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In re *Inter Partes Review* of:	)	
	)	
U.S. Patent No. 8,956,371 B2	)	
	)	
Issued: February 17, 2015	)	Attorney Docket No. 68890-286961
	)	
Inventors: Daniel Hawkins, et al.	)	
	)	
Application No. 12/482,995	)	
	)	
Filed: June 11, 2009	)	
	)	FILED ELECTRONICALLY
For: SHOCKWAVE BALLOON CATHETER SYSTEM	)	PER 37 C.F.R. § 42.6(b)(1)
	)	

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PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,956,371 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 requests *inter partes* review of claims 1-17 of U.S. Patent No. 8,956,371 B2 ("the '371 patent," attached as Exhibit 1001), now purportedly assigned to Shockwave Medical, Inc.

An electronic payment in the amount of $31,700 for the *inter partes* review fee specified by 37 C.F.R. § 42.15(a)(1), 42.15(a)(2) and 42.15(a)(4)—comprising the $15,500.00 request fee and $16,200.00 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

LIST OF EXHIBITS

Exhibit 1001:	U.S. Patent No. 8,956,371
Exhibit 1002:	Declaration of Dr. Morten Olgaard Jensen
Exhibit 1003:	EP 0571306
Exhibit 1004:	U.S. Patent Appl. Publ. No. U.S. 2010/0036294
Exhibit 1005:	Japanese Unexamined Patent Application Publication, Publ. No. S62-275446
Exhibit 1006	German Patent Application, DE 3038445 A1
Exhibit 1007	U.S. Patent No. 7,309,324
Exhibit 1008	U.S. Patent Appl. Publ. No. U.S. 2002/0082553 ,
Exhibit 1009	U.S. Patent No. 7,569,032
Exhibit 1010	U.S. Patent Appl. Publ. No. U.S. 2006/0190022
Exhibit 1011	U.S. Patent Appl. Publ. No. U.S. 2007/0239082
Exhibit 1012	U.S. Patent No. 5,152,768
Exhibit 1013	File History for U.S. Patent No. 8,956,371
Exhibit 1014	U.S. Patent No. 4,445,509
Exhibit 1015	U.S. Patent No. 4,990,134
Exhibit 1016	U.S. Patent No. 5,584,843
Exhibit 1017	U.S. Patent No. 6,132,444
Exhibit 1018	U.S. Patent No. 6,494,890
Exhibit 1019	U.S. Patent No. 8,353,923
Exhibit 1020	U.S. Patent No. 8,177,801
Exhibit 1021	U.S. Patent No. 5,116,227

Exhibit 1022	Canfield J, Totary-Jain H. 40 Years of Percutaneous Coronary Intervention: History and Future Directions. J Pers Med. 2018;8(4).
Exhibit 1023	Myler RK, Shaw RE, Stertzer SH, Clark DA, Fishman J, Murphy MC. Recurrence after coronary angioplasty. Cathet Cardiovasc Diagn. 1987;13(2):77-86.
Exhibit 1024	U.S. Patent No. 5,891,089
Exhibit 1025	Salunke NV, Topoleski LD, Humphrey JD, Mergner WJ. Compressive stress-relaxation of human atherosclerotic plaque. J Biomed Mater Res. 2001;55(2):236-41.
Exhibit 1026	Lee RT, Grodzinsky AJ, Frank EH, Kamm RD, Schoen FJ. Structure-dependent dynamic mechanical behavior of fibrous caps from human atherosclerotic plaques. Circulation. 1991;83(5):1764-70.
Exhibit 1027	Doshi R, Shlofmitz E, Patel K, Meraj P. Clinical Outcomes of Atherectomy Prior to Percutaneous Coronary Intervention: A Comparative Assessment of Atherectomy in Patients With Obesity (COAP-PCI Subanalysis). J Invasive Cardiol. 2018.

Exhibit 1028	Dodd AT. Two Cases of Calculus in the Bladder, in which Lithotripsy was Performed. Prov Med Surg J (1840). 1842;3(71):368-70.
Exhibit 1029	Nisonson I, Witus WS, Madorsky ML, Weems WS. Ambulatory extracorporeal shockwave lithotripsy. Urology. 1986;28(5):381-4.
Exhibit 1030	Patterson DE, Segura JW, LeRoy AJ, Benson RC, Jr., May G. The etiology and treatment of delayed bleeding following percutaneous lithotripsy. J Urol. 1985;133(3):447-51.
Exhibit 1031	Grocela JA, Dretler SP. Intracorporeal lithotripsy. Instrumentation and development. Urol Clin North Am. 1997;24(1):13-23.
Exhibit 1032	Tanaka K, Satake S, Saito S, Takahashi S, Hiroe Y, Miyashita Y, Tanaka S, Tanaka M, Watanabe Y. A new radiofrequency thermal balloon catheter for pulmonary vein isolation. J Am Coll Cardiol. 2001;38(7):2079-86.
Exhibit 1033	Kaplan J, Barry KJ, Connolly RJ, Nardella PC, Hayes LL, Lee BI, Waller BF, Becker GJ, Callow AD. Healing after arterial dilatation with radiofrequency thermal and

	nonthermal balloon angioplasty systems. J Invest Surg. 1993;6(1):33-52.
Exhibit 1034	Becker GJ, Lee BI, Waller BF, Barry KJ, Kaplan J, Connolly R, Dreesen RG, Nardella P. Radiofrequency balloon angioplasty. Rationale and proof of principle. Investigative radiology. 1988;23(11):810-7.
Exhibit 1035	Smith DL, Walinsky P, Martinez-Hernandez A, Rosen A, Sterzer F, Kosman Z. Microwave thermal balloon angioplasty in the normal rabbit. Am Heart J. 1992;123(6):1516-21.
Exhibit 1036	Knuttinen MG, Van Ha TG, Reilly C, Montag A, Straus C. Unintended thermal injuries from radiofrequency ablation: organ protection with an angioplasty balloon catheter in an animal model. J Clin Imaging Sci. 2014;4:1.
Exhibit 1037	Liu W, Zhang Y, Yu CM, Ji QW, Cai M, Zhao YX, Zhou YJ. Current understanding of coronary artery calcification. J Geriatr Cardiol. 2015;12(6):668-75.
Exhibit 1038	Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and

	clinical implications. Catheter Cardiovasc Interv. 2014;83(6):E212-20.
Exhibit 1039	Fung YC. Biomechanics - Mechanical Properties of Living Tissues: Springer; 1993.
Exhibit 1040	Nichols WW, O'Rourke MF. McDonald's Blood Flow in Arteries, Fifth Edition. Theoretical, Experimental and Clinical Principles: Oxford University Press; 2005. 607 p.
Exhibit 1041	Athanasoulis CA. Percutaneous transluminal angioplasty: general principles. AJR Am J Roentgenol. 1980;135(5):893-900.
Exhibit 1042	Simpson JB, Baim DS, Robert EW, Harrison DC. A new catheter system for coronary angioplasty. Am J Cardiol. 1982;49(5):1216-22.
Exhibit 1043	Linnemeier TJ, McCallister SH, Lips DL, Klette MA, Rothbaum DA, Ball MW, Landin RJ, Hodes ZI, Riddell RV. Radiation exposure: comparison of rapid exchange and conventional over-the-wire coronary angioplasty systems. Cathet Cardiovasc Diagn. 1993;30(1):11-4.

Exhibit 1044	Mooney MR, Douglas JS, Jr., Mooney JF, Madison JD, Brandenburg RO, Jr., Fernald R, Van Tassel RA. Monorail Piccolino catheter: a new rapid exchange/ultralow profile coronary angioplasty system. Cathet Cardiovasc Diagn. 1990;20(2):114-9.
Exhibit 1045	Amighi J, Sabeti S, Dick P, Schlager O, Ahmadi R, Minar E, Schillinger M. Impact of the rapid-exchange versus over-the-wire technique on procedural complications of renal artery angioplasty. J Endovasc
Exhibit 1046	Jahnke T, Schafer JP, Bolte H, Schafer F, Michalek J, Charalambous N, Sapoval M, Muller-Hulsbeck S. Retrospective study of rapid-exchange monorail versus over-the-wire technique for femoropopliteal angioplasty. Cardiovasc Intervent Radiol. 2008;31(5):854-9.
Exhibit 1047	U.S. Patent No. 6,364,894

I. PRELIMINARY STATEMENT

Surgical electrohydraulic lithotripsy ("EHL") is a procedure in which an electrical spark is applied within a fluid to produce a mechanical shockwave. EHL has been used for decades to break-up kidney stones by applying the shockwave to the calcified deposit within the passages of the kidney to disintegrate the "stone" allowing for easier extraction. Not surprisingly, the success of EHL to break up calcified deposits has led to its use in other applications where the removal of calcified deposits is desired. One such application involves angioplasty procedures to remove calcified deposits within the blood vessel.

The '371 patent allegedly improves on conventional angioplasty balloon catheter systems by including a shockwave generator within an angioplasty balloon. Yet, more than one year before the effective filing date of the '371 patent (i.e. June 11, 2009), angioplasty balloon catheter systems having a shockwave generator within the balloon was already known from at least the prior art references of Levy (Ex. 1003) and Mantell (Ex. 1004).

