IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

In re *Inter Partes Review* of:	)	
U.S. Patent No. 9,089,362 B2	)	
Issued: July 28, 2015	)	Attorney Docket No. 68890-280125
Inventor: Leonid Shturman	)	
Application No. 14/170,923	)	
Filed: February 3, 2014	)	
	)	FILED ELECTRONICALLY
For: ROTATIONAL ATHERECTOMY DEVICE WITH ECCENTRIC ABRASIVE ELEMENT AND METHOD OF USE	)	PER 37 C.F.R. § 42.6(b)(1)

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<u>PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,089,362 UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104</u>

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 1-11 of U.S. Patent No. 9,089,362 B2 ("the '362 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.

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Exhibit 1003:	U.S. Patent No. 8,177,801
Exhibit 1004:	U.S. Patent No. 5,250,060
Exhibit 1005:	U.S. Patent No. 4,784,636
Exhibit 1006:	U.S. Patent Appl. Publ. No. 2007/0066888
Exhibit 1007	U.S. Provisional Appl. No. 61/046145
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Exhibit 1013	U.S. Patent No. 6,132,444
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Exhibit 1015	U.S. Patent No. 8,353,923
Exhibit 1016	File History for U.S. Patent No. 9,089,362
Exhibit 1017	U.S. Patent No. 5,584,843

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 certifies 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 1-11, 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 1-11 of the '362 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. Carbo, et al., U.S. Patent No. 5,250,060, "Angioplasty Apparatus," filed June 26, 1992 ("Carbo") (Ex. 1004).
3. Rydell, U.S. Patent No. 4,784,636, "Balloon Atheroectomy Catheter," filed April 30, 1987 ("Rydell") (Ex. 1005).

4. Maschke, U.S. Patent Appl. Publ. No. U.S. 2007/0066888, "Catheter Device with a Position Sensor System for Treating a Vessel Blockage Using Image Monitoring," filed September 21, 2006 ("Maschke") (Ex. 1006).

5. Prudnikov, et al., U.S. Patent No. 8,348,965, "Rotational Atherectomy Device With Counterweighting," filed October 23, 2007 ("Prudnikov") (Ex. 1009)

6. Shturman, U.K. Patent Appl. Publ. GB 2,426,458, "Atherectomy Device," filed May 26, 2005 ("Shturman '458") (Ex. 1010).

According to their issuance or publication, each of Carbo, Rydell, Maschke, and Shturman '458 is prior art under 35 U.S.C. §§ 102(b) as being patented or published more than one year before the presumed effective filing date of the '362 patent (i.e., before the presumed effective filing date of April 3, 2009). Kallok and Prudnikov are prior art under at least 35 U.S.C. §§ 102(e) as U.S. patents that were effectively filed, naming another inventor, before the presumed effective filing date of the '362 patent.

Kallok was filed as a U.S. non-provisional application on March 17, 2009 based on Provisional application no. 61/046,145, filed on April 18, 2008 (Ex. 1007). The specification of Provisional application no. 61/046,145 (Ex. 1007) is nearly verbatim identical to Kallok (Ex. 1003) and accordingly, at least one claim of Kallok is supported by the disclosure of the provisional application in compliance with 35 U.S.C. § 112, ¶1. In fact, the specification filed in the Kallok non-provisional application (*See* Ex. 1008, p. 232-254) is verbatim identical to the disclosure in the Provisional Application (Ex. 1007). Moreover, there was no new matter added to this specification during the prosecution of the Kallok non-provisional application (Ex. 1008). Accordingly, the filing date of the Kallok non-provisional application on March 17, 2009 pre-dates the presumed effective filing date of the '362 patent and thus establishes Kallok as prior art under 35 U.S.C. § 102(e). In addition, Kallok is prior art under 35 U.S.C. § 102(e) as of the relied upon provisional application's filing date of April 18, 2008.

Kallok, Prudnikov, Shturman '458 and Maschke were not made of record or cited by the examiner during prosecution of the '362 patent. Although Carbo and Rydell were previously applied by the examiner, the Office has not previously considered these references 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 Carbo in combination with Kallok or Prudnikov	1-4, 7-11
2	§ 103 Carbo in combination with Kallok or Prudnikov and in further view of Rydell	5
3	§103 Carbo in combination with Kallok or Prudnikov and in further view of Maschke.	6
4	§ 103 Shturman '458 in combination with Kallok or Prudnikov	1-4, 7-11
5	§ 103 Shturman '458 in combination with Kallok or Prudnikov and in further view of Rydell	5
6	§103 Shturman '458 in combination with Kallok or Prudnikov and in further view of Maschke.	6

B. There is a Reasonable Likelihood that at least One Claim of the '362 Patent is Unpatentable under 35 U.S.C. § 103

The '362 patent is directed to wholly conventional and obvious method for treating an iliac artery using a rotational atherectomy device with eccentric abrasive element. *See, e.g.*, '362 patent at Title; Abstract; 1:15-30 (Ex. 1001). In fact, the '362 patent does not disclose anything new or nonobvious about the method for treating an iliac artery other than the use of the disclosed rotational atherectomy device. In the described method, a drive shaft is positioned in the iliac artery such that an abrasive element mounted to the drive shaft is positioned within the stenotic lesion to be treated, occlusion balloons of the distal sheath are then inflated, a flow of pressurized fluid is introduced through a first sheath and drained through a second sheath, the drive shaft is rotated along with the abrasive element and moved back and forth across the stenotic lesion, and finally deflating the occlusion balloons and repeating along the iliac artery as necessary to treat the artery. This method is identical to the use of known prior art angioplasty devices except replacing the radially expandable cutter of the angioplasty devices disclosed in Carbo (Ex. 1004) and Shturman '458 (Ex. 1010) with another known rotational atherectomy device using abrasive and stability elements. *See*, *e.g.* Ex. 1003, Kallok and Ex. 1009, Prudnikov. Moreover, in claim 6 of the '362 patent, the inventors add the use known intravascular ultrasound imaging catheter to provide the known and expected cross-sectional images of the stenotic lesion area. The use of such intravascular ultrasound imaging catheter to provide cross-sectional images of the stenotic lesion area was also already known, and far more advanced than the nominal disclosure of such intravascular ultrasound imaging catheters disclosed in the '362 patent. *See, e.g.*, Ex. 1006, Maschke.

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 '362 PATENT

A. Overview of the '362 Patent and Prosecution History

The '362 patent relates to treating peripheral artery using a rotational atherectomy device with eccentric abrasive element. *See, e.g.*, Ex. 1001, Title; Abstract; 1:15-30. According to the patent, a drive shaft is positioned in the iliac artery such that an eccentric abrasive element (and corresponding stability elements) mounted to the drive shaft is positioned within the stenotic lesion to be treated, occlusion balloons of the distal sheath are then inflated, a flow of pressurized fluid is introduced through a first sheath and drained through a second sheath, the drive shaft is rotated along with the abrasive element and moved back and forth across the stenotic lesion, and finally deflating the occlusion balloons and repeating along the iliac artery as necessary to treat the artery.

