view of the cited references. Jensen Decl. (Ex. 1002) ¶¶ 42, 93.

C. Claim 2 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[2] *The system of claim 1, further comprising a second stability element fixed to the drive shaft and located proximally of the abrasive elements.*

The references and arguments applied to claim 1, are incorporated here. In addition, Shturman '633 teaches a second stability element 18, fixed to the drive shaft and located proximally of the abrasive element 16. *See* Ex. 1010 Figs. 1-6, 7, 8. Similarly, Kallok also teaches a second stability element fixed to the drive shaft and located proximally of the abrasive element. *See* Ex. 1003 Fig. 6, 10-18.

The POSITA will have readily understood that the second proximal stability element was a known structure. Accordingly, claim 2 is obvious in view of the cited references. Jensen Decl. (Ex. 1002) ¶ 94.

D. Claim 3 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[3] *The system of claim 1, further comprising a guidewire to be slidably disposed within a fluid-impermeable lumen of the drive shaft.*

The references and arguments applied to claim 1are incorporated here. In addition, Shturman '633 teaches a guidewire to be slidably disposed within a fluid-impermeable lumen of the drive shaft 10. *See* Ex. 1010 ¶¶ 0054, 58.

The POSITA will have understood that a guidewire will be translatable within a lumen of the drive shaft and that the drive shaft lumen is fluid-impermeable.

Accordingly, claim 3 is obvious in view of the cited references. Jensen Decl. (Ex. 1002) ¶ 95.

E. Claim 4 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[4] *The system of claim 1, wherein the abrasive elements comprise five spherical abrasive elements positioned adjacent to one another along the drive shaft.*

The arguments and references discussed in connection with claim 1 above are all incorporated here. Further, as discussed *supra* in connection with claim 1, it will be obvious to the POSITA to modify a single eccentric spherical abrasive element to at least three or more spherical abrasive elements. Raising the number of spherical elements to specifically five does not add anything non-obvious to the structure or eliminate any predictability of the effects of the spherical eccentric abrasive elements or modification and/or control of the rotational characteristics of the individual spherical eccentric abrasive elements or the system of five spherical eccentric abrasive elements. Jensen Decl. (Ex. 1002) ¶ 96. Indeed, the '853 patent does not disclose any advantages or unknown characteristics that would result from having five spherical eccentric abrasive elements.

Moreover, Narveson specifically teaches 5 eccentric abrading head 100 sections: a proximal segment (130); a distal segment (140) and three intermediate segments (135), each mounted in spaced-apart relationship from the adjacent segment(s) along the drive shaft 20. Ex. 1005, Figs 5 and 6; 6:43-67. And, Cambronne discloses one or more eccentric abrading heads 27 in spaced-apart configuration along the drive shaft 20. *Id.*, 4:8-22; Jensen Decl. (Ex. 1002) ¶ 97.

Accordingly, at least Shturman '633, Narveson, Cambronne and/or Wulfman and/or as modified by Kallok, teach two or more, which necessarily includes five, eccentric spherical abrasive elements in longitudinal spaced-apart disposition along a drive shaft. Jensen Decl. (Ex. 1002) ¶ 98.

The POSITA will have readily understood that modifying a single abrasive element with a center of mass radially offset from the drive shaft's rotational longitudinal axis into five abrasive elements, each of which have a center of mass spaced radially away from the axis of the drive shaft was known and provided highly predictable results. Jensen Decl. (Ex. 1002) ¶¶ 54-71, 96-99.

For at least these reasons, Claim 4 is obvious over the cited references.

F. Claim 5 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[5] *The system of claim 4, wherein the array comprises outer spherical abrasive elements and at least one inner spherical abrasive element, wherein an outer diameter of the outer spherical abrasive element is smaller than an outer diameter of the at least one inner spherical abrasive element.*

The arguments and references applied to claim 4 are incorporated herein. Narveson teaches spaced-apart abrasive elements, with two outer abrasive elements of smaller diameter than the inner eccentric abrasive elements. Ex. 1005, Fig. 6, 9:13-51; Jensen Decl. (Ex. 1002) ¶ 100. Cambronne teaches more than two spaced-apart abrasive elements, wherein the distal-most eccentric abrasive element is the smallest in the system of eccentric abrasive elements. Ex. 1006, Fig. 2, 4:8-31; Jensen Decl. (Ex. 1002) ¶ 100. And, as discussed above, Shturman '633, Narveson and/or Cambronne and/or Kallok teach(es) that the eccentric abrasive elements may be spherical.

