

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

In re *Inter Partes Review* of:)
)
U.S. Patent No. 9,642,673 B2)
)
Issued: May 9, 2017) Attorney Docket No. 68890-286962
)
Inventors: John Adams, et al.)
)
Application No. 13/534,658)
)
Filed: June 27, 2012)
) FILED ELECTRONICALLY
For: SHOCKWAVE BALLOON) PER 37 C.F.R. § 42.6(b)(1)
CATHETER WITH MULTIPLE)
SHOCKWAVE SOURCES)

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PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,642,673
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 1-20 of U.S. Patent No. 9,642,673 B2 (“the ‘673 patent,” attached as Petition Exhibit 1001), now purportedly assigned to Shockwave Medical, Inc.

An electronic payment in the amount of \$33,500.00 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 \$18,000.00 post-institution fee—is

being paid at the time of filing this petition. If there are any additional fees due in connection with the filing of this paper, please charge the required fees to our deposit account no. 505196.

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LIST OF EXHIBITS

Exhibit 1001:	U.S. Patent No. 9,642,673
Exhibit 1002	Declaration of Morten O. Jensen
Exhibit 1003	U.S. Patent Appl. Publ. No. U.S. 2009/0312768
Exhibit 1004	U.S. Patent Appl. Publ. No. U.S. 2010/0114020
Exhibit 1005	U.S. Patent No. 7,850,685
Exhibit 1006	U.S. Patent Appl. Publ. No. U.S. 2005/0251131
Exhibit 1007	U.S. Patent 5,454,809
Exhibit 1008	File History for U.S. Patent No. 9,642,673
Exhibit 1009	U.S. Patent Appl. No. 61/061,170
Exhibit 1010	German Patent Application, DE 3038445 A1
Exhibit 1011	EP 0571306
Exhibit 1012	U.S. Patent No. 5,152,768
Exhibit 1013	Millman J, Grabel A. Microelectronics Second Edition International Edition: McGraw-Hill, Inc. International Editions; 1987. 1001 p.
Exhibit 1014	Tomlinson GH. Electrical Networks and Filters: Theory and Design: Prentice Hall; 1991. 320 p.
Exhibit 1015	Johnson DE, Johnson JR, Hilburn JL. Electric Circuit Analysis - Second Edition: Prentice-Hall International Editions; 1992. 779 p.
Exhibit 1016	Jacob JM. Applications and Design with Analog Integrated Circuits - Second Edition: Prentice-Hall International Editions; 1993. 575 p.
Exhibit 1017	U.S. Patent No. 4,445,509
Exhibit 1018	U.S. Patent No. 4,990,134

- Exhibit 1019 U.S. Patent No. 5,584,843
- Exhibit 1020 U.S. Patent No. 6,132,444
- Exhibit 1021 U.S. Patent No. 6,494,890
- Exhibit 1022 U.S. Patent No. 8,353,923
- Exhibit 1023 U.S. Patent No. 8,177,801
- Exhibit 1024 U.S. Patent No. 5,116,227
- Exhibit 1025 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 1026 Nisonson I, Witus WS, Madorsky ML, Weems WS. Ambulatory extracorporeal shockwave lithotripsy. *Urology*. 1986;28(5):381-4.
- Exhibit 1027 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 1028 Grocela JA, Dretler SP. Intracorporeal lithotripsy. Instrumentation and development. *Urol Clin North Am*. 1997;24(1):13-23.
- Exhibit 1029 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 1030 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 1031 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 1032 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 1033 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 1034 Fung YC. *Biomechanics - Mechanical Properties of Living Tissues*: Springer; 1993.
- Exhibit 1035 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 1036 Athanasoulis CA. Percutaneous transluminal angioplasty: general principles. *AJR Am J Roentgenol*. 1980;135(5):893-900.
- Exhibit 1037 Simpson JB, Baim DS, Robert EW, Harrison DC. A new catheter system for coronary angioplasty. *Am J Cardiol*. 1982;49(5):1216-22.
- Exhibit 1038 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 1039 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 1040 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 Ther.* 2005;12(2):233-9.
- Exhibit 1041 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 1042 Achim M. Loske, Ph.D., Shock Wave Physics for Urologists (2007)
- Exhibit 1043 Wakerly JF. *Digital Design: Principles and Practices*: Prentice-Hall, Inc.; 1990. 716 p.