The application that issued as the '362 patent was filed on February 3, 2014, as a continuation of U.S. Patent Application No. 13/262,795, filed on October 21, 2001(now issued as U.S. Patent No. 8,663,260), which is the national phase application based on PCT/EP2010/054550, filed on April 6, 2010, which claims priority to UK Patent Application No. 0905748.0 filed on April 3, 2009. It was filed with 45 claims (Ex. 1016, p. 149 – 156), which were canceled by Preliminary Amended dated March 7, 2014 and new claims 46-57 were added (Ex. 1016, p. 107 – 110). In response to a restriction requirement dated September 25, 2014, on

October 20, 2014, the Applicant elected Group II (claims 52-57) for examination, filed another Preliminary Amendment canceling claims 46-51, amending claims 52-57 and adding new claims 58-62. Ex. 1016, p. 77-82. On November 21, 2014, the Examiner entered a Non-Final Rejection rejecting all of the pending claims under pre-AIA 35. U.S. C. § 103(a). Ex. 1016, p. 48 – 56. Following a March 17, 2015 applicant initiated interview, the Applicant responded to the November 21, 2014 Office Action indicating that the Examiner agreed that the prior art combinations identified in the Office Action failed to provide all of the features of the independent claim. Ex. 1016, p. 40. Specifically, according to the Applicant, the proposed combination would fail to disclose to provide "at least the distal portion of the drive shaft that 'extends distally of the second stability element.'" Ex. 1016, p. 40-41. This was also confirmed in the Applicant Initiated Interview Summary (Ex. 1016, p. 34) ("The Examiner agreed that the combination of Carbo et al., Shturman and Wulfaman [sic] would not result in a distal drive shaft centering element disposed on the drive shaft and wherein the distal portion of the drive shaft would extend beyond the distal drive shaft centering element."), and the April 2, 2015 Examiner Initiated Interview Summary (Ex. 1016, p. 23) ("Permission was granted for an Examiner's Amendment to place the application in condition for allowance by clarifying that the drive shaft extends distally of a distal end of the second stability element to distinguish over Shturman.") As a result, the Office allowed the claims. Notice of Allowance, Ex. 1016 p. 15-21.

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 '362 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 '362 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 '362 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. "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, ¶ 29; The term "abrasive element" is interchangeable with the term "abrasive burr." Ex. 1001, 1:55-56.

2. "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, ¶ 30.

3. "elongate catheter"

An elongated catheter is a well known and common component of many medical devices. They are generally tubular in shape and have a longer length compared to its width. Often, these elongated catheters are used for insertion into vessels, passageways or body cavities to permit the insertion fluids or other devices, or to keep the passage open. Ex. 1002, ¶ 31. A POSITA would understand the broadest reasonable interpretation of "elongated cathether" to mean "a tubular device having a longer length compared to its width and configured for insertion into vessels, passageways, or body cavities for the insertion of fluids or other devices, or to keep the passage open." *Id.*

4. "prime mover"

A POSITA would understand the broadest reasonable interpretation of "prime mover" to mean "a component of a device that generates the mechanical motion for the device." Ex. 1002, ¶ 32. A gas turbine is an example of a prime mover, and the terms are used interchangeably in the '362 patent. Ex. 1001, 7:44-45 ("The terms "prime mover" and "gas turbine" are used interchangeably throughout this specification.")

V. CLAIMS 1-11 OF THE '362 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 The Method of Using A Rotational Atherectomy Device Having An Elongated Drive Shaft, Abrasive Element, And Stability Elements

The '362 patent claims focus on the well-known method of using a rotational atherectomy device. Indeed, the '362 patent uses the same method of treating iliac artery that was known at least as early as the mid-1980's, except replacing the abrading mechanism with other known rotational atherectomy devices. The invention claimed in the '362 patent is nothing more than natural evolution of rotational atherectomy devices that began at least as early as the early 1980's. Ex. 1002, ¶ 33.

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. *Id.* at ¶ 34.

A variety of techniques and medical devices have been developed to remove or shrink the stenotic material. In the mid-1960's, Dr. Charles Dotter pioneered angioplasty and the catheter delivered stent to treat peripheral arterial disease. By the mid-1980's a common approach to treating atherosclerosis was the use of a balloon angioplasty. Ballon angioplasty involve the use of a guiding cathether placed in the peripheral artery and passing a balloon catheter through the guiding cather to the section of the artery to be treated. Once the balloon is located at the location of the stenotic lesion, the balloon is inflated to disrupt or push aside the obstruction to improve blood flow. *Id.* at ¶ 35.

Despite the great success of balloon angioplasty to treat atherosclerosis, there continued to be a need for improvement to address some disadvantages. For example, in some patients, the stenosis are shaped in a manner that balloon angioplasty are not effective. One solution is to remove the stenosis by cutting, scraping, abrading or vaporizing the obstruction. *Id.* at ¶ 36.

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. *Id.* at ¶ 37. 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. *Id.* at ¶ 37

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. 1017) 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. *Id.* at ¶ 38

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. *Id.* at ¶ 39; s*ee, 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). *Id.* at ¶ 39.

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. *Id.* at ¶ 40. 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. *Id.; see, e.g.,* U.S. Patent No. 8,353,923 (Ex. 1015) (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.). *Id.* at ¶ 40.

Accordingly, for many years prior to the effective filing date of the '362 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. *Id.* at ¶ 41. Not surprising, using these rotational atherectomy devices in known methods for treating iliac artery to replace the older rotational removal means to provide the predictable result of producing centrifugal forces to remove stenotic lesions was well within the skill and knowledge of the POSITA. *Id.*

B. Claim 1 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov

[1a]. *A method of treating an iliac artery of a patient, comprising*: *positioning an elongate catheter of a system for performing rotational atherectomy in a blood vessel of a patient, the elongate catheter defining a first lumen and a second lumen,*

Carbo teaches a method of treating an iliac artery of a patient including the step of positioning an elongate catheter (30) of a system in a blood vessel. The catheter defines a first lumen (47) and a second lumen into which a rotational atherectomy device (drive cable 32) is inserted. Ex. 1004, Figs 1-9; 2:9-58; 3:60-5:7; Ex. 1002, ¶ 42 – 43.

[1b] *the elongate catheter including an inflatable balloon member attached to and surrounding an outer diameter of an end portion of the elongate catheter, the balloon member in fluid communication with the first lumen,*

Carbo teaches an inflatable balloon member (44) attached to and surrounding an outer diameter of an end portion of the elongate catheter (30). The balloon member (44) is in fluid communication with the first lumen (47). Ex. 1004, Figs 2-3; 4:17-26; Ex. 1002, ¶ 44.