As discussed in additional detail herein, the Examiner did not previously apply Levy to the claims. Levy expressly teaches a catheter system, including an angioplasty balloon, for treatment of arterial plaque, utilizing a shockwave created by a shockwave generator located within the balloon. Although the shockwave generator of Levy is a laser, and not a pair of electrodes, it was known from prior

art references such as Bhatta that a laser system and EHL were interchangeable for generating a shockwave to be used for treating arteriosclerotic plaque. (Ex. 1012). Moreover, design features such as the electrodes being metallic, the balloon being formed of compliant or non-compliant materials, use of a reflector to focus the shockwaves were commonly known with EHL systems and angioplasty procedures. Accordingly, as discussed in greater detail herein, the '371 patent fails to define patentable subject matter within its claims in view of the prior art.

II. 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.

III. OVERVIEW OF CHALLENGES

A. Identification of Challenges

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1-17 of the '371 patent (Ex. 1001) as unpatentable in view of, the following patents and printed publications:

1. Levy, Guy, EP 0571306, "Device and Method For Removing Deposits On The Walls Of Passages," published November 24, 1993 ("Levy") (Ex. 1003).
2. Mantell, et al., U.S. Patent Appl. Publ. No. U.S. 2010/0036294, "Radially-Firing Electrohydraulic Lithotripsy Probe," filed May 6, 2009 ("Mantell") (Ex. 1004).
3. Uchiyama, Naoki, Japanese Unexamined Patent Application Publication, Publ. No. S62-275446, "Electrical Discharge Lithotripter," published November 30, 1987 ("Uchiyama") (Ex. 1005).
4. Willneff, Rainer, German Patent Application, DE 3038445 A1, "Shockwave Generator for Medical Applications," published May 27, 1982 ("Willneff") (Ex. 1006).

5. Hayes, et al., U.S. Patent No. 7,309,324, "Non-Compliant Medical Balloon Having An Integral Woven Fabric Layer," filed October 15, 2004 ("Hayes") (Ex. 1007).

6. Duchamp, Jacky, U.S. Patent Appl. Publ. No. U.S. 2002/0082553, "Balloon Designs For Angioplasty," filed December 22, 2000 ("Duchamp") (Ex. 1008).

7. Naimark, et al., U.S. Patent No. 7,569,032, "Medical Device for Delivery of a Biologically Active Material to a Lumen," filed November 28, 2000 ("Naimark") (Ex. 1009).

8. Beyar, et al., U.S. Patent Appl. Publ. No. U.S. 2006/0190022, "Material Delivery System," filed July 14, 2004 ("Beyar") (Ex. 1010).

9. Schultheiss, et al., U.S. Patent Appl. Publ. No. U.S. 2007/0239082, "Shockwave Treatment Device," filed January 27, 2006 ("Schultheiss") (Ex. 1011).

10. Bhatta, Krishna, U.S. Patent No. 5,152,768, "Electrohydraulic Lithotripsy," filed February 26, 1991 ("Bhatta") (Ex. 1012).

11. Healy, et al., U.S. Patent No. 6,364,894, "Method of Making An Angioplasty Balloon Catheter," filed June 12, 2000, ("Healy") (Ex. 10

According to their issuance or publication, each of Levy, Uchiyama, Willneff, Hayes, Duchamp, Naimark, Beyar, Schultheiss, and Bhatta are 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 '371 patent (i.e., before the presumed effective filing date of June 11, 2009). Mantell is prior art under at least 35 U.S.C. § 102(e) as a published U.S. Patent application that was effectively filed, naming another inventor, before the presumed effective filing date of the '371 patent.

Willneff, Hayes, and Duchamp were not made of record or cited by the examiner during prosecution of the '371 patent. Levy and Uchiyama were cited by the examiner, but were not applied by the Office during prosecution of the '371 patent. Although Mantell, Naimark, Beyar, Schultheiss, and Bhatta were previously applied by the examiner, the Office has not previously considered these referenced 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 the POSITA in consideration of these prior art references.

Ground	**Reference(s)**	**Challenged Claims**
1	§ 103 Levy as modified by AAPA in combination with Mantell, Uchiyama or Willneff	1-6,11, 14-16
2	§ 103 Levy as modified by AAPA in combination with Mantell, Uchiyama or Willneff, and in further view of Hayes	7, 12
3	§ 103 Levy as modified by AAPA in combination with Mantell, Uchiyama or Willneff, and in further view of Duchamp	8, 12

4	§ 103 Levy as modified by AAPA in combination with Mantell, and in further view of Naimark	9
5	§ 103 Levy as modified by AAPA in combination with Mantell, and in further view of Beyar	10
6	§ 103 Levy as modified by AAPA in combination with Mantell, and in further view of Bhatta	13
7	§ 103 Levy as modified by AAPA in combination with Mantell, and in further view of Schultheiss	17
8	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell	1-4, 6, 11, 15-16
9	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Uchiyama	5, 14
10	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Hayes	7, 12
11	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Duchamp	8, 12
12	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Naimark	9
13	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Beyar	10
14	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Bhatta	13
15	§ 103 Willneff as modified by AAPA in combination with Levy or Mantell, and Schultheiss	17

B. There is a Reasonable Likelihood that at least One Claim of the '371 Patent is Unpatentable under 35 U.S.C. § 103

The '371 patent is directed to a conventional angioplasty catheter system for generating a shockwave within an angioplasty balloon to remove or reduce calcified stenotic lesions in blood vessels. *See, e.g.,* '371 patent at Title; Abstract; 1:40-45 (Ex. 1001). In the described embodiment, a shockwave generator in the form of an arc generator including at least one electrode pair is positioned within a conventional fluid filled angioplasty balloon system. When high voltage pulses are

applied to the shockwave generator, a plasma is created between the electrodes resulting in the generation of a mechanical shockwave. The shockwave is transmitted through the fluid within the balloon, through the balloon and directed to a calcified stenotic lesion in the blood vessel to break or crack the calcified lesion and thus improve blood flow. But before the alleged invention of the '371 patent, others arrived at the same solution of inserting a shockwave generator, within a fluid filled angioplasty balloon to generate shockwaves directed at calcified stenotic lesions to provide the same function, in the same manner, as disclosed and claimed in the '371 patent. *See, e.g.* Ex. 1003, Levy; Ex. 1004, Mantell; Ex. 1005, Uchiyama; and Ex. 1006, Willneff.

These references demonstrate 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 (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 '371 PATENT

A. Overview of the '371 Patent

The '371 patent is directed to a balloon angioplasty catheter device for removing or reducing stenotic lesions in blood vessels utilizing shockwaves. *See,*

e.g., '371 patent at Title; Abstract; 1:40-45 (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. The clogging of the arteries with plaque 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 plaque. 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 remove or reduce the plaque and thereby improve blood flow. Another technique is angioplasty. Angioplasty involves the use of dilation catheter to cross a lesion and inflating a balloon. The inflation of a balloon dilates the lesion by breaking the lesion and pushing it back towards the blood vessel and thus restoring blood flow. One modification of the traditional angioplasty procedure is to utilize additional forces, such as a shockwave, that can be focused on calcified plaque. Indeed, the '371 patent acknowledges that its invention is directed to the addition of a shockwave generator to traditional prior art angioplasty catheter devices and systems. *See* Ex. 1001, Fig. 1 & 2; 3:65-4:4. The use of shockwaves in conjunction with angioplasty, however, was known for nearly a decade prior to the effective filing date of the '371 patent. Nevertheless, the '371 patent does not identify any problems associated with these prior

shockwave angioplasty catheter devices. Instead, the '371 patent offers routine design modifications to existing angioplasty catheter devices utilizing shockwaves to achieve known and predictable results. In particular, the '371 patent simply modifies prior shockwave angioplasty catheter devices utilizing laser energy to generate a shockwave by substituting a pair of electrodes to generate the shockwave. As discussed herein, it was known to the ordinary artisan that the use of a laser or an electrode pair to generate a shockwave was interchangeable and the ordinary artisan would have been motivated to try an electrode pair to address known thermal effects from the use of a laser versus an electrode pair, as well as to address the substantially higher costs associated with the use of a laser compared to an electrode pair which makes the devices less practical.

B. Claim Construction

A claim term is given its "ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Computer Entm't America LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (emphasis added) (*citing Phillips*, 415 F.3d at 1313). The *Phillips* decision made clear that patent claims should be construed in context and that "the specification necessarily informs the proper construction . . . ." *Phillips*, 415 F.3d at 1316; *Abbott Labs. v. Sandoz, Inc.,* 566 F.3d 1282, 1288 (Fed. Cir. 2009) (patent specification "provides necessary context for

understanding the claims"). Further, statements about the invention as a whole, such as those found in the Abstract and Summary of the Invention, are given particular weight. *E.g., Silicon Graphics, Inc., v. ATI Techs., Inc.*, 607 F.3d 784, 793 (Fed. Cir. 2010). Claim terms must also be interpreted in light of the problem intended to be solved. *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1160 (Fed. Cir. 1997). "The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." *Phillips*, 415 F.3d at 1315 (internal quotations omitted); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings,* 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention.").

A person of ordinary skill in the art at the time of the alleged invention of the '371 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 three to five years of practical experience (or comparable and/or equivalent education or training), including familiarity with the various medical devices and techniques for treating plaque buildup in blood vessel or body passages, such as balloon angioplasty, ablation, rotational atherectomy, lithotripsy. Ex. 1002, 63-66.