I. PRELIMINARY STATEMENT

The '673 patent claims an angioplasty catheter system with multiple shockwave sources. One of the inventors of the '673 patent was also the inventor in two U.S. Patent Applications that published more than one year prior to the effective date of the '673 patent teaching an angioplasty catheter systems with a shockwave generator, including one publication disclosing the use of multiple shockwave sources. *See* Hawkins '768 (Ex. 1003); Hawkins '020 (Ex. 1004). Not surprisingly, nearly every claim limitation of the '673 patent is expressly disclosed in those prior publications. In fact, the examiner correctly rejected the claims multiple times primarily relying on Hawkins '020. The primary claim limitation argued by the applicant as rendering the claims patentably distinct from Hawkins '020 is "creating a series connection running from the first electrode in the first electrode pair to the second electrode of the second pair." Throughout the prosecution, however, the examiner correctly and consistently rejected the applicant's arguments. Recognizing that the examiner was not going to be persuaded by their arguments, the applicant finally amended the claims to add the limitation "wherein one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair." Surprisingly, without any discussion or analysis of new limitation, the examiner allowed the claims. The examiner simply did not fully appreciate that the prior art also expressly disclosed

electrodes having different relative surface areas. For example, Hawkins ‘768 discloses that one electrode can be shaped and act as a parabolic reflector. The parabolic reflector/electrode has a greater surface area than the other electrode of the pair. This relative size limitation, however, was disclosed in the prior art and accordingly, none of the claims of the ‘673 patent should have been allowed. In addition, other prior art references make clear that the basic concept claimed by the ‘673 patent, namely a device having multiple shockwave generators within a balloon configured to produce shockwaves that can treat calcium deposits in blood vessels and heart valves is not new and obvious to a person of ordinary skill in the art at the time of the alleged invention of the ‘673 patent (a “POSITA”). As discussed in greater detail herein, all 20 claims of the ‘673 patent are obvious over the combination of Hawkins ‘020 and Hawkins ‘768 and Kunis.

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

III. RELIEF REQUESTED

Petitioner requests institution of an *inter partes* review and cancellation of claims 1-20, as unpatentable under 35 U.S.C. § 103.

IV. OVERVIEW OF CHALLENGES

A. Identification of Challenges

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1-20 of the '673 patent (Ex. 1001) as unpatentable in view of the following patents and printed publications:

1. Hawkins, et al., U.S. Patent Appl. Publ. No. U.S. 2009/0312768, "Shockwave Balloon Catheter System" published December 17, 2009 ("Hawkins '768") (Ex. 1003).
2. Hawkins, et al., U.S. Patent Appl. Publ. No. U.S. 2010/0114020, "Shockwave Valvuloplasty Catheter System," published May 6, 2010 ("Hawkins '020") (Ex. 1004).
3. Kunis, et al., U.S. Patent No. 7,850,685, "Ablation Catheter," filed June 20, 2006 ("Kunis") (Ex. 1005).
4. Lesh, Michael D., U.S. Patent Appl. Publ. No. 2005/0251131, "Circumferential Ablation Device Assembly," published November 10, 2005 ("Lesh") (Ex. 1006).

According to their issuance or publication, each of Hawkins '768, Hawkins '020, Kunis and Lesh¹ is prior art under 35 U.S.C. § 102(b) as being patented or

¹ Unlike Hawkins '768 and Hawkins '020, Kunis and Lesh are directed to ablation devices. Ablation devices are from the same field of endeavor as the claimed invention. Both the claimed invention and ablation devices are minimally invasive

published more than one year before the presumed effective filing date of the ‘673 patent (i.e., before the presumed effective filing date of June 27, 2012).