The POSITA will, accordingly, understand that a distal-most element in the array will have a smaller diameter than the more proximal elements to aid in, *inter alia*, ease in accessing and piloting occlusions. Jensen Decl. (Ex. 1002) ¶¶ 100, 111-114.

Accordingly, claim 5 is obvious over the cited references.

G. Claim 6 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[6] *The system of claim 1, wherein the drive shaft has a central lumen extending along the longitudinal axis that is configured to receive a guidewire.*

The arguments and references applied to claim 1 are incorporated here.

Further, Shturman '633 teaches a guidewire to be slidably disposed within a fluid-impermeable lumen of the drive shaft 10 and further teaches the drive shaft lumen extending along the longitudinal axis and that is configured to receive a guidewire. *See, e.g.,* Ex. 1010 . *See* Ex. 1010 ¶¶ 0006, 0054, 58.

Accordingly, the POSITA will have, based on the teachings of at least Shturman '633, understood that the drive shaft of a rotational atherectomy system will comprise a central lumen along a longitudinal axis configured to allow translation of a guidewire therein and therealong. Jensen Decl. (Ex. 1002) ¶¶ 101-102.

Accordingly, claim 6 is obvious over the cited references.

H. Claim 7 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[7] *The system of claim 1, wherein the drive shaft comprises a torque-transmitting coil and wherein the stability element comprises a hollow metallic cylinder with an inner diameter that is fixed along the inner diameter to an outer diameter of the torque-transmitting coil.*

The references and arguments applied to claim 1 are incorporated here. Kallok, Narveson and Cambronne all disclose a drive shaft constructed from helically coiled wires. Kallok Ex. 1003 4:51-53; Narveson Ex. 1005 5:37-39; Cambronne Ex. 1006 3:50-51. Kallok, Narveson and Cambronne also each teach that the helically coiled drive shaft is further connected at a proximal end to a turbine (or similar rotational mechanism) for rotating the drive shaft at high speeds.

Kallok Ex. 1003 4:62-64; Narveson Ex. 1005 5:48-50; Cambronne Ex. 1006 3:63-65. Moreover, the helically coiled drive shafts in Kallok, Narveson and Cambronne all comprise at least an abrasive element disposed on the drive shaft and distally spaced from the turbine. Kallok Ex. 1003 Fig. 1 (element 28); Narveson Ex. 1005 Figs. 1, 5 and 6 (element 100); Cambronne Ex. 1006 Fig. 1, (element 27). Thus, the helically coiled drive shaft is configured to transmit rotational energy (torque) down the length of the drive shaft from the rotational mechanism to the abrasive element. As a result, the POSITA will readily understand the helically coiled wire drive shaft as a torque-transmitting structure. Jensen Decl. (Ex. 1002) ¶ 103.

Moreover, as discussed in connection with claim 1 *supra*, the distal stability element will be reasonably construed as a symmetric and concentric element, including of course a cylinder, wrapped around and attached to the outer surface of the drive shaft, with a center of mass on the longitudinal axis of the drive shaft. *See, e.g.*, Ex. 1004, Wulfman, Fig. 5 and/or Ex. 1003, Kallok and related arguments *supra* regarding claim 1. Because the cylindrical element of Wulfman and/or Kallok wrap around the drive shaft to connect thereto by a lumen centrally through the cylindrical element (*see* Ex. 1004, Wulfman, Fig. 5), the lumen provides an inner diameter which will interface and fix to the outer surface, *i.e.*, outer diameter of the drive shaft and/or torque-transmitting coil. Jensen Decl. (Ex. 1002) ¶¶ 104-105.

The POSITA will have readily understood that the stability element will include a cylindrical shape with a lumen whereby the drive shaft's outer surface is engaged for fixation of the stability element thereto.