[1c] *the balloon member configured to contact a blood vessel wall when the balloon member is in an inflated configuration;*

Carbo teaches the balloon member (44) inflated to contact a blood vessel wall when the balloon is in an inflated configuration. Ex. 1004, Fig. 5, 4:58-5:1; Ex. 1002, ¶ 45.

[1d] *rotating a rotational atherectomy device of the system while the rotational atherectomy device is at least partially disposed within the second lumen of the elongate catheter,*

Carbo teaches a rotational atherectomy device that is rotated while the device is at least partially disposed within the second lumen of the elongate catheter. Ex. 1004, Figs 2-3; 4:45-5:7; Ex. 1002, ¶ 46.

[1e] *the rotational atherectomy device comprising an elongate flexible drive shaft defining a central lumen and a longitudinal axis, the drive shaft configured for rotation about the longitudinal axis,*

Carbo teaches an elongate flexible drive shaft (32) that defines a central lumen and a longitudinal axis, the drive shaft (32) configured for rotation about the longitudinal axis. Ex. 1004, Figs 4-9; Ex. 1002, ¶ 47.

To the extent that Carbo does not explicitly teach a drive shaft configured for rotation about a longitudinal axis, Kallok (Ex. 1003) does disclose an elongate flexible drive shaft (20, 120) defining a central lumen and a longitudinal axis

(125), the drive shaft (20, 120) configured to rotate about the longitudinal axis (125). Ex. 1003, Figures 19-23; 14:34-36; 12:54-13:35; Ex. 1002, ¶ 48.

Alternatively, Prudnikov (Ex. 1009) discloses an elongate flexible drive shaft (20) having an inner lumen (19) and a longitudinal axis. Ex. 1009, Fig. 1-3; 4:3-10; 4:28-33. The drive shaft (20) is configured to rotate about the longitudinal axis. Ex. 1009, Fig. 1-3; 4:8-11; Ex. 1002, ¶ 49.

[1f] *an eccentric abrasive element that is mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft, and*

To the extent that Carbo does not expressly disclose an eccentric abrasive element that is mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft, a POSITA would have modified Carbo to substitute the abrasive element with the eccentric abrasive element and stability elements mounted to the drive shaft, as taught by Kallok or Prudnikov, as this modification involves the simple substitution of one rotational removal means with another for the predictable result of producing centrifugal forces to remove occlusions. Ex. 1002, ¶ 50.

Kallok teaches an eccentric abrasive element (28B, 28C, 121E) that is mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis (125) of the drive shaft (20, 120). Ex. 1003, Figs 4, 5A-5C, 10-18; 10:28-60; Ex. 1002, ¶ 51.

Alternatively, Prudnikov teaches an eccentric abrasive element that is mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft. Ex. 1009, Figs 4, 5A-5C, 7A-7C; 5:3-48; 9:24-13; Ex. 1002, ¶ 52.

Accordingly, a POSITA could modify the abrasive element from Carbo to have an eccentric abrasive element mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft to have the benefits known to POSITA and/or as suggested by Kallok or Prudnikov, for example but without limitation, to enhance the working diameter over the resting diameter of the device. Those modifications are well within the knowledge and skill of the POSITA. Ex. 1002, ¶ 53.

[1g] *a pair of stability elements including a first stability element that is fixed to the drive shaft at a location proximal to the abrasive element, and a second stability element that is fixed to the drive shaft at a location distal to the abrasive element,*

Kallok teaches a pair of stability elements including a first stability element that is fixed to the drive shaft at a location proximal to the abrasive element and a second stability element that is fixed to the drive shaft at a location distal to the abrasive element. Ex. 1003, Figs 10-18; 13:35-10; Ex. 1002, ¶ 54.

Alternatively, Prudnikov teaches a pair of stability elements including a first stability element (100) that is fixed to the drive shaft (20) at a location proximal to the abrasive element (28) and a second stability element (102) that is fixed to the drive shaft (20) at a location distal to the abrasive element (20). Figs 4, 5A-5C, 6; 5:3-6:21; Ex. 1002, ¶ 55.

The POSITA will readily recognize that the counterweights (100, 102) are interchangeable with stability elements. Ex. 1002, ¶ 56. Throughout the specification of the '362 patent, the stability elements are referred to as "counterweights" (18, 19). *Id.;* Ex. 1001, Figs. 1-6, 7-8. In fact, nowhere in the specification is the term "stability element" used. The originally filed claims used the term "counterweights" and did not use the term "stability element." Ex. 1016, Claims dated February 3, 2014, pp. 149-156. The term "stability element" was first introduced in the claims filed with the Preliminary Amendment dated March 7, 2014. Ex. 1016, Preliminary Amendment, pp. 107-109. Accordingly, the POSITA will recognize that the counterweights of Prudnikov are interchangeable with the term "stability elements." Ex. 1002, ¶ 56.

Moreover, the POSITA will readily recognize that the counterweights of Kallok or Prudnikov are mounted to the drive shaft, thus tying the wire turns of the drive shaft together and preventing flexion in the tied-together wire turns. Ex. 1002, ¶ 57. The POSITA will recognize that this configuration will provide stability to the system during high-speed rotation. Moreover, Kallok and Prudnikov teaches that the counterweights have mass and are spaced apart by a distance from the abrasive element. *Id.* Prudnikov further teaches that each of these variables may be modified and, therefore, may assist in either increasing or dampening the rotational diameter of the abrasive element during high-speed rotation. *Id.* Thus, the POSITA will readily understand that Kallok's and Prudnikov's counterweights function as stability elements. *Id.*

[1h] *wherein a distal portion of the drive shaft extends distally of a distal end of the second stability element,*

Kallok teaches the distal portion of the drive shaft (120) extending distal of a distal end of the second stability element (124E, 124C). Ex. 1003, Figs. 10-17 (broken away drawings with drive shaft (120) extending distally beyond the second distal stability element (124E, 124C)). Ex. 1002, ¶ 58.

Alternatively, Prudnikov teaches the distal portion of the drive shaft (20) extending distal of a distal end of the second stability element (102). *See* Ex. 1009, Fig. 6 (illustrating a broken away and cross-sectional view of the drive shaft (20) having a distal portion that extends a distance distally beyond the second distal stability element (102)). Ex. 1002, ¶ 59.