Kunis was not cited by the examiner. Hawkins ‘768 was cited by the examiner, but was not applied by the Office during prosecution of the ‘673 patent. Although Hawkins ‘020 and Lesh were previously applied by the examiner, the Office has not previously considered these references or applied them 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 presents testimony from Dr. Morten Jensen (Ex. 1002) establishing that all of the limitations recited in the challenged claims would have been obvious to a POSITA in consideration of these prior art references.

tools used to treat atherosclerosis, or build up upon and within vessel walls and body passages, among other abnormalities. Ex. 1001, 1:5-2:34; Ex. 1005, 1:20-30; Ex. 1006, 0002; Ex. 1007, 1:15-25; 3:25-29. Moreover, ablation devices are reasonably pertinent to the problem faced by the inventor, for example, treating areas that are often much wider and/or longer than what can be effectively covered by one electrode. Ex. 1002, ¶ 82; Ex. 1005, 2:43-46; 5:14-18; 6:20-32; Ex. 1006, 0038-0039; Ex. 1007, 3:25-49. Ablation devices have long been adapted to utilized multiple electrode pairs to cover the elongated treatment area to provide a more effective and efficient treatment. *Id.* These devices provide some solutions to common problems faced by the inventors, including using series and parallel circuits to connect multiple electrodes. *See, e.g.*, Ex. 1005, Fig. 17b; 5:18-37; 25:38-42; 25:59-67. Not surprisingly, the examiner relied on references directed to ablation devices during prosecution, and the ‘673 patent includes U.S. Classification for “AB61B 18/1492” which are directed to ablation devices such as Kunis and Lesh. Accordingly, ablation devices are analogous art to the claimed invention.

Ground	Reference(s)	Challenged Claims
1	§ 103 Hawkins '020 and in further view of Hawkins '768 and Kunis	1, 2, 5-8, 15, 16, 19, 20
2	§ 103 Hawkins '020 and in further view of Hawkins '768, Kunis and Lesh	3, 4, 9-14, 17, 18

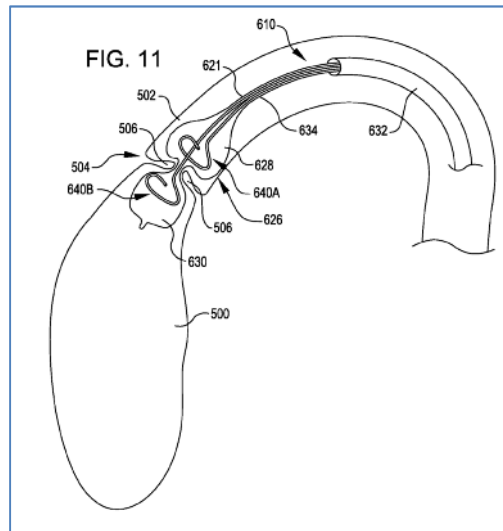
B. There is a Reasonable Likelihood that at least One Claim of the '673 Patent is Unpatentable under 35 U.S.C. § 103

The '673 patent is directed to a wholly conventional angioplasty catheter to treat calcified plaque in blood vessels using a shockwave. *See, e.g.*, '673 patent at Title; Abstract; 1:40-45 (Ex. 1001); Ex. 1008 at p. 466 (“The subject invention relates to a device that can be used to treat calcified plaque in arteries.”), p. 368 (“The subject invention relates [to] a device for treating calcified lesions in the vascular system of a patient.”).