Petitioner believes that the all of the terms and phrases from the claims of the '371 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 '371 patent. Nevertheless, Petitioner proposed claim construction for select terms and phrases for this proceeding are set forth below.

1. "angioplasty catheter"

A POSITA would understand that the ordinary and customary meaning of the claim term "angioplasty catheter" when read in the context of the specification and prosecution history to mean "a flexible tube configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels." Ex. 1002, 76; Ex. 1001, 1:13-18 ("The present invention relates to a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is used to cross a lesion in order to dilate the lesion and restore normal blood flow in the artery.")

2. "angioplasty balloon"

A POSITA would understand that the ordinary and customary meaning of the claim term "angioplasty balloon" when read in the context of the specification and prosecution history to mean "an inflatable sac that is configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels." Ex. 1002, 77; Ex. 1001, 1:13-18 ("The present invention relates to

a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is used to cross a lesion in order to dilate the lesion and restore normal blood flow in the artery.")

V. CLAIMS 1-17 OF THE '371 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 Dr. Jensen's declaration (Ex. 1002), 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 Angioplasty Catheters Using Shockwaves To Remove Plaque Deposits From Blood Vessels

A variety of techniques and medical devices have been developed to remove or disrupt 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 1980's, a common approach to treating atherosclerosis was the use of a balloon angioplasty. Balloon angioplasty involves the use of a catheter placed in the peripheral artery and passing a balloon catheter along and over a guidewire 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. Ex. 1002, 80-81.

Despite the great success of balloon angioplasty to treat atherosclerosis, there continued to be a need for improvement to address some disadvantages. For example, one disadvantage of traditional balloon angioplasty described in the '371 patent is the trauma to the vessel walls when treating calcified lesions. Ex. 1001, '371 patent at 1:18-23. When plaque has calcified with deposit within the vessel's lumen and/or within the intima layer (or deeper) of the vessel wall itself, applying too much (uncontrolled) pressure to the balloon can cause damage to the vessel. To treat calcified lesions, high pressures are needed to break the calcified atherosclerotic plaque. As the angioplasty balloon is inflated under high pressure, a tremendous amount of energy is stored in the balloon until the calcified lesion breaks. *Id.* at 1:25-33. The release of energy upon breaking of the calcified lesion may result in the angioplasty balloon expanding rapidly to its maximum dimensions causing stress and injury to the vessel walls. *Id.* at 1:33-36.

It is known that calcification can reach into at least the intimal layer of the vessel wall. It was also known that shockwaves will penetrate the vessel wall and will preferentially act on the calcified material to disrupt it, thereby enabling the vessel to restore significant levels of compliance in the affected area without damaging other body parts. Ex. 1002, 84; Ex. 1006, p. 3 ("It has now been discovered that the sound wave resistance of human or animal tissue is approximately equal to the sound wave resistance of water, and that the sound

wave resistance of the concretions differs considerably therefrom. It has also been demonstrated that shock waves do not affect other body parts of the human body and that the bones of the human body are not damaged because of their high tensile strength and the shortness of the signal.")

One solution to remove the calcified stenosis was the use of shockwaves. Ex. 1002, 86. For example, by 1992 it was known that generating shockwaves within a blood vessel could be employed to remove plaque deposits within the blood vessels. *See, e.g.,* U.S. Patent No. 5,116,227 (Ex. 1021).

Pulsed laser energy was used for removing plaque deposits in blood vessels. Ex. 1002, 87; *See*, e.g., Ex. 1021, '227 patent, 2:31-34; Fig. 3 (illustrating insertion of the hollow catheter 7 with optical fiber 3 within tube 7). The '227 patent discloses positioning an optical fiber lens a short distance from the plaque deposit in the subject vessel, followed by laser pulses that generate cavitation of the fluid distal to the catheter, wherein the fluid is not contained within a balloon or other inflatable body. Shockwaves are thus produced by the laser pulses within the fluid that disintegrate the calcified plaque material. *See* Ex. 1021, 3:31-61 (discussing shockwave generation and the resulting disintegrating effects on targeted calcified material). Accordingly, by at least the early 1990's, POSITA knew that the use of shockwaves produced within a blood vessel may be used to disrupt calcified plaque deposits located within the blood vessel. Ex. 1002, 88.

Around the same time, Levy disclosed the production and use of shockwaves within an angioplasty balloon to disintegrate calcified lesions within a blood vessel. Levy discloses a catheter (8) with a lumen within which an optical fiber (12) is provided. The optical fiber (12) is connected with a laser light source (20) capable of producing laser beam pulses of a suitable duration and energy level. Ex. 1002, 89-90.

The catheter (8) is flexible and carries an inflatable body (10) fixed by any suitable means on the distal end (6) of the catheter (8). The inflatable body (10) is taught as having the shape of a balloon of the kind used with catheters used to perform treatments in blood vessels (i.e. an angioplasty balloon). The balloon (10) may be of a type having a high degree of flexibility and need not produce significant expansion of the blood vessel (2). The lumen of catheter (8) is fluidly connected with a liquid supply source (22) for sending fluid, e.g., saline, through the lumen of catheter (8) to the balloon (inflatable body). *Id.* at 90

The device is inserted into a blood vessel (2) where a deposit (4) such as a plaque or atheroma has developed for removal of the deposit (4) using an inflatable angioplasty balloon with relatively low inflation pressure since the inflated body need not produce significant expansion of the blood vessel (2). The device is inserted into the blood vessel with inflatable body (10) in the deflated state proximately to the deposit 4. The inflatable body (10) is inflated with fluid from

supply source (22) until the inflating inflatable body (10) touches the exposed surface of the deposit (4), without producing a force that would cause a radial expansion of the vessel (2). With the optical fiber (12) then positioned within the inflated inflatable body (10), laser beam pulses are produced by the laser source (20) and emitted by the distal end of the optical fiber (12) into the fluid within inflatable body (10) at a point that is spaced away from the inflatable body (10) by focusing the emitted laser beam in the fluid within the inflatable body (10). *Id.* at ¶ 91.

This pulsed energy emission creates a plasma that results in formation and cavitation of vapor within the liquid, producing an implosion of gas bubbles for each laser beam pulse. Ex. 1002, 92. The mechanism for generating shockwaves by the creation of a plasma resulting in the cavitation of vapor within the fluid and producing an implosion of gas bubbles is the same for any shockwave generator regardless of the energy source, including laser or electrode pairs. Ex. 1002, 92; Ex. 1012 1:11-30. The resulting shockwave generated by this process travels through the fluid in the inflatable body, transmitted through the walls of the inflatable body (4) and subsequently to the deposit (4) which is disintegrated. Accordingly, by at least 1993, the POSITA knew it was possible to conduct a balloon angioplasty procedure enhanced by the use of shockwaves. In particular, Levy taught that it is possible to generate shockwaves within an inflated

angioplasty balloon using pulse laser beam energy without melting, tearing or otherwise damaging the inflated balloon. *Id.*, 93.

One improvement taught by Levy over the '227 patent is that the generation of shockwaves within a fluid-filled balloon that is touching the occlusive plaque or vessel wall having calculi embedded in the intima is a more focused and efficient way to deliver the shockwave energy to the treatment area. Ex. 1002, 94. One problem associated with the use of a laser source to generate the shockwaves is the cost. The use of a laser source to generate shockwave energy is known to be expensive. Ex. 1002, 95. The high costs associated with a laser system to generate shockwave energy represents a clear motivation for the POSITA to seek an alternative mechanism to generate the shockwave within the angioplasty balloon, wherein the alterative shockwave generation mechanism preferably can be interchangeable with the laser requiring little modification to the remaining system and at significantly reduced costs. *Id.*

Another problem associated with the use of a laser source to generate the shockwaves is the known problems associated with overheating. The overheating issue described in Levy represents a clear motivation for the POSITA to seek an alternative mechanism to generate the shockwave within the angioplasty balloon, wherein the alternative shockwave generation mechanism preferably does not contribute as much heat to the fluid within the angioplasty balloon and, therefore,

does not require cooling consideration for the fluid within the inflated angioplasty balloon. Ex. 1002, 96.

One known alternative method for generating shockwaves, also known well before the effective filing date of the '371 patent, was the use of pairs of electrodes to generate shockwaves. Ex. 1002, 97; Ex. 1028-1033. The spark generated between the electrodes is known to create a plasma resulting in the generation of shockwaves. *Id.*; Ex. 1004 – 1006, 1012. In addition, the production of a spark between two electrodes within a fluid-filled balloon that is in contact with material targeted for disruption or disintegration, wherein the spark generates a shockwave that travels through the fluid and balloon into the targeted material, is also known and well understood. Ex. 1002, 84; Ex. 1006, p. 3. These are the foundational principles of EHL used first in disruptions of kidney stones and other calcified concretions. Ex. 1002, 97; Ex. 1012. However, EHL has also been long known to have utility in blood vessels for disrupting calcified lesions. *Id.*; Ex. 1004; 1012. Importantly, it was known to the POSITA that EHL systems are relatively inexpensive compared to laser systems. Ex. 1002, 97; Ex. 1012.