Accordingly, claim 7 is obvious over the cited references.

I. Claim 8 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[8] *The system of claim 7, wherein the hollow metallic cylinder has an axial length that is greater than a maximum exterior diameter of the hollow metallic cylinder.*

The arguments and references applied to claims 7 and 1 above are incorporated here.

Regarding the relationship of the cylindrical cuffs taught by Wulfman (Ex. 1004 Fig. 5 and 2:54-56, 3:46-55), the length and height of the cylindrical cuffs are dictated the following dimensional ranges:

- Wulfman's drive shaft diameter: 0.020 to 0.035 inches (outer diameter);
- Wulfman's cylindrical cuffs extend / protrude from the surface of the drive shaft by .1 mm to .5 mm (.0039 inches to .0197 inches);

- Therefore, largest outer diameter of an installed cylindrical cuff is:
- 0.020 inches (maximum drive shaft OD) + (2) x (0.0197. inches) maximum cuff extension/protrusion from drive shaft surface = .0594 inches.
- The cuff length range in Wulfman is 1 – 6 mm (.0394 inches to .2362 inches).

Therefore, for cylindrical cuff lengths in the range of .0595 up to .2362 inches disclosed in Wulfman, the cylindrical cuff length is greater than an outer diameter of the cuff. Further, the relative dimensions as recited in claim 8 do not amount to patentable significance where the system of the combined art would perform no differently. *In Gardner v. TEC Syst., Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

The POSITA will have readily understood that the hollow metal cylinder comprises a length greater than its maximum outer diameter (OD). Jensen Decl. (Ex. 1002), ¶¶ 106-110.

Accordingly, claim 8 is obvious over the cited references.

J. Claim 9 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[9] *The system of claim 1, wherein each spherical abrasive element of the at least three spherical abrasive elements has an abrasive outer surface, and*

wherein a middle spherical abrasive element of the at least three spherical abrasive elements has a larger outer diameter than a proximal spherical abrasive element of the at least three spherical abrasive elements and a larger outer diameter than a distal spherical abrasive element of the at least three spherical abrasive elements.

The arguments and references applied to claim 1 are incorporated here.

Further, Shturman '633, Narveson, and Cambronne, as modified by Kallok, teach spherical abrasive elements, including but not limited to three spherical abrasive elements. Each of the spherical abrasive elements comprises an abrasive surface. *See, e.g.,* Shturman '633 Ex. 1010, Fig. 1-8; Cambronne, Ex. 1006, 8:19-44; Kallok, Ex. 1003, Figs. 2 & 3, (28).

Moreover, at least Cambronne teaches an increasing diameter in its system of eccentric abrading heads moving from the distal to the proximal direction (*See* Ex. 1006, 4:20-31), while Narveson teaches a middle eccentric abrasive element that is larger in diameter than both the proximal and distal eccentric abrasive element (*See* Ex. 1005, Figs 5 and 6).

Thus, the POSITA will have understood that an array of spherical abrasive elements may comprise proximal and distal elements with diameters that are smaller than a middle spherical abrasive element that is disposed between the proximal and distal elements. Jensen Decl. (Ex. 1002), ¶¶ 111-114.

Accordingly, claim 9 is obvious over the cited references.

K. Claim 10 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[10] *The system of claim 1, wherein the metallic stability element comprises a hollow metallic cylinder with an exterior cylindrical surface.*

The references and arguments applied to claims 1 and 7 are incorporated here. As discussed *supra,* the cited references of at least Wulfman and/or Kallok teach a metallic cylinder that is concentrically attached to the outer surface of a drive shaft by a lumen (*See* Ex. 1004, Wulfman, Fig. 5). Wulfman teaches a cylindrical exterior surface in its cylindrical "cuffs" 38. Further, as discussed above, the metallic stability element is reasonably construed as geometrically symmetric and concentrically wrapped and fixed around the drive shaft by a central lumen. The POSITA will have therefore understood that the metallic stability element comprises a hollow metallic cylinder with an exterior cylindrical surface. Jensen Decl. (Ex. 1002), ¶ 115.