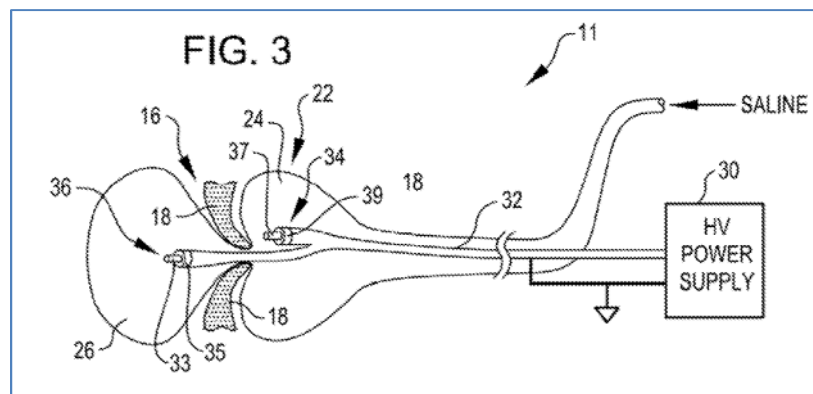
In the described embodiment, a shockwave generator defined by a plurality of electrode pairs is positioned within a conventional fluid filled angioplasty balloon system. Ex. 1001, Abstract, 2:41-52; Ex. 1008, p. 466. When high voltage pulses are applied to the shockwave generator, the flow of current across the electrode pairs within the fluid result in the generation of a shockwave that can crack calcified plaque. *Id.*

Using a shockwave generator within a fluid filled angioplasty balloon to generate shockwaves directed at calcified plaque was not new. Indeed, more than one year prior to the effective filing date of the '673 patent, two of the three inventors of Hawkins '768 disclosed in U.S. Patent Appl. Publ. US 2010/0114020

(Ex. 1004) (“Hawkins ‘020”) a shockwave balloon catheter system using a plurality of shockwave generators defined by a plurality of electrode pairs within a fluid filled balloon to generate shockwaves directed at calcified plaque. A comparison of exemplary figures from the ‘673 patent and Hawkins ‘020 is shown in the following:



‘673 Patent, Fig. 11.



Hawkins ‘020, Fig. 3.

Although the '673 patent shares a common inventor to Hawkins '020, the '673 patent does not add anything new or inventive to its claims. Each and every claim limitation was known to the POSITA, and disclosed in prior art publications more than one year prior to the effective filing date of the '673 patent. Indeed, as set forth in more detail below, and as supported by the Declaration of Dr. Morten Jensen, an Associate Professor of Biomedical Engineering at the University of Arkansas ("Jensen Decl.") (Ex. 1002), the cited patents and printed publications establish a reasonable likelihood that Petitioner will prevail with at least one of the challenged claims. *See* 35 U.S.C. § 314(a).

V. THE '673 PATENT

A. Overview of the '673 Patent

The '673 patent is directed to an angioplasty catheter to treat calcified plaque in blood vessels using a shockwave. *See, e.g.*, '673 patent at Title; Abstract; 1:40-45 (Ex. 1001); Ex. 1008 at p. 466 ("The subject invention relates to a device that can be used to treat calcified plaque in arteries."), p. 368 ("The subject invention relates [to] a device for treating calcified lesions in the vascular system of a patient.").

As the background section of the '673 patent recognizes, the buildup of calcium deposits on the aortic valve and within blood vessels, known as calcification, can lead to thickening and narrowing of the valve or blood vessel

leading to cardiac disease. Ex. 1001, 1:5-2:38. One treatment for calcification is placement of a balloon adjacent to the treatment area and inflated with a fluid.

Within the balloon is a shockwave generator that produces shockwaves that propagate through the fluid and the balloon to disrupt the calcification. *Id.* at 1:64-2:8. A known problem with this shockwave treatment is that the intensity of the shockwave on the area to be treated diminishes as a function of distance from the point of shockwave origination to the treatment point. *Id.* at 2:17-34.

In view of this, the '673 patent suggests to improve the effectiveness of the treatment, it would be desirable to minimize the distance between the shockwave origination point and the point of treatment. *Id.* The '673 patent accomplishes this by distributing a plurality of shockwave generators within the balloon. Ex. 1001, 2:41-53. By distributing a plurality of shockwave generators within the balloon, longitudinally and circumferentially, the distance from the point of a shockwave origination and the calcified lesion to be treated can be minimized.