The interchangeability of a laser system to generate a shockwave with an EHL system is also known to a POSITA. Ex. 1012; Ex. 1002, 98. Bhatta discloses that the shockwave of a laser system and EHL system can be used for fracturing removing arteriosclerotic plaque. Ex. 1012, 1:5-10 ("The present invention relates

to a system for fracturing hard formations in the body, and more specifically, to a method and apparatus for fracturing deposits such as urinary and biliary calculi as well as arteriosclerotic plaque in the body."). In addition, Bhatta discloses that the laser system and the EHL system both utilize plasma to generate the shockwave. Ex. 1012, 1:15-30 ("Electrohydraulic lithotripsy and laser lithotripsy systems frequently are used to fragment urinary and biliary stones. Both systems utilize plasma-induced stress waves to fragment calculi.").[1] Accordingly, the POSITA understood the utility of using an electrode pair to generate a shockwave within a liquid-filled environment, with subsequent transference of the shockwave and energy thereof to a calcified plaque within an artery to disrupt and/or disintegrate the calcification. Ex. 1002, 97-102; Ex. 1004 – 1006; 1012. Moreover, the POSITA would understand that the characteristics of shockwave generated by a laser source are identical to those generated by an electrode pair. Ex. 1002, 98; Ex. 1012. As previously discussed, *supra* at p. 19-20, the POSITA knows that any calcification within the plaque and/or within the wall of the blood vessel aligned

[1] Bhatta's recognition that both the laser and EHL systems utilize plasma to generate the shockwave is in the "Background of Invention" and thus within the knowledge of the ordinary artisan even prior to its disclosure in 1991, and more than a decade prior to the effective filing date of the '371 patent. Notably, Levy '227 (Ex. 1021) is similar to Bhatta, but using a laser to generate the shock wave. Not surprisingly, the natural progression of these devices lead Levy to place the laser shockwave generator within an angioplasty balloon. It would have been obvious to an ordinary artisan to similarly place the electrode pairs of Bhatta within an angioplasty balloon as well. Ex. 1002, at ¶ 100 n. 1; Ex. 1003, 1012 and 1021.

with the energy transmission will be disrupted because the energy from the transmitted shockwaves continues into these regions. Ex. 1002, 98-102; Ex. 1006, p. 3.

Uchiyama (Ex. 1005) taught a pair of electrodes (3) on a tube (8), wherein the electrode pair (3) is disposed within a fluid-filled inflatable balloon (7). The device is arranged so that the inflated balloon (7) is in contact with the lesion and then a spark is generated between the electrodes (3) to generate a shockwave that is transmitted through the fluid of the inflated balloon and impinge the targeted material, wherein the balloon remains intact. Ex. 1002, 103; Ex. 1005, p. 298 & Figs. 1-7.

Uchiyama further teaches that the shockwave disrupts calcifications without damaging surrounding human tissue. Ex. 1002, 104; Ex. 1005, p. 298. Importantly, Uchiyama teaches that placement of the electrodes within the balloon prevents the discharge sparks from directly hitting human tissue and thus improving safety. *Id.* Accordingly, it was known that it is possible to generate a shockwave within a fluid-filled balloon, wherein the shockwave is created by two spaced-apart electrodes, transferred, transmitted or propagated through the fluid within the balloon and the balloon material and into the contacted material without adverse effects to the surrounding human tissue or the device (e.g. the inflated balloon). *Id.*

Willneff (Ex. 1006) teaches that it is possible to create a shockwave generator for therapeutic application that can be introduced into body orifices and brought close to body parts or calculi that need to be subject to shockwaves and, at the same time, the spark gap (16) does not touch body tissue and is also electrically insulated from the spark. Willneff enclosed the spark gap between two electrodes of an electrode pair in a balloon (18) arranged at the distal end of a catheter (12) that is capable of introduction into body cavities near the area of application of the shockwaves, wherein the balloon is expanded or inflated with a liquid. Ex. 1002, 105; Ex. 1006, pp. 5, 10 & Figs 1-3.

Willneff further teaches that the spark gap (16) is centered within the balloon (18) to avoid both mechanical damage or burning of tissue and the interior of the balloon is electrically conductive and connected to the shielding of the catheter. Ex. 1002, 106; Ex. 1006, pp. 5-6. Willneff also recognized that the EHL balloon device has many indications that require intravascular access, including positioning of the device near the heart. *See*, *e.g.*, coronary heart disease, idiopathic hypertrophic sub-aortic stenosis. Ex. 1002, 106; Ex. 1006, p. 8.

Accordingly, for many years prior to the effective filing date of the '371 patent, it was known that it is possible to modify the laser-generating shockwave device of Levy by substituting an electrode pair within the fluid-filled balloon. Ex. 1002, 107. The shockwaves generated by either type of shockwave generator

(laser or electrodes) are identical in physical characteristics and, therefore, will have the same effects on the targeted material and on non-targeted soft human tissue. *Id.* Moreover, there was ample motivation to at least try modifying the well-known electrode-generated sparking mechanism due to the long-known use of these mechanisms to break up concretions and calcified arterial lesions, to mitigate heat issues caused by laser as identified in Levy, and to reduce the cost of these systems. *Id.* Not surprisingly, substituting the shockwave generator using a laser with a shockwave generator using a pair of electrodes from known angioplasty catheter systems to provide the same and predictable result of generating shockwaves to remove stenotic lesions was well within the range of design choices brought by the experience and knowledge of the POSITA. *Id.*

B. Claim 1 is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff

[1a]. *An angioplasty catheter comprising:*

an elongated carrier sized to fit within a blood vessel, said carrier having a guidewire lumen extending therethrough

The '371 patent admits that the prior art discloses an angioplasty catheter having an elongated carrier sized to fit within a blood vessel and having a guidewire lumen therethrough. Ex. 1001, Fig. 1; 3:65-4:2 ("Fig. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter 10. Such catheters are usually non-compliant with a fixed maximum dimension when

expanded with a fluid such as saline."). Ex. 1002, 109. This typical prior art over-the-wire angioplasty balloon catheter is the same as disclosed in numerous references, including Healy and Hayes. Accordingly, for the sake of brevity, Petitioner refers to the typical prior art over-the-wire angioplasty balloon catheter described in the '371 patent and as disclosed in Healy and Hayes herein as "AAPA."

In addition, Levy discloses an angioplasty catheter that includes an elongated carrier sized to fit within a blood vessel. Ex. 1003, Fig 1 (catheter 8 with a longitudinal bore as inserted into blood vessel 2 in a location where a plaque deposit 4 has developed with balloon); p. 1 ("The present invention relates to the removal of deposits which form on the interior walls of passages, and in particular the removal, by disintegration, of plaque deposits, or atheromas, which form on the inner walls of the blood vessels."). It is known to POSITA that the catheter of Levy is an angioplasty catheter. Ex. 1002, 110-111.

Levy also discloses that the catheter 8 has an elongated bore that may serve as a guidewire lumen as the distal end of the catheter 8 is open. Ex. 1003, Fig. 1. In addition, the use of a guidewire to assist the physician to navigate the angioplasty catheter through tortuous passages to reach the area for treatment is known to POSITA. Ex. 1002, 112.

[1b] *an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon*

The AAPA discloses an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon. Ex. 1001, Fig. 1; 3:65-4:2 ("Fig. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter 10. Such catheters are usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline."). Ex. 1002, 113.

In addition, Levy discloses an angioplasty balloon located near a distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon. Ex. 1003, Fig 1 (angioplasty balloon 10 is connected with distal end 6 of catheter 8. The proximal end of the balloon defines an annular channel at the connection point with the catheter); p. 3 ("The balloon 10 may be of a type having a high degree of flexibility and need not produce significant expansion of the vessel 2.") The balloon 10 is inflated with a liquid supplied from supply source 22, so that the wall of the balloon 10 bears against the exposed surface of the deposit 4. *Id.*, Fig 1 and P. 4.

It is known to POSITA that the balloon of Levy is an angioplasty balloon. Ex. 1002, 114.

It would have been obvious to a POSITA to implement the AAPA with the angioplasty balloon described in Levy. The POSITA knows how to implement the angioplasty balloon in this way. This is routine design choice well within the skill and know-how of the POSITA. Moreover, by the time of the '371 patent, angioplasty balloon with guidewire lumens was the most common and widely used type of angioplasty catheter and balloon design being used in conjunction with balloon angioplasty procedure. It would have been obvious for the POSITA to have implemented and utilized the most common angioplasty catheter and balloon design, with predictable and expected results. Ex. 1002, 115.

[1c] *an arc generator including a pair of electrodes*

Levy discloses a laser 20 to generate laser beam pulses within the fluid filled balloon 10 which, in turn, "causes formation and cavitation of vapor within the liquid, resulting in the implosion of gas bubbles at the end of each laser pulse." The resulting energy "is transmitted to the wall of balloon 10 and thus to the regions of the deposit 4 in contact with the walls of the body 10, which causes disintegration of the deposit." As noted in Dr. Jensen's declaration (Ex. 1002), it is known to POSITA that this results in a shockwave and, therefore, the laser system comprises a shockwave generator. Ex. 1002, 116. Indeed, Levy refers to the '227

patent with respect to the use of the laser energy (Ex. 1003 at p. 3), which expressly describes the generation of "shockwave" produced by these radiation pulses. Ex. 1021, at 3:58-61 ("a shockwave produced by each radiation pulse propagates and terminates within a period of 50 nanoseconds and a pulse repetition rate of between 1 and 100 Hz can be suitably employed."). Ex. 1002, 116.