A POSITA would recognize that extending the drive shaft distally from a distal end of the second (distal-most) stability element may be advantageous in several respects. First, the drive shaft portion extending distally away from the second stability element is flexible and, therefore, will function as a lead and/or guide as the device is translated over the pre-positioned guide wire and through the tortuous vasculature of the patient to the stenosis. Ex. 1002, ¶ 60. In this sense, the smaller diameter of the distal portion of the drive shaft will be an obvious advantage. Secondly, when the drive shaft has reached the stenosis, the distally extending portion of the drive shaft may serve as a piloting element through the occlusion in preparation for translation of the larger diameter second stability element and ultimately the still-larger diameter eccentric abrasive element(s). *Id.* Finally, the distally extending portion of the drive shaft carries a mass that will assist in stabilizing the second stability element and, in turn, the eccentric abrasive element during high-speed rotation. *Id.* These modifications are well within the knowledge and skill of the POSITA.

[1i] *wherein said rotating the rotational atherectomy device is caused by a prime mover for rotating the drive shaft; and*

Carbo discloses a prime mover for rotating the drive shaft. Ex. 1001, Fig. 1, 4:63-5:4 ("With these balloons expanded as seen in FIG. 5, the section of blood vessel to be treated is sealed from the remaining portions of the vessel and fluid pressure is applied to connector 24 to partially expand the milling balloon 43 and at the same time *the rotator 14 is rotating drive cable 32 which in turn rotates the milling section 34.* As the plaque is cut away the milling balloon 43 is gradually inflated to increase its diameter as plaque is being ground off the surface of the artery.") (emphasis supplied); Ex. 1002, ¶ 61.

Kallok teaches a prime mover (turbine or similar rotational drive mechanism) for rotating the drive shaft. Ex. 1003, 4:62-66; Ex. 1002, ¶ 62.

Alternatively, Prudnikov teaches a prime mover (turbine or similar rotational drive mechanism) for rotating the drive shaft. Ex. 1003, 4:15-19; Ex. 1002, ¶ 63.

> [1j] *repeatedly moving the rotating drive shaft and its abrasive element back and forth across a stenotic lesion to remove stenotic lesion material from the blood vessel, wherein the abrasive element abrades the stenotic lesion material from the blood vessel.*

Kallok teaches repeatedly moving the rotating drive shaft and its abrasive element back and forth across a stenotic lesion to remove the stenotic lesion material from the blood vessel, wherein the abrasive element abrades the stenotic lesion material from the blood vessel. Ex. 1003, Figs 8, 9; 10:61-11:4; Abstract; Ex. 1002, ¶ 64.

Accordingly, the elements of claim 1 are obvious over Carbo in view of Kallok, or alternatively Prudnikov.

C. Claim 2 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[2] *The method of claim 1, further comprising locating the elongate catheter in the blood vessel such that a distal end of the elongate catheter is spaced away from the first stability element.*

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

In addition, Kallok teaches locating the distal end of the elongate catheter spaced away from the first (proximal) stability element. Ex. 1003, Figs 1, 10-18, and 19-23; Ex. 1002, ¶ 67.

Alternatively, Prudnikov teaches locating the distal end of the elongate catheter spaced away from the first (proximal) stability element. Ex. 1009, Fig 1; 4:5-8; Ex. 1002, ¶ 68. The POSITA will readily understand that the proximal (first) stability element must be advanced on the drive shaft distally and away from the distal end of the catheter in order for the first stability element to function within the system also comprising an eccentric abrading head and a second stability element. Ex. 1002, ¶ 68. The POSITA will understand that the stability function, and/or stimulation and/or dampening of the working diameter traced by the eccentric abrading head during high-speed rotation may be maximized when the proximal stability element is distally spaced from the distal end of the catheter. *Id.; see, e.g.,* Ex. 1009, Figs 8-9; 10:19-41; 5:49-7:61.

Accordingly, claim 2 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

D. Claim 3 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[3] *The method of claim 1, wherein the first stability element is a first counterweight, and the second stability element is a second counterweight.*

Kallok teaches the first stability element is a first counterweight and the second stability element is a second counterweight. Ex. 1003, Figs 10-18; 6:29-14:10; Ex. 1002, ¶ 71.

Alternatively, Prudnikov teaches the first stability element is a first counterweight and the second stability element is a second counterweight. Ex. 1009, Fig 6; 5:49-7:61; Ex. 1002, ¶ 72.

Accordingly, claim 3 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

E. Claim 4 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[4] *The method of claim 3, further comprising inflating the inflatable balloon member and aspirating stenotic lesion material through the second lumen of the elongate catheter.*

Carbo teaches inflating the inflatable balloon member (44) and aspirating stenotic lesion material through the second lumen of the elongate catheter (30).

Ex. 1004, Fig. 6. An infusion channel (50) exists between the outer surface of the guidewire and the inner surface of the tube (38) for aspirating stenotic lesion material. *Id.* at 4:37-44 and 5:4-8; Ex. 1002, ¶ 75.

Accordingly, claim 4 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

F. Claim 5 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov, And In Further View Of Rydell

[5] *The method of claim 4, further comprising:*

deflating the inflatable balloon member; repositioning the drive shaft within the blood vessel; and repeating the steps of rotating the rotational atherectomy device and repeatedly moving the rotating drive shaft and its abrasive element back and forth across the stenotic lesion.

The arguments and references applied to claim 4 are incorporated herein.

Rydell teaches an atherectomy catheter including the step of inflating a balloon and aspirating debris through the catheter. The balloon is subsequently deflated and repositioned within the lesion and the steps of rotating are repeated. Ex. 1006, 2:44-3:2; Ex. 1002, ¶ 77.

The POSITA will understand that deflating the inflatable balloon member, repositioning of the drive shaft within the blood vessel and repeating the steps of rotating the rotational atherectomy device and repeatedly moving the rotating drive shaft and its abrasive element back and forth across the stenotic lesion may be necessary to ensure proper treatment and reduction of the stenotic lesions present within the blood vessel. Accordingly, advancing the device by repeating these steps are well within the knowledge and skill of the POSITA. Ex 1002, ¶ 78.

Accordingly, claim 5 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov, and Rydell.

G. Claim 6 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov,. And In Further View Of Maschke

[6] *The method of claim 1, further comprising: advancing an intravascular ultrasound imaging catheter over the drive shaft into the blood vessel and across the stenotic lesion, and acquiring cross-sectional images of the stenotic lesion area.*

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

Further, the use of an intravascular ultrasound imaging catheter in connection with atherectomy devices to acquire images of the stenotic lesion was well known to the POSITA. In fact, at most, the ‘362 patent merely discloses mounting a plurality of ultrasound transducers to the distal end portion of the drive shaft sheath (43) and those transducers allow for acquiring cross-sectional ultrasound images. Ex. 1001, 9:42-49. The ‘362 patent does not teach anything about how merely mounting ultrasonic transducers to the drive shaft sheath creates an intravascular ultrasound imaging catheter, or how images of the stenotic lesion area are acquired. In contrast, Maschke teaches an intravascular ultrasound imaging catheter that is advanced over the drive shaft into the blood vessel and across the stenotic lesion, and acquiring cross-sectional images of the stenotic lesion area. Ex. 1007, Abstract; Fig. 2 and para [0059]. Maschke discloses the problems associated with prior image monitoring used with atherectomy devices and sought to improve those problems with the development of an intravascular catheter that is far more advance than the disclosure of merely mounting ultrasound transducers on the drive shaft sheath. Ex. 1002, ¶ 81; Ex. 1007.