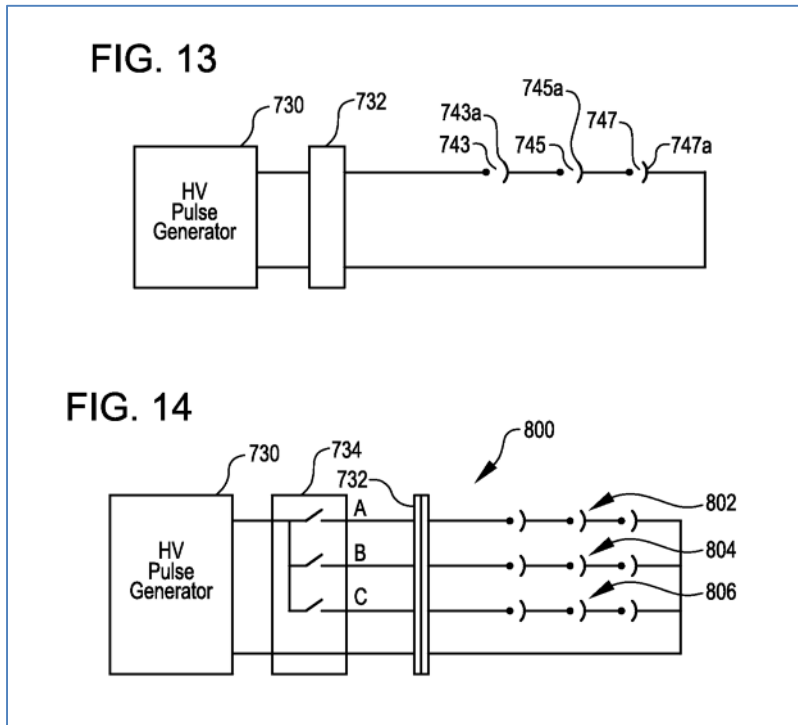
Importantly, the problem identified by the '673 patent was known to those skilled in the art. It has long been known that the intensity of the shockwave is reduced inversely as the square of its distance from the source. Ex. 1042, p. 44 (“Since the energy emitted from a point source spreads out in all directions its intensity reduces significantly with distance. The intensity of any wave is proportional to the square of the amplitude. For spherical waves, the amplitude

varies as the wavefront travels (see Figure 14). Due to this, the wave intensity is reduced inversely as the square of its distance from the source.”). It is also known that plaque buildup within the vessels are elongated. Ex. 1002, ¶ 82; Ex. 1005, 2:43-46; 5:14-18; 6:20-32; Ex. 1006, 0038-0039; Ex. 1007, 3:25-49. Accordingly, the intensity of the shockwave originating from a single shockwave generator may vary across an elongated treatment area. Ex. 1002, ¶ 82. This is a similar problem that was faced by ablation devices where a single electrode is not capable of treating the entire treatment area without the need to reposition the ablation device. Accordingly, it has been known that utilizing multiple electrodes to cover the entire size or length of the target area is an obvious solution to more efficiently and effectively treat these elongated lesions. Ex. 1002, ¶ 82; Ex. 1005 – 1007.

B. Prosecution History

The application that issued as the ‘673 patent was filed on June 27, 2012. The ‘673 patent does not claim priority to any prior application. The initial application was filed with 45 claims. Ex. 1008, p. 1769-1778. Claims 1-45 were cancelled and replaced with new claims 46-62 by Preliminary Amendment filed April 30, 2015. Ex. 1008, pp. 659-662. On August 18, 2015, the examiner issued an office action with a restriction and/or election requirement. Ex. 1008, pp. 588-593. The restriction and/or election requirement identified that the pending claims

appeared to be directed to patentably distinct species as embodied by figures 13 and 14. Ex. 1008, p. 590.



The difference between the embodiments of Figures 13 and 14 is that the plurality of electrode pairs in Figure 13 are serially connected, whereas in Figure 14 groups of serially connected electrode pairs are also connected by a parallel connection. On October 16, 2015, the applicant responded to the restriction and/or election requirement electing to prosecute the claims that read on the embodiments of Figure 14. Ex. 1008, pp. 466-467. Notably, the applicant argued that “Figure 14 includes the series connected electrodes of Figure 13. Thus, Species B (Figure

14) includes all of the subject matter that is disclosed in Figure 13.” Ex. 1008, p. 467.