Levy does not explicitly teach a shockwave generator including a pair of electrodes, but does teach a shockwave generator including a laser source. Mantell discloses an arc generator including a pair of electrodes. Mantell discloses an elongated catheter 102 with a fluid-fillable balloon 118 attached to a distal end of the catheter 102, and first and second electrodes 104, 106 located within the balloon 118. Electrodes 104, 106 are adapted to generate an electrical arc between them, causing formation of a steam bubble in the balloon's liquid which contracts quickly, creating a shockwave in the liquid of the balloon that radiates away from the electrodes. Ex. 1004 at 0029. The electrodes are coupled with an electrohydraulic generator. *Id.* at 0024. Moreover, Mantell's catheter 102 may be threaded through veins or arteries to "address concretions". *Id.* at 0021; *see also* Fig. 1-2, 5-7. Thus the POSITA will understand Mantell's device is designed for treating intravascular plaque with balloon delivered shockwaves. Ex. 1002, 117.

Similar to Mantell, Uchiyama discloses an arc generator including a pair of electrodes. Uchiyama discloses a pair of electrodes (3) on a tube (8) wherein the

electrode pair (3) is disposed within a fluid-filled inflatable balloon (7). Ex. 1002, 118; Ex. 1005, p. 298 & Figs. 1-7. The inflated balloon (7) is placed in contact with the calcification and then a spark is generated between the electrodes (3) to generate a shockwave that is transmitted through the fluid of the inflated balloon and to the contacted targeted material to destroy calcification without damaging human tissue. *Id.*

Willneff is another alternative that has similar teachings as Mantell and Uchiyama. Willneff discloses a spark gap between two electrodes of an electrode pair in a balloon (18) arranged at the distal end of a catheter (12) that is capable of introduction into body cavities near the area of application of the shockwaves, wherein the balloon is expanded or inflated with a liquid. Ex. 1002, 119; Ex. 1006, pp. 5, 10 & Figs 1-3. The spark gap (16) is centered within the balloon (18) to avoid both mechanical damage or burning of tissue and the interior of the balloon is electrically conductive and connected to the shielding of the catheter. Ex. 1002, 119; Ex. 1006, pp. 5-6.

It would have been obvious to the POSITA to implement the shockwave generator comprising the pair of electrodes of Mantell or Uchiyama or Willneff to provide the shockwave generator in the angioplasty catheter described in Levy and/or as modified by the AAPA. The POSITA knows how to implement the pair of electrodes in this way. Ex. 1002, 120. The interchangeability of a laser source

and a pair of electrodes was known to the POSITA. *Id*. Indeed, the shockwave generator including a pair of electrodes disclosed in Mantell or Uchiyama or Willneff performs the same function (generating a shockwave) as in Levy in the same manner as Levy. *Id.* Moreover, as discussed by Dr. Jensen, the POSITA would have been motivated to seek a substitute for the shockwave generator of Levy for at least the reason that the complexities and expense of a laser source compared to a pair of electrodes to perform the same function in the same manner is less practical. *Id.* An additional motivation to seek a substitute shockwave generator is articulated in Levy, including inter alia, excessive heat generation requiring filling the balloon with coolant that may need to be cycled to remove the heat. POSITA would, therefore, be motivated based on Levy's teachings to seek a shockwave generator that generates less heat in the liquid of the balloon as the laser beam pulses and, therefore, may not require coolant and/or cycling of coolant during the procedure, conditions that the POSITA would consider potentially satisfied by electrode pair shockwave generators. *Id*.

[1d] *said electrodes being positioned within and in non-touching relation to the balloon*

In each of Levy, Mantell, Uchiyama or Willneff, the shockwave generator (laser source or electrodes) is positioned within the balloon and does not touch the

inflated balloon. Ex. 1003, Fig. 1; Ex. 1004, Fig. 1-2, 5-7; Ex. 1005, Fig. 1, 3-4, 6-7; Ex. 1006, pp. 5-6; Ex. 1002, 121.

[1e] *said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shockwave within the balloon that is conducted through the balloon and wherein the balloon is arranged to remain intact during the formation of the shockwave*

In each of Levy, Mantell, Uchiyama or Willneff the shockwave generator generates a high voltage pulse sufficient to create a plasma resulting in a mechanical shockwave within the balloon that is conducted through the balloon. Ex. 1002, 122. As previously discussed, both a laser source such as disclosed in Levy, and the pair of electrodes such as disclosed in Mantell, Uchiyama or Willneff, generate plasma when sufficient energy is supplied. In each case, the plasma causes formation of a steam bubble in the balloon's liquid which contracts (implodes) quickly, creating a shockwave that propagates through the liquid of the balloon radiating away from the shockwave generator. *Id*. The resulting shockwave in the liquid of the balloon radiating away from the shockwave generator whether induced by laser or electrode pairs, will transmit very rapidly – at or near the speed of sound – towards the balloon wall material and be conducted through the balloon wall material and into the calcified lesion and vessel wall. *Id.*

In addition, the angioplasty balloons of Levy and/or as modified by the AAPA remain intact and there is no disclosure or suggestion that the balloons are at risk of being breached during the formation of a shockwave. Ex. 1002, 123.

Accordingly, the combination of Levy with Mantell or Uchiyama or Willneff renders claim 1 obvious.

C. Claim 2 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff

[2] *The catheter of claim 1, wherein the pair of electrodes includes a pair of metallic electrodes.*

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

In addition, Mantell teaches that the electrodes may be metallic. Ex. 1004 at 0023. Further, the POSITA would recognize that the electrodes must comprise a conductive material and, therefore, metallic electrodes would be an obvious choice. Ex. 1002, 126.

D. Claim 3 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff

[3] *The catheter of claim 2, wherein the electrodes are radially displaced from each oth*er.

The references and arguments applied to claim 2 are incorporated here.

In addition, Mantell teaches that the electrodes are radially displaced from each other. Ex. 1004, Fig. 2 (electrode (106) is radially displaced from electrode

(104)); and Fig. 7 (illustrating a coaxial electrode pair (504, 506), wherein by definition the outer electrode (504) is radially displaced from the inner electrode (506)). Ex. 1002, 128.

E. Claim 4 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff

[4] *The catheter of claim 2, wherein the electrodes are longitudinally displaced from each other.*

The references and arguments applied to claim 2 are incorporated here.

Willneff discloses electrodes that are longitudinally displaced from each other. Ex. 1006, Fig. 1 (spark gap 16 arranged between two longitudinally displaced electrodes (not numbered elements) in operative communication with co-axial, flexible current supply (6)). Ex. 1002, 130.

F. Claim 5 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff

[5] *The catheter of claim 2, wherein the pair of electrodes is disposed adjacent to and outside of the guidewire lumen*.

The references and arguments applied to claim 2 are incorporated here.

Uchiyama further discloses a shockwave generator including a pair of electrodes (3) that are disposed radially spaced away from the lumen of tube (8). Ex. 1002, 132; Ex. 1005, Fig. 1, 3-4, and 6-7.

It would have been obvious to a POSITA to implement the features of Uchiyama to provide the pair of electrodes that are disposed radially spaced away from the lumen tube. Such an implementation is a routine design choice and well within the knowledge and know-how of the POSITA. Ex. 1002, 133.

G. Claim 6 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff

[6] *The catheter of claim 2, wherein the catheter has a distal end and wherein the pair of electrodes is disposed proximal to the distal end of the catheter.*

The references and arguments applied to claim 2 are incorporated here.

The pair of electrodes disclosed in Willneff are disposed proximal to the distal end of the catheter. Ex. 1005, Fig. 1 (showing spark gap (16) formed between two electrodes disposed proximal to the distal end of catheter (element 22)). Ex. 1002, 135.

It would have been obvious to a POSITA to implement the features of Willneff to provide the pair of electrodes that are disposed proximal to the distal end of the catheter. Such an implementation is a routine design choice and well within the knowledge and know-how of the POSITA. Ex. 1002, 136.

H. Claim 7 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff, and In Further View of Hayes.

[7] *The catheter of claim 1, wherein the balloon is formed of non-compliant material.*

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

Non-complaint angioplasty balloons are known to the POSITA. Ex. 1002, 137. In fact, the '371 patent admits that prior art angioplasty balloon catheters are "usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline." Ex. 1001, 3:65-4:2. In addition, Hayes also discloses non-complaint angioplasty balloons. Ex. 1007, 1:5-10 ("This invention is related to medical balloons, in particular non-compliant medical balloons used with a balloon catheter in medical procedures such as angioplasty."). The POSITA would readily recognize that the angioplasty balloon of Levy as modified by the AAPA can include the non-complaint angioplasty balloon of Hayes. Moreover, the POSITA knows how to implement the non-complaint angioplasty balloon in this way. Ex. 1002, 137.

I. Claim 8 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff, and In Further View of Duchamp

[8] *The catheter of claim 1, wherein the balloon is formed of compliant material.*

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

Angioplasty balloons formed of compliant materials are known to the POSITA. Ex. 1002, 138. For example, Duchamp discloses angioplasty balloons formed of compliant materials. Ex. 1008 at 0040 ("In one embodiment, the [angioplasty] balloon is formed from compliant material, compliant at least within a working range of the balloon, and which therefore provides for substantially uniform radial expansion within the working range."). The POSITA would readily recognize that the angioplasty balloon of Levy as modified by the AAPA can be substituted to include the complaint angioplasty balloon of Duchamp. Moreover, the POSITA knows how to implement the non-complaint angioplasty balloon in this way. *Id*.