The POSITA will have, based on the teachings of at least Maschke, understood that the an intravascular ultrasound imaging catheter can be used and advanced over the drive shaft into the blood vessel and across the stenotic lesion and acquiring cross-sectional images of the stenotic lesion area. Ex. 1002, ¶ 82.

Accordingly, claim 6 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov, and in further view of Maschke.

H. Claim 7 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[7] *The method of claim 1, wherein the distal portion of the drive shaft that extends distally of the second stability element has a length that is greater than an axial length of the second stability element.*

The references and arguments applied to claim 1 are incorporated here. The '362 patent discloses that the distal portion of the draft shaft extends distally of the second stability element, and that the length of that elongated portion should have at least 10 centimeters in its length, and preferably 30 centimeters. Ex. 1001, 8:1-7. The '362 patent does not teach or even discuss the reason for the length of this elongated portion or that the length being at least 10 centimeters or preferably 30 centimeters is important, provide any improvement or advantage, solve any particular problem or provide any unexpected results. Indeed, the determination of the optimal length for the distal portion of the drive shaft that extends distally from the second stability element is a routine design choice well within the purview of the POSITA. Ex. 1002, ¶ 85.

In addition, Kallok teaches a distal portion of the drive shaft that extends distally of the second stability element. Figs 10-17 (showing distal stability element 124E, 124C with broken away drive shaft 120 extending distally beyond 124E, 124C). Kallok further teaches that the position of the distal stability element (124E, 124C), relative to the abrasive element (121), may be varied. Fig. 18; 14:10. The POSITA will readily understand that the distal stability element (124E, 124C) may therefore also comprise a position relative to the distal end of the drive shaft (120) to which it is attached and that determining an optimal position for the stability element (124E, 124C) relative to the distal end of the drive shaft (120) will include a configuration wherein the distal portion of the drive shaft extending distally beyond the second stability element (124E, 124C) has a length greater than the second stability element's axial length. Ex. 1002, ¶ 86.

Alternatively, Prudnikov teaches a distal portion of the drive shaft that extends distally of the second stability element. See Ex. 1009, Fig. 6 (showing distal stability element 102 mounted on a broken away drive shaft 20 that is extending distally beyond distal stability element 102). Prudnikov further teaches that the stability elements 100, 102 may, or may not, be equidistantly spaced from the eccentric abrasive element, may comprise equivalent masses and/or locations of the respective centers of mass and that these variables, in combination with rotational speed, may be manipulated by the skilled artisan to achieve the desired result. 5:34-9:23. The POSITA will readily understand the likelihood that using a distal stability element (102) spaced proximally from the distal end of the drive shaft is an obvious combination to try in order to maximize results. It follows that it will be obvious to the POSITA that one such combination comprises a portion of the drive shaft extending distally away from the distal stability element (102) that has a length greater than the second stability element's axial length. Ex. 1002, ¶ 87.

Accordingly, claim 7 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

I. Claim 8 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[8] *The method of claim 7, wherein the distal portion of the drive shaft extends at least 10 centimeters.*

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

Kallok teaches a distal portion of the drive shaft that extends distally of the second stability element. Ex. 1003, Figs 10-17 (showing distal stability element 124E, 124C with broken away drive shaft (120) extending distally beyond 124E, 124C). Kallok further teaches that the position of the distal stability element (124E, 124C), on the drive shaft, relative to the abrasive element (121), may be varied. Ex. 1003, Fig. 18; 14:10. The POSITA will readily understand that, when determining an optimal position for the distal stability element (124E, 124C) relative to the abrasive element (121) distal end of the drive shaft (120) to which it is attached and that locating the position of the stability element (124E, 124C) relative to the distal end of the drive shaft (120) will include a configuration wherein the distal portion of the drive shaft extending distally beyond the second stability element (124E, 124C) has a length that is at least 10 centimeters. Ex. 1002, ¶ 90.

Alternatively, Prudnikov teaches a distal portion of the drive shaft that extends distally of the second stability element. *See* Ex. 1009, Fig. 6 (showing distal stability element 102 mounted on a broken away drive shaft 20 that is extending distally beyond distal stability element 102). Prudnikov further teaches that the positions of the distal stability element (102) and proximal stability element (100) on the drive shaft 20 may, or may not, be equidistantly spaced away from the eccentric abrasive element. Ex. 1009, 5:34-9:23. The POSITA will readily understand that, when determining an optimal position for the distal stability element (102) relative to the abrasive element, the proximal stability element (100) and the distal end of the drive shaft (20), such configurations will include at least some wherein the distal portion of the drive shaft (20) extending distally beyond the second stability element (102) for a length of at least 10 centimeters. Ex. 1002, ¶ 91.

Accordingly, claim 8 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

J. Claim 9 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[9] *The method of claim 1, wherein the first and second stability elements are equally spaced apart from the abrasive element.*

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

Kallok teaches that the first and second stability elements are equally spaced apart from the abrasive element. Ex. 1003, Figs 9-18; 14:1-6; Ex. 1002, ¶ 94.

Alternatively, Prudnikov teaches that the first and second stability elements (100, 102) may be equally spaced apart from the abrasive element. Ex. 1009, 3:34-9:23; Ex. 1002, ¶ 95.

Accordingly, claim 9 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

K. Claim 10 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[10] *The method of claim 1, further comprising advancing the rotational atherectomy device over a guidewire and toward the stenotic lesion material, the guidewire being configured to be slidably disposed within the central lumen of the drive shaft.*

Kallok teaches advancing the rotational atherectomy device over a guidewire and toward the stenotic material, the guidewire being configured to be slidably disposed within the central lumen of the drive shaft. Ex. 1003, 2:50-60; 12:54-13:35; Ex. 1002, ¶ 98.

Alternatively, Prudnikov teaches advancing the rotational atherectomy device over a guidewire (15) and toward the stenotic material, the guidewire (15) being configured to be slidably disposed within the central lumen of the drive shaft (20). Ex. 1009, 4:8-11; Figs 6; 7A-7B; Ex. 1002, ¶ 99.

Accordingly, claim 10 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

L. Claim 11 Is Obvious In View Of Carbo In Combination With Kallok, Or Alternatively, Prudnikov.

[11] *The method of claim 1, wherein the elongate catheter operates as an elongate drainage catheter.*

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

Carbo teaches the elongate catheter (30) operates as an elongate drainage catheter. Ex. 1004, 4:38-67; Ex. 1002, ¶ 102.