On March 11, 2016, the examiner rejected all pending claims based on nonstatutory double patenting and an obviousness rejection based primarily on Hawkins ‘020. As the examiner correctly recognized, Hawkins ‘020 expressly taught “an axially extending elongate member, a balloon surrounding a portion of the elongate member, said balloon fillable with a conductive fluid, a first electrode pair having first and second spaced apart electrodes and a second electrode pair having first and second spaced apart electrodes, said electrode pairs being located within and spaced from the balloon, wherein the electrode pairs are configured to produce shockwaves that propagate through the liquid while the balloon remains intact, and a high voltage source connectable to the first electrode of first electrode pair, and with the second electrode of first electrode pair being connected to the first electrode of the second electrode pair, and with the second electrode of the second electrode pair being connectable to the high voltage source, and wherein when a high voltage pulse is supplied to the first and second electrode pairs, a first arc is generated in conductive fluid allowing current to flow across the first electrode pairs, a first arc is generated in the conductive fluid allowing current to flow across the first electrode pair and a second arc is generated in the conductive

fluid allowing current to flow across the second electrode pair.” Ex. 1008, pp. 390 – 391.

The examiner also acknowledged that Hawkins ‘020 taught that the two pairs of electrodes are connected in such a way that it can be synchronized to concurrently impinge upon both sides of the leaflets [heart valve]. Ex. 1008, p. 391. Accordingly, although the examiner did not believe that Hawkins ‘020 explicitly teach the electrodes connected in series or parallel, the examiner correctly recognized that it would have been obvious to one of ordinary skill in the art at the time of the invention to try a series or parallel connection between the two pairs of electrodes since they are the two of the well-known methods of connecting adjacent and commonly driven electrode pairs in synchrony. *Id.* Moreover, the examiner correctly noted that “such a modification would be functionally equivalent design choice and obvious to try since there are only two fundamental ways for analogue connections, namely series or parallel.” *Id.* at p. 392.

In response to the March 11, 2016 Office Action, the applicant amended each independent claim to recite “said electrode pairs being mounted on the elongate member and within the conductive fluid.” Ex. 1008, pp. 364-367. Notably, the applicant did not dispute the examiner’s application of Hawkins ‘020 as teaching all claim limitations except how the electrode pairs are connected.

With respect to how the electrode pairs are connected, the applicant argued that Hawkins '020 teaches away from a series connection because according to the applicant, Hawkins '020 does not say that the electrode pairs should be fired at the same time, but rather the structure of Hawkins '020 would require firing the electrodes at different times requiring different circuits to connect to the high voltage supply. In addition, the applicant offered an alternative, unsupported theory, that one skilled in the art would not connect the electrodes in series because of potential shunting concerns from the first electrode in the first pair to the second electrode in the second pair reducing the available energy for generating a shockwave. Ex. 1008, p. 370. Finally, the applicant argued that the electrodes of Hawkins '020 are mounted on separate members, spaced apart in two different balloon chambers. *Id.*

The examiner again rejected all of the pending claims maintaining the previously rejections based primarily on Hawkins '020 in the Final Office Action dated August 23, 2016. Ex. 1008, pp. 334-343. The examiner was not persuaded by any of the applicant's argument concerning why one of ordinary skill in the art would not connect the electrode pairs in series. *Id.* at pp. 336-338. Moreover, the examiner correctly noted that Hawkins '020 leaves open how the electrodes should be connected, and one of ordinary skill in the art would know that "there are limited well-known options for linking and controlling electrodes (series, parallel)"

and thus it would have been a design choice and obvious to try a series connection based on the design preferences of the operator. *Id.* at pp. 336-337. The examiner also correctly recognized that the applicant's amended limitation "said electrode pairs being mounted on the elongate member and within the conductive fluid" is still taught by Hawkins '020. *Id.* at p. 337-338 ("Hawkins still teaches the amended limitation of "said electrode pairs being mounted on the elongate member and within the conductive fluid" (see fig. 3, the electrode can be considered the stub and item 34 which is mounted on the elongate member 32)" . . . and that the different balloon chambers of fig. 3 are still the same balloon, and the electrode 34 can be considered the assembly that includes the stub.).