J. Claim 9 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff, and In Further View of Naimark.

[9] *The catheter of claim 1, wherein the balloon has a surface, and wherein the catheter further comprises at least one stress riser carried on the surface of the balloon.*

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

Angioplasty balloons with stress risers carried on the surface of the balloon are known to the POSITA. Ex. 1002, 140. For example, Naimark discloses a shockwave generator adapted to produce a shockwave within a balloon having

raised structures in the form of microneedles (21, 31) carried on the balloon surface (302), rising above or outwardly away from the balloon surface. *See* Ex. 1008, Abstract; Figs 2 and 3. When inflated against a lumen, the microneedles (21, 31) will create stress points against the lumen wall and/or occlusion. Ex. 1002, 140 The POSITA would readily recognize that the angioplasty balloon of Levy as modified by AAPA can be substituted to include the angioplasty balloon of Naimark having microneedles. Moreover, the POSITA knows how to implement the non-complaint angioplasty balloon in this way. Ex. 1002, 140.

K. Claim 10 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff, and In Further View of Beyar.

[10] *The catheter of claim 1, further comprising a sensor that senses reflected energy.*

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

The use of a sensor with a shockwave created within a fluid-filled balloon is known to the POSITA. Ex. 1002, 142. For example, Beyar teaches a shockwave created within a fluid-filled balloon (*see* Ex. 1010 at 0192) and a pressure sensor (Ex. 1010 at 0243). *Id.*

L. Claim 11 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff.

[11] *The catheter of claim 1, further comprising a reflector within the balloon that focuses the shockwaves.*

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

Willneff discloses a wall 34 (the claimed "reflector") that reflects and focuses the shockwave. Ex. 1006, Fig. 2 and p. 10 ("Fig. 2 shows a spark gap 16 from a top view wherein the shock or pressure waves are reflected by a wall 34 in such a way that they come together outside of the balloon 18 at a focal point 36. Through the appropriate rotation of the shell 12, a focused shockwave can thus be brought to any desired point"). Ex. 1002, 144.

M. Claim 12 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff, and In Further View of Hayes, or Duchamp.

[12] *The catheter of claim 1, wherein the balloon electrically insulates the pair of electrodes from tissue external to the catheter.*

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

The POSITA knows that the balloon's material will generally be non-conductive and, therefore, insulating as to the electrodes therein. Ex. 1002, 146. For example, Uchiyama teaches that the inflatable body (the claimed "balloon") helps to regulate the explosive force to avoid damaging human tissue. Ex. 1005 at 2 ("With this sort of structure, the inflatable body regulates the spread of the explosive force of the explosive, so that it is possible to crush stones without damaging human tissue."); 3 ("With this sort of lithotripter, the discharge spark from by the pair of electrodes is generated inside the balloon 7, so there is no risk

that the discharge spark directly hitting human tissue."). Similarly, the listing of compliant and non-compliant materials in Duchamp (Ex. 1008) and Hayes (Ex. 1007) include non-conductive materials that would insulate the pair of electrodes from the tissue. Ex. 1002, 146.

N. Claim 13 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff, and In Further View of Bhatta.

[13] *The catheter of claim 1, wherein the pair of electrodes includes a first electrode and a second electrode, the second electrode being arranged to form an electrical arc with the first electrode to generate the mechanical shockwave and to reflect the mechanical shockwave in a desired pattern.*

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

Bhatta teaches a shockwave generator comprising an electrode and metallic nozzle (30). An electrical arc is formed between the electrode and the metallic nozzle, and the metallic nozzle focuses the shockwave. The metallic nozzle is a second electrode as it is connected to the energy source (44) and is part of the unit that generates the electrical arc. Moreover, the nozzle is utilized to reflect and focus the shockwave in a desired pattern. Ex. 1012, 3:17-25. Accordingly, it would have been obvious to the POSITA to have modified Levy in view of Mantell to include the use of a nozzle like that disclosed in Bhatta to also serve as a

second electrode and reflect and focus the mechanical shockwave in a desired pattern. Ex. 1002,148.

O. Claim 14 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff.

[14] *The catheter of claim 1, wherein the balloon has a center axis and the guidewire lumen has a center axis in common with the balloon center axis; and wherein at least one electrode of the electrode pair is disposed in non-intersecting relation with respect to the balloon center axis.*

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

Uchiyama discloses a balloon with a center of axis that is collinear with the guidewire lumen. As previously discussed above, the electrodes (3) of Uchiyama are disposed on the outside of the guidewire lumen and thus are in a non-intersecting relation with respect to the balloon center of axis. Ex. 1002, 150.

P. Claim 15 is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff.

[15a] A system comprising:

an angioplasty catheter including an elongated carrier sized to fit within a blood vessel, said carrier having a guidewire lumen extending therethrough

[15b] an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the

carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon

[15c] and an arc generator including a pair of electrodes

[15d] being positioned within and in non-touching relation to the balloon

[15e] *a power source configured to provide a high voltage pulse to the arc generator*, said high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shockwave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shockwave

Claim 15 is identical to Claim 1 in all material respects except for the addition of the "a power source configured to provide a high voltage pulse to the arc generator" shown in italics. Claim 1 implies that the arc generator includes a power source to provide a high voltage pulse, whereas Claim 15 separately includes a power source as a claim limitation. Accordingly, all of the arguments related to Claim 1 are equally applicable and are incorporated herein.

With respect the power source limitation, each of Levy, Mantell, Uchiyama or Willneff expressly disclose a power source that is configured to provide a high voltage pulse sufficient to create a plasma resulting in a mechanical shockwave within the balloon that is conducted through the balloon. Ex. 1003, Fig. 1 and p. 4 ("The proximal end of the fiber 12 is connected to a laser light source 20 capable

of producing laser beam pulses of a suitable duration and energy level."); Ex. 1004, 0024 ("As known in the art, the first conductive structure 112 may be coupled with an electrical source, such as electrohydraulic generator (Autolith, Supplied by Northgate Technologies Inc.), used to charge the first electrode 104 to a first polarity."); Ex. 1005, 299 ("high voltage is supplied to the pair of electrodes 3 and a discharge spark is generated between them. When this happens, the shock caused by the discharge spark is transmitted to the stone S through the medium of the fluid in the balloon 7, so said stone S is crushed as shown in Fig. 3(d)."); and Ex. 1006, 9 ("The electrical supply of the spark gap 16 takes place by means of the current feed 6."); *See also* Ex. 1002, 164.

Accordingly, the POSITA would have been motivated to include a power source that is configured to provide a high voltage pulse sufficient to create a plasma resulting in a mechanical shockwave. Ex. 1002, 164. Indeed, the generation of a shockwave is the purpose of these devices and would be inoperable without the power source. *Id*. It would have been obvious to a POSITA to configure a power source to provide sufficient high voltage pulse to the arc generator (i.e. the shockwave generator) so that a shockwave can be generated. *Id. T*he combination of Levy with Mantell or Uchiyama or Willneff renders claim 15 obvious.

Q. Claim 16 Is Obvious In View of Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff.

[16] *The system of claim 15, wherein the power source is arranged to provide high voltage pulses having at least one of selectable pulse durations, selectable voltage amplitudes, and selectable pulse repetition rates.*

The references and arguments applied to claim 15 are incorporated here.

Levy discloses that the power source is arranged to provide selectable durations, voltage amplitudes and pulse repetition rates. Ex. 1003 at p.3 ("As disclosed in US-A-5,166,227, the optical fiber 12 may have a diameter of the order of 150 μ, and the pulses of the radiation produced by the laser source 20 may have a pulse energy of the order 5-200mJ, higher energy levels preferably being used for larger diameter vessels, a pulse frequency of 30-100Hz and a pulse duration of 10 ns to a few ms.").[2] Ex. 1002, 168.

Mantell also discloses that the power source provides high voltage pulses having selectable voltage amplitudes (e.g. power level) and selectable pulse repetition rates (e.g. number of pulses). Ex. 1005 at 0051 and 0082. Ex. 1002, ¶169.

[2] The '227 patent incorporated in Levy also expressly describes the generation of "shockwave" produced by these radiation pulses. Ex. 1021, at 3:58-61 ("a shockwave produced by each radiation pulse propagates and terminates within a period of 50 nanoseconds and a pulse repetition rate of between 1 and 100 Hz can be suitably employed.").

Accordingly, it was well known to a POSITA that the power source is arranged to provide selectable durations, voltage amplitudes and pulse repetition rates.

R. Claim 17 Is Obvious In View of Levy as Modified by AAPA In Combination Mantell or Uchiyama or Willneff, And In Further View of Schultheiss

[17] *The system of claim 15, further comprising an R wave detector that synchronizes the mechanical shockwaves with a cardiac R waves.*

The references and arguments applied to claim 15 are incorporated here.