Accordingly, claim 11 is obvious over Carbo in view of Kallok, or alternatively, Prudnikov.

M. Claim 1 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov

[1a]. *A method of treating an iliac artery of a patient, comprising*: *positioning an elongate catheter of a system for performing rotational atherectomy in a blood vessel of a patient, the elongate catheter defining a first lumen and a second lumen,*

Shturman '458 teaches positioning an elongate catheter (12) of a system for performing rotational atherectomy in a blood vessel (1) of a patient, the elongate catheter defining a first lumen (30) and a second lumen (26). Ex. 1010, Abstract; Fig. 7; 53:5-31; Ex. 1002, ¶ 104.

[1b] *the elongate catheter including an inflatable balloon member attached to and surrounding an outer diameter of an end portion of the elongate catheter, the balloon member in fluid communication with the first lumen,*

Shturman '458 teaches including an inflatable balloon member (29) attached to and surrounding an outer diameter of an end portion of the elongate catheter (12), the balloon member (29) in fluid communication with the first lumen (30). Ex. 1010, Fig. 7; 53:5-31; Ex. 1002, ¶ 105.

[1c] *the balloon member configured to contact a blood vessel wall when the balloon member is in an inflated configuration;*

Shturman '458 teaches the balloon member (29) configured to contact a blood vessel wall (1) when the balloon member (29) is in an inflated configuration. Ex. 1010, Fig. 7; 53:5-31; Ex. 1002, ¶ 106.

[1d] *rotating a rotational atherectomy device of the system while the rotational atherectomy device is at least partially disposed within the second lumen of the elongate catheter,*

Shturman '458 teaches rotating a rotational atherectomy device (drive shaft (5)) while the rotational atherectomy device (5) is at least partially disposed within the second lumen of the elongate catheter (12). Ex. 1010, Fig. 7; 53:5-31; Ex. 1002, ¶ 107.

[1e] *the rotational atherectomy device comprising an elongate flexible drive shaft defining a central lumen and a longitudinal axis, the drive shaft configured for rotation about the longitudinal axis,*

Shturman '458 teaches the rotational atherectomy device comprising an elongate flexible drive shaft (5) defining a central lumen (A) and a longitudinal axis, the drive shaft configured for rotation about the longitudinal axis. Ex. 1010, Fig. 7; 53-5:31; 26:20-23; 33:15-17; claim 39; Ex. 1002, ¶ 108.

[1f] *an eccentric abrasive element that is mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft, and*

Shturman '458 teaches an eccentric abrasive element (6) that is mounted to the drive shaft (5) such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft (5). Ex. 1010, Figs 2-7, 31:5-11, 33:1-14 ("the abrasive element 6 takes the form of a rounded eccentric mass positioned a short distance proximal to the distal end of the drive shaft 5 . . . the abrasive element 6, its centre of mass is not coaxial with the rotational (longitudinal) axis Y-Y of the drive shaft 5."). Ex. 1002, ¶ 109.

[1g] *a pair of stability elements including a first stability element that is fixed to the drive shaft at a location proximal to the abrasive element, and a*

second stability element that is fixed to the drive shaft at a location distal to the abrasive element,

Shturman '458 teaches a pair of stability elements (8a, 8b) including a first stability element (8b) that is fixed to the drive shaft (5) at a location proximal to the abrasive element (6) and a second stability element (8a) that is fixed to the drive shaft (5) at a location distal to the abrasive element (6). Ex. 1010, Figs 2-7, 33:15-29; Ex. 1002, ¶ 110.

The POSITA will readily recognize that the counterweights (100, 102) are interchangeable with stability elements. Throughout the specification of the '362 patent, the stability elements are referred to as "counterweights" (18, 19). Ex. 1001, Figs. 1-6, 7-8; Ex. 1002, ¶ 111. In fact, nowhere in the specification is the term "stability element" used. The originally filed claims used the term "counterweights" and did not use the term "stability element." Ex. 1016, Claims dated February 3, 2014, pp. 149-156. The term "stability element" was first introduced in the claims filed with the Preliminary Amendment dated March 7, 2014. Ex. 1016, Preliminary Amendment, pp. 107-109. Accordingly, the POSITA will recognize that the counterweights of Prudnikov are interchangeable with the term "stability elements."

[1h] *wherein a distal portion of the drive shaft extends distally of a distal end of the second stability element,*

Kallok teaches the distal portion of the drive shaft (120) extending distal of a distal end of the second stability element (124E, 124C). Ex. 1003, Figs. 10-17 (broken away drawings with drive shaft (120) extending distally beyond the second distal stability element (124E, 124C)). Ex. 1002, ¶ 112.

Alternatively, Prudnikov teaches the distal portion of the drive shaft (20) extending distal of a distal end of the second stability element (102). *See* Ex. 1009, Fig. 6 (illustrating a broken away and cross-sectional view of the drive shaft (20) having a distal portion that extends a distance distally beyond the second distal stability element (102)). Ex. 1002, ¶ 113.

A POSITA would recognize that extending the drive shaft distally from a distal end of the second (distal-most) stability element may be advantageous in several respects. First, the drive shaft portion extending distally away from the second stability element is flexible and, therefore, will function as a lead and/or guide as the device is translated over the pre-positioned guide wire and through the tortuous vasculature of the patient to the stenosis. Ex. 1002, ¶ 114. In this sense, the smaller diameter of the distal portion of the drive shaft will be an obvious advantage. Secondly, when the drive shaft has reached the stenosis, the distally extending portion of the drive shaft may serve as a piloting element through the occlusion in preparation for translation of the larger diameter second stability element and ultimately the still-larger diameter eccentric abrasive element(s). *Id.*

Finally, the distally extending portion of the drive shaft carries a mass that will assist in stabilizing the second stability element and, in turn, the eccentric abrasive element during high-speed rotation. *Id.* These modifications are well within the knowledge and skill of the POSITA. *Id.*

[1i] *wherein said rotating the rotational atherectomy device is caused by a prime mover for rotating the drive shaft; and*

Shturman '458 teaches a prime mover (turbine or similar rotational drive mechanism) for rotating the drive shaft. Ex. 1010, 37:4-14 ("The prime mover may be comprised by at least one turbine 17 mounted on a rigid hollow bearing supported shaft 18 which is connected to the flexible drive shaft (5) for rotation together with the flexible drive shaft (5). The rigid hollow shaft 18 is supported by bearings 19 mounted to the bearing support housing 16. The turbine 17 is located within the housing 16 so that its axis of rotation is substantially at a right angle to a gas supply port 20 extending radially from the wall of the housing 16 and to which a gas supply conduit 21 may be connected so that, when air or other gas is supplied under pressure through the gas supply conduit 21 and through the gas supply port 20 into the housing 16, it impinges on the turbine 17 causing the turbine 17, and the flexible drive shaft 5 to which it is operatively connected to rotate relative to the housing 16 and to the sheath 12 mounted to the drive shaft sheath support housing 13.") Ex. 1002, ¶ 115.