On November 15, 2016, the applicant filed a Request for Continued Examination (Ex. 1008, p. 317), and cancelled claims 60-62 and amended all pending independent claims to add the claim limitation "and wherein one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair." Ex. 1008, p. 321-325. While the applicant indicated continued disagreement with the examiner concerning whether a series connection would have been obvious, the applicant added the new claim limitation to overcome the obviousness rejection. Ex. 1008, p. 326 – 327. Notably, the applicant again did not contest whether Hawkins '020 discloses all of the other limitations of the pending claims.

With the November 15, 2016 amendment, the examiner allowed the claims.

Ex. 1008, p. 31-34. The Notice of Allowance addressed a couple of examiner's amendments; however, no statement concerning the reasons for allowance was provided. The '673 patent then issued on May 9, 2017.

C. Claim Construction

A claim term is given its “ordinary and customary meaning as understood by a POSITA 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”).

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, ¶¶ 19.

Petitioner believes that the all of the terms and phrases from the claims of the '673 patent are well understood to a POSITA. Accordingly, it is not necessary to provide a construction for the claims of the '673 patent as the ordinary and customary meaning as understood by a POSITA when read in the context of the specification and prosecution history are sufficiently clear.

VI. CLAIMS 1-20 OF THE '673 PATENT ARE UNPATENTABLE

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

A. There Is Nothing New About A Shockwave Balloon Catheter With Multiple Shockwave Sources

Atherosclerosis is characterized by the buildup of fatty deposits in blood vessels. Over time, the fatty deposits harden into calcified atherosclerotic plaque. The plaque deposit restricts the flow of blood and is often referred to as stenotic lesions or stenoses and the blocking materials as stenotic material. The clogging of the arteries with plaque is a cause of coronary heart disease or vascular disease. Ex. 1002 at ¶ 23.

A variety of techniques and medical devices have been developed to remove or shrink the stenotic material. In the mid-1960's, Dr. Charles Dotter pioneered

angioplasty and the catheter delivered stent to treat peripheral arterial disease. By the mid-1980's a common approach to treating atherosclerosis was using balloon angioplasty. Balloon angioplasty involves using a guiding catheter placed in the peripheral artery and passing a balloon catheter through the guiding catheter 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 at ¶¶24-25.

Another known device and method for clearing an occlusion in blood vessels was using shockwaves. 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. 1043).

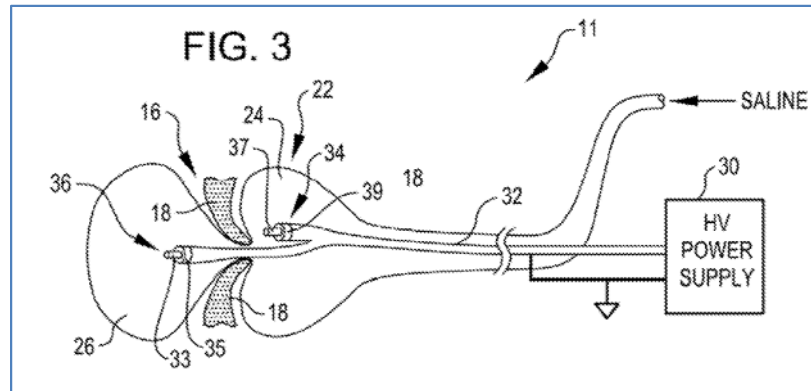
Pulsed laser energy was used for removing plaque deposits in blood vessels. *See, e.g.*, Ex. 1009, '227 patent, 2:31-34; Fig. 3 (illustrating insertion of the hollow catheter 7 with optical fibre 3 within tube 7). The '227 patent discloses positioning an optical fiber lens a short distance from the plaque 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 plaque material. *See* '227 3: 31-61 (discussing shockwave generation and the resulting disintegrating effects on targeted material). Accordingly, by at least the

early 1990's, a POSITA knew that using shockwaves produced within a blood vessel may be used to disrupt plaque deposits located within the blood vessel.