Schultheiss discloses a shockwave applicator and an R wave detector that synchronizes the mechanical shockwaves with cardiac waves. Ex. 1011 at 0072. Ex. 1002, 171. It would have been obvious to a POSITA to have used an R-wave detector that synchronizes the shockwaves with the cardiac R-waves of the patient in order to avoid a fibrillation in the patient. *Id.* Moreover, implementing an R-wave detector in this manner is well known to the POSITA with reasonable expectations of success using well known techniques. *Id.*

VI. ALTERNATIVE GROUNDS THAT CLAIMS 1-17 OF THE '371 PATENT ARE UNPATENTABLE

A. Claim 1 is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell

[1a]. *An angioplasty catheter comprising:*

an elongated carrier sized to fit within a blood vessel, said carrier having a guidewire lumen extending therethrough

Willneff discloses a spark gap between two electrodes of an electrode pair in a balloon (18) arranged at the distal end of a catheter (12) that is capable of introduction into body cavities near the area of application of the shockwaves, wherein the balloon is expanded or inflated with a liquid. Ex. 1002, 172; Ex. 1006, pp. 5, 10 & Figs 1-3. Willneff may not expressly disclose that the device is used within a blood vessel as part of an angioplasty catheter.

The AAPA discloses an angioplasty catheter having an elongated carrier sized to fit within a blood vessel and having a guidewire lumen therethrough. Ex. 1001, Fig. 1; 3:65-4:2 ("Fig. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter 10. Such catheters are usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline."). Ex. 1002, 173.

It would have been obvious to the POSITA to implement the angioplasty catheter of the AAPA to the shockwave generator system of Willneff and would have been motivated to use the AAPA angioplasty catheter because of the improved safety and efficacy and because it was well established as the standard and conventionally used in the overwhelming majority of angioplasty procedures. Ex. 1002, 82. It was also known to the POSITA that a shockwave generator could be implemented with known angioplasty catheter systems, including placing the shockwave generator (e.g. the pair of electrodes) within an angioplasty balloon.

Ex. 1002, 174. For example, Levy discloses an angioplasty catheter with a shockwave generator located within a balloon that is used for "the removal of deposits which form on the interior walls of passages, and in particular the removal, by disintegration, of plaque deposits, or atheromas, which form on the inner walls of the blood vessels." Ex. 1003, Fig 1 and p. 1 ("The present invention relates to the removal of deposits which form on the interior walls of passages, and in particular the removal, by disintegration, of plaque deposits, or atheromas, which form on the inner walls of the blood vessels."). Similarly, Mantell also discloses an angioplasty catheter with a shockwave generator located within a balloon that "may be threaded through appropriate veins or arteries to address concretions either forming in vessels or even in the valves of the heart or other organs." Ex. 1004, Figs. 1-6, and 0021. Moreover, the POSITA knows how to implement the pair of electrodes in this way. Ex. 1002, 174.

[1b] *an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon*

The AAPA discloses an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid

therein that inflates the balloon. Ex. 1001, Fig. 1; 3:65-4:2 ("Fig. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter 10. Such catheters are usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline."). Ex. 1002, 175.

[1c] *an arc generator including a pair of electrodes*

Willneff discloses a spark gap between two electrodes of an electrode pair in a balloon (18) arranged at the distal end of a catheter (12) that is capable of introduction into body cavities near the area of application of the shockwaves, wherein the balloon is expanded or inflated with a liquid. Ex. 1002, 176; Ex. 1006, pp. 5, 10 & Figs 1-3. The spark gap (16) is centered within the balloon (18) to avoid both mechanical damage or burning of tissue and the interior of the balloon is electrically conductive and connected to the shielding of the catheter. Ex. 1002, 176; Ex. 1006, pp. 5-6.

It would have been obvious to the POSITA to implement the shockwave generator comprising the pair of electrodes of Willneff to provide the shockwave generator in the angioplasty catheter of the admitted prior art. Indeed, it was known to the POSITA that a shockwave generator could be implemented with known angioplasty catheter systems, including placing the shockwave generator (e.g. the pair of electrodes) within an angioplasty balloon. For example, Levy discloses an angioplasty catheter with a shockwave generator located within a

balloon that is used for "the removal of deposits which form on the interior walls of passages, and in particular the removal, by disintegration, of plaque deposits, or atheromas, which form on the inner walls of the blood vessels." Ex. 1003, Fig 1 and p. 1 ("The present invention relates to the removal of deposits which form on the interior walls of passages, and in particular the removal, by disintegration, of plaque deposits, or atheromas, which form on the inner walls of the blood vessels."). Similarly, Mantell also discloses an angioplasty catheter with a shockwave generator located within a balloon that "may be threaded through appropriate veins or arteries to address concretions either forming in vessels or even in the valves of the heart or other organs." Ex. 1004, Figs. 1-6, and 0021. Moreover, the POSITA knows how to implement the pair of electrodes in this way. Ex. 1002, 177.

[1d] *said electrodes being positioned within and in non-touching relation to the balloon*

The shockwave generator (a pair of electrodes) of Willneff are positioned within the balloon and does not touch the inflated balloon. Ex. 1006, pp. 5-6. Ex. 1002, 178.

[1e] *said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shockwave*

within the balloon that is conducted through the balloon and wherein the balloon is arranged to remain intact during the formation of the shockwave

In Willneff, the shockwave generator generates a high voltage pulse sufficient to create a plasma resulting in a mechanical shockwave within the balloon that is conducted through the balloon. Ex. 1002, 179. As previously discussed, the pair of electrodes such as disclosed in Willneff generate plasma when sufficient energy is supplied. In each case, the plasma causes formation of a steam bubble in the balloon's liquid which contracts (implodes) quickly, creating a shockwave that propagates through the liquid of the balloon radiating away from the shockwave generator. *Id*. Moreover, as discussed in Dr. Jensen's report, the resulting shockwave in the liquid of the balloon radiating away from the shockwave generator will transmit very rapidly – at or near the speed of sound – towards the balloon wall material and be conducted through the balloon wall material and into the calcified lesion and vessel wall. *Id*.

In addition, the angioplasty balloons of the AAPA remain intact in all cases and there is no disclosure or suggestion that the balloons are at risk of being breached during the formation of a shockwave. Ex. 1002, 180.

Accordingly, the combination of Willneff with the admitted prior art and in further view of Levy or Mantell renders claim 1 obvious.

B. Claim 2 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell

[2] *The catheter of claim 1, wherein the pair of electrodes includes a pair of metallic electrodes.*

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

In addition, Mantell teaches that the electrodes may be metallic. Ex. 1004 at 0023. The POSITA would recognize that the electrodes must comprise a conductive material and, therefore, metallic electrodes would be an obvious choice. Ex. 1002, 183.

C. Claim 3 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell.

[3] *The catheter of claim 2, wherein the electrodes are radially displaced from each oth*er.

The references and arguments applied to claim 2 are incorporated here.

In addition, Mantell teaches that the electrodes are radially displaced from each other. Ex. 1004, Fig. 2 (electrode (106) is radially displaced from electrode (104)); and Fig. 7 (illustrating a coaxial electrode pair (504, 506), wherein by definition the outer electrode (504) is radially displaced from the inner electrode (506)). Ex. 1002, 185.

D. Claim 4 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell.

[4] *The catheter of claim 2, wherein the electrodes are longitudinally displaced from each other.*

The references and arguments applied to claim 2 are incorporated here.

Willneff discloses a shockwave generator including a pair of electrodes that are longitudinally displaced from each other. Ex. 1006, Figs 2 and 3; p. 5 ("[A] shock wave generator for diagnostic or therapeutic applications that can be introduced through body orifices and can be brought close to body parts or calculi that need to be subjected to shock waves. . . ."); Fig. 1 (spark gap 16 arranged between two longitudinally displaced electrodes (not numbered elements) in operative communication with co-axial, flexible current supply (6)). Ex. 1002, 187.

E. Claim 5 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Uchiyama

[5] *The catheter of claim 2, wherein the pair of electrodes is disposed adjacent to and outside of the guidewire lumen*.

The references and arguments applied to claim 2 are incorporated here.

Uchiyama further discloses a shockwave generator including a pair of electrodes (3) that are disposed radially spaced away from the lumen of tube (8). Ex. 1002, 189; Ex. 1005, Fig. 1, 3-4, and 6-7.

It would have been obvious to a POSITA to implement the features of Uchiyama to provide the pair of electrodes that are disposed radially spaced away from the lumen tube. Such an implementation is a routine design choice and well within the knowledge and know-how of the POSITA. Ex. 1002, 190.

F. Claim 6 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell.

[6] *The catheter of claim 2, wherein the catheter has a distal end and wherein the pair of electrodes is disposed proximal to the distal end of the catheter.*

The references and arguments applied to claim 2 are incorporated here.

The pair of electrodes disclosed in Willneff are disposed proximal to the distal end of the catheter. Ex. 1005, Fig. 1 (showing spark gap (16) formed between two electrodes disposed proximal to the distal end of catheter (element 22)). Ex. 1002, 192.

G. Claim 7 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Hayes.

[7] *The catheter of claim 1, wherein the balloon is formed of non-compliant material.*

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

Non-complaint angioplasty balloons are known to the POSITA. Ex. 1002, 194. In fact, the '371 patent admits that prior art angioplasty balloon catheters are

"usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline." Ex. 1001, 3:65-4:2. In addition, Hayes also discloses non-complaint angioplasty balloons. Ex. 1007, 1:5-10 ("This invention is related to medical balloons, in particular non-compliant medical balloons used with a balloon catheter in medical procedures such as angioplasty."). The POSITA would readily recognize that the angioplasty balloon of Levy as modified by the admitted prior art can include the non-complaint angioplasty balloon of Hayes. Moreover, the POSITA knows how to implement the non-complaint angioplasty balloon in this way. Ex. 1002, 194.