[1j] *repeatedly moving the rotating drive shaft and its abrasive element back and forth across a stenotic lesion to remove stenotic lesion material from the blood vessel, wherein the abrasive element abrades the stenotic lesion material from the blood vessel.*

Shturman '458 teaches repeatedly moving the rotating drive shaft (5) and its abrasive element 6 back and forth across a stenotic lesion to remove stenotic lesion material from the blood vessel, wherein the abrasive element 6 abrades the stenotic lesion material from the blood vessel. Ex. 1010, 49:22-25; Ex. 1002, ¶ 116.

In addition, Kallok teaches repeatedly moving the rotating drive shaft and its abrasive element back and forth across a stenotic lesion to remove the stenotic lesion material from the blood vessel, wherein the abrasive element abrades the stenotic lesion material from the blood vessel. Ex. 1003, Figs 8, 9; 10:61-11:4; Abstract; Ex. 1002, ¶ 117.

Accordingly, the elements of claim 1 are obvious over Shturman '458 in view of Kallok, or alternatively Prudnikov.

N. Claim 2 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[2] *The method of claim 1, further comprising locating the elongate catheter in the blood vessel such that a distal end of the elongate catheter is spaced away from the first stability element.*

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

Kallok teaches locating the distal end of the elongate catheter spaced away from the first (proximal) stability element. Ex. 1003, Figs 1, 10-18, and 19-23; Ex. 1002, ¶ 120.

Alternatively, Prudnikov teaches locating the distal end of the elongate catheter spaced away from the first (proximal) stability element. Ex. 1009, Fig 1; 4:5-8. The POSITA will readily understand that the proximal (first) stability element must be advanced on the drive shaft distally and away from the distal end of the catheter in order for the first stability element to function within the system also comprising an eccentric abrading head and a second stability element. The POSITA will understand that the stability function, and/or stimulation and/or dampening of the working diameter traced by the eccentric abrading head during high-speed rotation may be maximized when the proximal stability element is distally spaced from the distal end of the catheter. *See* Ex. 1009, Figs 8-9; 10:19-41; 5:49-7:61; Ex. 1002, ¶ 121.

Accordingly, claim 2 is obvious over Shturman '458 in view of Kallok, or alternatively, Prudnikov.

O. Claim 3 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[3] *The method of claim 1, wherein the first stability element is a first counterweight, and the second stability element is a second counterweight.*

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

Shturman '458 teaches a pair of counterweights (8a, 8b) including a first counterweight (8b) that is fixed to the drive shaft (5) at a location proximal to the abrasive element (6) and a second counterweight (8a) that is fixed to the drive shaft (5) at a location distal to the abrasive element (6). Ex. 1010, Figs 2-7, 33:15-29; Ex. 1002, ¶ 124.

Accordingly, claim 3 is obvious over Shturman '458 in view of Kallok, or alternatively Prudnikov..

P. Claim 4 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[4] *The method of claim 3, further comprising inflating the inflatable balloon member and aspirating stenotic lesion material through the second lumen of the elongate catheter.*

The references and arguments applied to claim 3 are incorporated here.

Shturman '458 teaches inflating the inflatable balloon member (29) and aspirating stenotic lesion material through the second lumen of the elongate catheter (12). Ex. 1010, Fig. 7; 53:5-31; 8:6-23; Ex. 1002, ¶ 127.

Accordingly, claim 4 is obvious over Shturman '458 in view of Kallok, or alternatively Prudnikov..

Q. Claim 5 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov, And In Further View Of Rydell

[5] *The method of claim 4, further comprising:*

deflating the inflatable balloon member; repositioning the drive shaft within the blood vessel; and repeating the steps of rotating the rotational atherectomy device and repeatedly moving the rotating drive shaft and its abrasive element back and forth across the stenotic lesion.

The arguments and references applied to claim 4 are incorporated herein.

Rydell teaches an atherectomy catheter including the step of inflating a balloon and aspirating debris through the catheter. The balloon is subsequently deflated and repositioned within the lesion and the steps of rotating are repeated. Ex. 1006, 2:44-3:2; Ex. 1002, ¶ 129.

The POSITA will understand that deflating the inflatable balloon member, repositioning of the drive shaft within the blood vessel and repeating the steps of rotating the rotational atherectomy device and repeatedly moving the rotating drive shaft and its abrasive element back and forth across the stenotic lesion may be necessary to ensure proper treatment and reduction of the stenotic lesions present within the blood vessel. Accordingly, advancing the device by repeating these steps are well within the knowledge and skill of the POSITA. Ex 1002, ¶ 130.

Accordingly, claim 5 is obvious over Shturman '458 in view of Kallok, or alternatively, Prudnikov and Rydell.

R. Claim 6 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov, And In Further View Of Maschke

[6] *The method of claim 1, further comprising: advancing an intravascular ultrasound imaging catheter over the drive shaft into the blood vessel and across the stenotic lesion, and acquiring cross-sectional images of the stenotic lesion area.*

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

Further, the use of an intravascular ultrasound imaging catheter in connection with an atherectomy devices to acquire images of the stenotic lesion was well known to the POSITA. Ex. 1002, ¶ 133 .In fact, at most, the '362 patent merely discloses mounting a plurality of ultrasound transducers to the distal end portion of the drive shaft sheath (43) and those transducers allow for acquiring cross-sectional ultrasound images. Ex. 1001, 9:42-49. The '362 patent does not teach anything about how merely mounting ultrasonic transducers to the drive shaft sheath creates an intravascular ultrasound imaging catheter, or how images of the stenotic lesion area are acquired. In contrast, Maschke teaches an intravascular ultrasound imaging catheter that is advanced over the drive shaft into the blood vessel and across the stenotic lesion, and acquiring cross-sectional images of the stenotic lesion area. Ex. 1007, Abstract; Fig. 2 and para [0059]; Ex. 1002, ¶ 133.. Maschke discloses the problems associated with prior image monitoring used with atherectomy devices and sought to improve those problems with the development of an intravascular catheter that is far more advance than the disclosure of merely mounting ultrasound transducers on the drive shaft sheath. Ex. 1002, ¶133; Ex. 1007.

The POSITA will have, based on the teachings of at least Maschke, understood that the an intravascular ultrasound imaging catheter can be used and advanced over the drive shaft into the blood vessel and across the stenotic lesion and acquiring cross-sectional images of the stenotic lesion area. Ex. 1002, ¶ 134.

Accordingly, claim 6 is obvious over Shturman '458 in view of Kallok, or alternatively, Prudnikov. and in further view of Maschke.