Accordingly, claim 10 is obvious over the cited references.

L. Claim 11 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444, Wulfman and Liprie

[11] *The system of claim 1, wherein an outer surface of the balloon member defines channel spaces configured to allow blood flow past the balloon*

member when the balloon member is in the inflated configuration and in contact with the blood vessel wall.

The reference and arguments applied to claim 1 are incorporated here.

Shturman '633 teaches "an occlusion balloon which are mounted to the distal drive shaft sheath near the distal end of the sheath." Ex. 1010, Fig. 2, ¶ 44 (Balloon 51 is inflated between the outer surface of distal drive shaft sheath 43 and the wall of vessel 1). Shturman '633 may not teach a balloon member defining channel spaces configured to allow blood flow therethrough when the balloon member is in the inflated configuration within the blood vessel. Jensen Decl. (Ex. 1002), ¶ 117.

However, Liprie teaches an angioplasty procedure and system configured to allow blood flow around a stenosis while the angioplasty balloon 18 is inflated in order to "greatly decrease the patient's risk of a myocardial infarction or heart attack." Ex. 1016, 2:66-4 3:3, 4:35-44. Balloon (18) defines locations 34 configured to allow blood flow to perfuse therealong when the balloon member is in the inflated configuration within the blood vessel (26). Ex. 1016, Figs 1-4; 4: 36-44. Jensen Decl. (Ex. 1002), ¶ 118.

The POSITA will recognize that the balloon of Shturman '633 may be advantageously modified to enable perfusion of blood through the subject blood vessel during the atherectomy procedure in order to, inter alia, greatly reduce the patient's risk of a myocardial infarction or heart attack. Jensen Decl. (Ex. 1002) ¶¶ 117-119. Accordingly, claim 11 is obvious over the cited references.

M. Claim 12 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[12] *The system of claim 1, wherein the flush tube includes an inflatable balloon member attached to and surrounding an outer diameter of a distal end portion of the flush tube, the balloon member is in fluid communication with the first lumen, and the balloon member is configured to contact a blood vessel wall when the balloon member is in an inflated configuration.*

The references and arguments applied to claim 1 are incorporated here. Shturman '633 further teaches "an occlusion balloon which are mounted to the distal drive shaft sheath near the distal end of the sheath." Ex. 1010, Fig. 2, ¶ 44 (Balloon 51 is inflated between the outer surface of distal drive shaft sheath 43 and the wall of vessel 1). Jensen Decl. (Ex. 1002), ¶ 120.

Accordingly, claim 12 is obvious over the cited art.

N. Claim 13 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[13] *The system of claim 1, wherein the device further comprises a flexible polymer coating covering an outer diameter of the metallic stability element and an outer diameter of at least a portion of the drive shaft, and wherein*

the drive shaft has an outer diameter covered by the flexible polymer coating.

The references and arguments applied to claim 1 are incorporated herein. In addition, Shturman '633 recognizes that the use a fluid impervious membrane may cover the outside of the drive shaft to allow antegrade flow of pressurized fluid through the lumen of the drive shaft is well known. Ex. 1010 ¶ 0006 ("Disadvantages associated with either limited or completely absent distal embolic protection of all commercially available rotational atherectomy devices have been addressed in WO 2006/126076 to Shturman (the instant inventor). In accordance with WO 2006/126076 drive shaft has a fluid impermeable wall and allows an antegrade flow of pressurised fluid through a lumen of the drive shaft from a proximal end towards a distal end of the drive shaft. . . . Several other embodiments of the device with distal embolic protection capability are disclosed in WO 2008/006704, WO 2008/006705, WO 2008/006706, WO 2008/006708, and WO 2008/062069 to Shturman (the instant inventor)").[3] WO 2006/126076 teaches that a fluid impervious membrane may cover the outside of the drive shaft. *See* Ex. 1008, ¶ 0037. The fluid impervious membrane may be "formed from plastic tubing, silicon resin tubing or other suitable fluid impervious materials. . . . " *Id.* at

[3] WO 2006/126076 (Ex. 1023) is International Application No. PCT/IB2006/001368, and shares the same specification with Shturman '829 (Ex. 1008), which claims priority to the PCT application.