H. Claim 8 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Duchamp.

[8] *The catheter of claim 1, wherein the balloon is formed of compliant material.*

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

Angioplasty balloons formed of compliant materials are known to the POSITA. Ex. 1002, 196. For example, Duchamp discloses angioplasty balloons formed of compliant materials. Ex. 1008 at 0040 ("In one embodiment, the [angioplasty] balloon is formed from compliant material, compliant at least within a working range of the balloon, and which therefore provides for substantially uniform radial expansion within the working range."). The POSITA would readily recognize that the angioplasty balloon of Levy as modified by the admitted prior

art can be substituted to include the complaint angioplasty balloon of Duchamp. Moreover, the POSITA knows how to implement the non-complaint angioplasty balloon in this way. Ex. 1002, 196.

I. Claim 9 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Naimark.

[9] *The catheter of claim 1, wherein the balloon has a surface, and wherein the catheter further comprises at least one stress riser carried on the surface of the balloon.*

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

Angioplasty balloons with stress riser carried on the surface of the balloon are known to the POSITA. Ex. 1002, 198. For example, Naimark discloses a shockwave generator adapted to produce a shockwave within a balloon having microneedles (21, 31) carried on the balloon surface (302) and rising above or outwardly away from the balloon surface. *See* Ex. 1008, Abstract; Figs 2 and 3. When inflated against a lumen, the microneedles (21, 31) will create stress points against the lumen wall and/or occlusion. Ex. 1002, 198. The POSITA would readily recognize that the angioplasty balloon of Levy as modified by the admitted prior art can be substituted to include the angioplasty balloon of Naimark having microneedles. Moreover, the POSITA knows how to implement the non-complaint angioplasty balloon in this way. *Id*.

J. Claim 10 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Beyar.

[10] *The catheter of claim 1, further comprising a sensor that senses reflected energy.*

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

The use of a sensor with a shockwave created within a fluid-filled balloon is known to the POSITA. Ex. 1002, 200. For example, Beyar teaches a shockwave created within a fluid-filled balloon (*see* Ex. 1010 at 0192) and a pressure sensor (Ex. 1010 at 0243). *Id*.

K. Claim 11 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell.

[11] *The catheter of claim 1, further comprising a reflector within the balloon that focuses the shockwaves.*

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

Willneff discloses a wall 34 (the claimed "reflector") that reflects and focuses the shockwave. Ex. 1006, Fig. 2 and p. 10 ("Fig. 2 shows a spark gap 16 from a top view wherein the shock or pressure waves are reflected by a wall 34 in such a way that they come together outside of the balloon 18 at a focal point 36. Through the appropriate rotation of the shell 12, a focused shock wave can thus be brought to any desired point."). Ex. 1002, 202.

L. Claim 12 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Hayes or Duchamp.

[12] *The catheter of claim 1, wherein the balloon electrically insulates the pair of electrodes from tissue external to the catheter.*

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

The POSITA knows that the balloon's material will generally be non-conductive and, therefore, insulating as to the electrodes therein. Ex. 1002, 204. For example, Willneff teaches that the balloon helps to prevent the electrodes from damaging human tissue by preventing the electrodes from touching and electrically insulating the electrodes from the human tissue. Ex. 1006 at 5 ("The invention [at hand] forms the basis for providing a shock wave generator for diagnostic or therapeutic applications, which can be inserted through body openings and brought into the vicinity of the body part or concretion to which the shock waves are to be applied, and yet the spark gap does not touch the body tissue and is also electrically isolated from it. As per this invention, this task is achieved in that the spark gap is located in a balloon, which is positioned at the end of a catheter; and in that the catheter can be inserted into body cavities, wherein the balloon is dilated by a liquid at the site of the application of shock waves."). Similarly, the listing of compliant and non-compliant materials in Duchamp (Ex. 1008) and Hayes (Ex. 1007) include non-conductive materials that would insulate the pair of electrodes from the tissue. Ex. 1002, 204.

M. Claim 13 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Bhatta.

[13] *The catheter of claim 1, wherein the pair of electrodes includes a first electrode and a second electrode, the second electrode being arranged to form an electrical arc with the first electrode to generate the mechanical shockwave and to reflect the mechanical shockwave in a desired pattern.*

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

Bhatta teaches a shockwave generator comprising an electrode and metallic nozzle (30). An electrical arc is formed between the electrode and the metallic nozzle, and the metallic nozzle focuses the shockwave. The metallic nozzle is a second electrode as it is connected to the energy source (44) and is part of the unit that generates the electrical arc. Moreover, the nozzle is utilized to reflect and focus the shockwave in a desired pattern. Ex. 1012, 3:17-25. Accordingly, it would have been obvious to the POSITA to have modified Levy in view of Mantell to include the use of a nozzle like that disclosed in Bhatta to also serve as a second electrode and reflect and focus the mechanical shockwave in a desired pattern. Ex. 1002, 206.

N. Claim 14 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Uchiyama.

[14] *The catheter of claim 1, wherein the balloon has a center axis and the guidewire lumen has a center axis in common with the balloon center axis;*

and wherein at least one electrode of the electrode pair is disposed in non-intersecting relation with respect to the balloon center axis.

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

Uchiyama discloses a balloon with a center of axis that is collinear with the guidewire lumen. As previously discussed above, the electrodes (3) of Uchiyama are disposed on the outside of the guidewire lumen and thus are in a non-intersecting relation with respect to the balloon center of axis. Ex. 1002, 208.

O. Claim 15 is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell.

[15a] A system comprising:

an angioplasty catheter including an elongated carrier sized to fit within a blood vessel, said carrier having a guidewire lumen extending therethrough

[15b] an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon

[15c] and an arc generator including a pair of electrodes

[15d] being positioned within and in non-touching relation to the balloon

[15e] *a power source configured to provide a high voltage pulse to the arc generator*, said high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shockwave within the balloon that is

conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shockwave

Claim 15 is identical to Claim 1 in all material respects except for the addition of the "a power source configured to provide a high voltage pulse to the arc generator" shown in italics. Claim 1 implies that the arc generator includes a power source to provide a high voltage pulse, whereas Claim 15 separately includes a power source as a claim limitation. Accordingly, all of the arguments related to Claim 1 are equally applicable and are incorporated herein.

With respect the power source limitation, each of Willneff, Levy, and Mantell expressly disclose a power source that is configured to provide a high voltage pulse sufficient to create a plasma resulting in a mechanical shockwave within the balloon that is conducted through the balloon. Ex. 1003, Fig. 1 and p. 4 ("The proximal end of the fiber 12 is connected to a laser light source 20 capable of producing laser beam pulses of a suitable duration and energy level."); Ex. 1004, 0024 ("As known in the art, the first conductive structure 112 may be coupled with an electrical source, such as electrohydraulic generator (Autolith, Supplied by Northgate Technologies Inc.), used to charge the first electrode 104 to a first polarity."); and Ex. 1006, 9 ("The electrical supply of the spark gap 16 takes place by means of the current feed 6."); *See also* Ex. 1002, 164.

In addition, in Willneff, the shockwave generator generates a high voltage pulse sufficient to create a plasma resulting in a mechanical shockwave within the balloon that is conducted through the balloon. Ex. 1002, 216 As previously discussed, the pair of electrodes such as disclosed in Willneff generate plasma when sufficient energy is supplied. In each case, the plasma causes formation of a steam bubble in the balloon's liquid which contracts (implodes) quickly, creating a shockwave that propagates through the liquid of the balloon radiating away from the shockwave generator. Ex. 1002 at ¶ 218. Moreover, as discussed in Dr. Jensen's report, the resulting shockwave in the liquid of the balloon radiating away from the shockwave generator will transmit very rapidly – at or near the speed of sound – towards the balloon wall material and be conducted through the balloon wall material and into the calcified lesion and vessel wall. Ex. 1002 at ¶ 218.

Accordingly, the combination of Willneff with the AAPA and in further view of Levy or Mantell renders claim 15 obvious.

P. Claim 16 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell.

[16] *The system of claim 15, wherein the power source is arranged to provide high voltage pulses having at least one of selectable pulse durations, selectable voltage amplitudes, and selectable pulse repetition rates.*

The references and arguments applied to claim 15 are incorporated here.

Mantell also discloses that the power source provides high voltage pulses having selectable voltage amplitudes (e.g. power level) and selectable pulse repetition rates (e.g. number of pulses). Ex. 1005 at 0051 and 0082. Ex. 1002, 220.

Q. Claim 17 Is Obvious In View of Willneff as Modified by AAPA In Combination With Levy or Mantell, and Schultheiss.

[17] *The system of claim 15, further comprising an R wave detector that synchronizes the mechanical shockwaves with a cardiac R waves.*

The references and arguments applied to claim 15 are incorporated here.

Schultheiss discloses a shockwave applicator and an R wave detector that synchronizes the mechanical shockwaves with cardiac waves. Ex. 1024 at 0072.

VII. CONCLUSION

For the foregoing reasons, claims 1-17 of the '371 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: December 7, 2018

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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. 8,956,371, all supporting exhibits (Exhibits 1001 through 1047), and the Power of Attorney were served on December 7, 2018 via Priority Mail Express® or equivalent, and are being served by personal hand delivery, 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. 8,956,371 Under 35 U.S.C. § 312 AND 37 C.F.R. § 42.104 totals 13,964, and within the 14,000 words allowed under 37 C.F.R. §42.24(a)(1)(i).

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