S. Claim 7 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[7] *The method of claim 1, wherein the distal portion of the drive shaft that extends distally of the second stability element has a length that is greater than an axial length of the second stability element.*

The references and arguments applied to claim 1 are incorporated here. The '362 patent discloses that the distal portion of the draft shaft extends distally of the second stability element, and that the length of that elongated portion should have at least 10 centimeters in its length, and preferably 30 centimeters. Ex. 1001, 8:1-7. The '362 patent does not teach or even discuss the reason for the length of this elongated portion or that the length being at least 10 centimeters or preferably 30 centimeters is important, provide any improvement or advantage, solve any particular problem or provide any unexpected results. Indeed, the determination of the optimal length for the distal portion of the draft shaft that extends distally from the second stability element is a routine design choice well within the purview of the POSITA. Ex. 1002, ¶ 137.

In addition, Kallok teaches a distal portion of the drive shaft that extends distally of the second stability element. Figs 10-17 (showing distal stability element 124E, 124C with broken away drive shaft 120 extending distally beyond 124E, 124C). Kallok further teaches that the position of the distal stability element (124E, 124C), relative to the abrasive element (121), may be varied. Fig. 18; 14:10. The POSITA will readily understand that the distal stability element (124E, 124C) may therefore also comprise a position relative to the distal end of the drive shaft (120) to which it is attached and that determining an optimal position for the stability element (124E, 124C) relative to the distal end of the drive shaft (120) will include a configuration wherein the distal portion of the drive shaft extending distally beyond the second stability element (124E, 124C) has a length greater than the second stability element's axial length. Ex. 1002, ¶ 138.

Alternatively, Prudnikov teaches a distal portion of the drive shaft that extends distally of the second stability element. See Ex. 1009, Fig. 6 (showing distal stability element 102 mounted on a broken away drive shaft 20 that is extending distally beyond distal stability element 102). Prudnikov further teaches that the stability elements 100, 102 may, or may not, be equidistantly spaced from the eccentric abrasive element, may comprise equivalent masses and/or locations of the respective centers of mass and that these variables, in combination with rotational speed, may be manipulated by the skilled artisan to achieve the desired result. Ex. 1009, 5:34-9:23. The POSITA will readily understand the likelihood that using a distal stability element (102) spaced proximally from the distal end of the drive shaft is an obvious combination to try in order to maximize results. It follows that it will be obvious to the POSITA that one such combination comprises a portion of the drive shaft extending distally away from the distal stability element (102) that has a length greater than the second stability element's axial length. Ex. 1002, ¶ 139.

Accordingly, claim 7 is obvious over Shturman '458 in view of Kallok, or alternatively Prudnikov..

T. Claim 8 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[8] *The method of claim 7, wherein the distal portion of the drive shaft extends at least 10 centimeters.*

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

Kallok teaches a distal portion of the drive shaft that extends distally of the second stability element. Ex. 1003, Figs 10-17 (showing distal stability element 124E, 124C with broken away drive shaft (120) extending distally beyond 124E, 124C). Kallok further teaches that the position of the distal stability element (124E, 124C), on the drive shaft, relative to the abrasive element (121), may be varied. Ex. 1003, Fig. 18; 14:10. The POSITA will readily understand that, when determining an optimal position for the distal stability element (124E, 124C) on the distal end of the drive shaft (120) and relative to the abrasive element (121) will include a configuration wherein the distal portion of the drive shaft extends distally beyond the second stability element (124E, 124C) and having a length that is at least 10 centimeters. Ex. 1002, ¶ 142.

Alternatively, Prudnikov teaches a distal portion of the drive shaft that extends distally of the second stability element. *See* Ex. 1009, Fig. 6 (showing distal stability element 102 mounted on a broken away drive shaft 20 that is extending distally beyond distal stability element 102). Prudnikov further teaches that the positions of the distal stability element (102) and proximal stability element (100) on the drive shaft 20 may, or may not, be equidistantly spaced away from the eccentric abrasive element. Ex. 1009, 5:34-9:23. The POSITA will readily understand that, when determining an optimal position for the distal stability element (102) relative to the abrasive element, the proximal stability element (100) and the distal end of the drive shaft (20), such configurations will include at least some wherein the distal portion of the drive shaft (20) extending distally beyond the second stability element (102) for a length of at least 10 centimeters. Ex. 1002, ¶ 143.

Accordingly, claim 8 is obvious over Shturman '458 in view of Kallok, or alternatively, Prudnikov..

U. Claim 9 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[9] *The method of claim 1, wherein the first and second stability elements are equally spaced apart from the abrasive element.*

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

Shturman '458 teaches that the first and second stability elements are equally spaced apart from the abrasive element. Ex. 1010, Figs. 2-7; 33:15-25; Ex. 1002, ¶ 146.

Accordingly, claim 9 is obvious over Shturman '458 in view of Kallok, or alternatively Prudnikov..

V. Claim 10 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[10] *The method of claim 1, further comprising advancing the rotational atherectomy device over a guidewire and toward the stenotic lesion*

material, the guidewire being configured to be slidably disposed within the central lumen of the drive shaft.

Shturman '458 teaches advancing the rotational atherectomy device over a guidewire and toward the stenotic material, the guidewire being configured to be slidably disposed within the central lumen of the drive shaft. Ex. 1010, Fig. 2-3; 31:5-11 ("Once the distal end 3a of the guidewire 3 has been located in the appropriate position distal to the stenotic lesion 2, the distal end 4 of a flexible hollow drive shaft 5 is advanced over the proximal end of the guidewire 3 protruding from the patient and is tracked over the guidewire 3 until an abrasive element 6, mounted on the drive shaft 5 a short distance proximal to the distal end 4 of the drive shaft 5, is situated close to the stenotic lesion 2 to be abraded."); Ex. 1002, ¶ 148..

Accordingly, claim 10 is obvious over Shturman '458 in view of Kallok, or alternatively, Prudnikov.

W. Claim 11 Is Obvious In View Of Shturman '458 In Combination With Kallok, Or Alternatively, Prudnikov.

[11] *The method of claim 1, wherein the elongate catheter operates as an elongate drainage catheter.*

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

Shturman '458 teaches the elongate catheter (12) operates as an elongate drainage catheter. Ex. 1010, Fig. 7; 35:25-36:14; Ex. 1002, ¶ 151.

Accordingly, claim 11 is obvious over Shturman '458 in view of Kallok, or alternatively, Prudnikov.

VI. CONCLUSION

For the foregoing reasons, claims 1-11 of the '362 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: September 5, 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. 9,089,362, all supporting exhibits (Exhibits 1001 through 1017), and the Power of Attorney were served on September 5, 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. 9,089,362 Under 35 U.S.C. § 312 AND 37 C.F.R. § 42.104 totals 11,276, and within the 14,000 words allowed under 37 C.F.R. §42.24(a)(1)(i).

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