¶ 0039. WO 2006/126076 further discloses that "[t]he membrane may be made from plastic tubing (e.g. Polytetrafluorothyline (PTFE) or Nylon) . . . ." *Id.* at ¶ 0042. PTFE is an exemplary polymer which may be applied by head-shrinking or immersion or the polymer may be a flexible tube. *Id*. at ¶ 0039. POSITA would readily appreciate that the polymer as applied to the drive shaft that must negotiate tortuous vasculature enroute to the occlusion of interest must allow the drive shaft to continue to be flexible, thus the polymer will also be flexible. Jensen Decl. (Ex. 1002) ¶ 122.

Accordingly, claim 13 is obvious over the cited art.

O. Claim 14 Is Obvious In View of Shturman '633 in Combination with Kallok and at least one or more of Narveson, Cambronne, Shturman '444 and Wulfman

[14] *The system of claim 13, wherein the flexible polymer coating comprises a fluid-impermeable material that provides a fluid-impermeable lumen along the drive shaft.*

The references and arguments applied to claim 13 are incorporated here.

As discussed in connection with Claim 13, Shturman '633 discloses that the fluid-impermeable material is a flexible polymer that may be coated on, or within, the drive shaft to provide a fluid-impermeable lumen. *See* Ex. 1010 ¶ 0006; Jensen Decl. (Ex. 1002), ¶¶ 123-124.

Accordingly, claim 14 is obvious over the cited references.

P. Claim 15 Is Obvious In View of Shturman '633 in Combination with Kallok, at least one or more of Narveson, Cambronne and Wulfman, and Campbell

[15] *The system of claim 13, wherein the flexible polymer coating has a different durometer at different locations on the drive shaft.*

The references and arguments applied to claim 13 are incorporated here.

Campbell teaches a percutaneous medical device comprising a rotational drive shaft 148; Figs 4A, 4B with a flexible polymer coating 624; Fig 16. Jensen Decl. (Ex. 1002), ¶ 126. The flexible polymer coating 624 has a different durometer at different locations along the drive shaft 148 (Ex. 1009, ¶¶ 0147-0148). POSITA would, in combination with at least Shturman '633, find that it would be obvious to include a flexible polymer coating that has a different durometer at certain locations along the drive shaft. Jensen Decl. (Ex. 1002), ¶ 126-127.

Accordingly, claim 15 is obvious over the cited art.

VI. CONCLUSION

For the foregoing reasons, claims 1-15 of the '853 patent are unpatentable. Petitioners has demonstrated a reasonable likelihood exists that at least one of the challenged claims is unpatentable. Petitioner, therefore, requests that an *inter partes* review of these claims be instituted under 35 U.S.C. § 314 and 37 C.F.R. § 42.108. Petitioner also reserves the right to apply additional prior art and arguments, depending on what arguments and/or amendments Patent Owner might present. Petitioner also reserves the right to cite and apply any additional art it might discover as relevant to the issued claims or any amended claims, as the *inter partes* review proceeds.

The undersigned attorneys welcome a telephone call should the Office have any requests or questions. If there are any additional fees due in connection with the filing of this paper, please charge the required fees to our deposit account no. 505,196.

Respectfully submitted,

Dated: August 17, 2018 By: /Anthony H. Son/

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CERTIFICATE OF SERVICE

The undersigned certifies that a complete true and correct copy of the Petition For *Inter Partes* Review Of U.S. Patent No. 9,788,853, all supporting exhibits (Exhibits 1001 through 1025), and the Power of Attorney were served on August 17, 2018 via Priority Mail Express® to the Patent Owner by serving the correspondence address of record as follows:

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

The undersigned certifies, pursuant to 37 C.F.R. §42.24(d) , that the word count for the foregoing Petition For Inter Partes Review Of U.S. Patent No. 9,788,853 Under 35 U.S.C. § 312 AND 37 C.F.R. § 42.104 totals 12,305, and within the 14,000 words allowed under 37 C.F.R. §42.24(a)(1)(i).

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