More than two years before the effective filing date of the '673 patent, Hawkins '768 disclosed an angioplasty catheter system for generating a shockwave within an angioplasty balloon to remove or reduce calcified stenotic lesions in blood vessels. *See, e.g.*, Ex. 1003, Title; 0003. In the described embodiment, a shockwave generator defined by 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 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. Hawkins '768 also discloses that one of the electrodes of the electrode pairs may be a parabolic reflector (Ex. 1003, Fig. 15 (114), 0064 "a parabolic reflector 114 acting as one electrode inside a fluid filled compliant balloon 116. The other electrode 112 is located at the coaxial center of the reflector 114." The reflector/electrode 114 has a different surface area than the other electrode 112.

At about the same time as Hawkins '768, two of the three inventors of Hawkins '768 disclosed in Hawkins '020, more than one year before the effective filing date of the '673 patent, a shockwave balloon catheter system using a

plurality of shockwave generators defined by a plurality of electrode pairs within a fluid filled balloon to generate shockwaves directed at calcified plaque.



Hawkins '020, Fig. 3.

Hawkins '020 teaches an axially extending elongate member (23), a balloon surrounding a portion of the elongate member (24), said balloon fillable with a conductive fluid (Ex. 1004, Abstract “The balloon is inflatable with a liquid”, 0027 “The chambers 24 and 26 are inflated with saline/contrast mixture, for example”), a first electrode pair (36) having first and second spaced apart electrodes (33 and 35) and a second electrode pair (34) having first and second spaced apart electrodes (37 and 39), said electrode pairs being located within and spaced from the balloon (fig. 3), wherein the electrode pairs are configured to produce shockwaves that propagate through the liquid (Ex. 1004, 0027 “Each chamber 24 and 26 may contain an electrode (as shall be seen subsequently) that can produce electrical arcs to deliver timed shockwaves. The shockwaves can be synchronized to concurrently impinge upon both sides of the leaflets to maximize the

effectiveness of breaking calcium deposits.”), and a high voltage source (30) connectable to the first electrode of first electrode pair (36), and with the second electrode of first electrode pair (36) being connected to the first electrode of the second electrode pair (34), and with the second electrode of the second electrode pair (34) being connectable to the high voltage source (30), and wherein when a high voltage pulse is supplied to the first and second electrode pairs, a first arc is generated in conductive fluid allowing current to flow across the first electrode pairs, a first arc is generated in the conductive fluid allowing current to flow across the first electrode pair and a second arc is generated in the conductive fluid allowing current to flow across the second electrode pair (Ex. 1004 at 0012, 0013, and 0027).

Accordingly, for more than a year prior to the effective filing date of the ‘673 patent, the prior art disclosed a shockwave balloon catheter system using a plurality of shockwave generators defined by a plurality of electrode pairs within a fluid filled balloon to generate shockwaves directed at calcified plaque. Indeed, as discussed earlier, the prosecution history confirmed that each and every claim limitation of the independent claims of the ‘673 patent is expressly disclosed in Hawkins ‘020, except the serial connection and the relative surface area limitations. The examiner correctly understood that connecting the plurality of electrodes using a serial connection would have been obvious to one of ordinary

skill in the art. Indeed, it was well known that there are two methods of connecting adjacent and commonly driven electrode pairs in synchrony, series and parallel. The examiner, however, did not fully appreciate that the prior art also expressly disclosed electrodes having different relative surface areas. For example, as discussed above, Hawkins '768 discloses that one electrode can be shaped and act as a parabolic reflector. The parabolic reflector/electrode has a greater surface area than the other electrode of the pair. In addition, Hawkins '020 discloses that its electrodes pairs are coaxial with the center conductor 33 and outer conductive shield 35. One of ordinary skill in the art would have known and readily appreciate that the relative surface area of the outer conductive shield is different than the surface area of the center conductor. Moreover, the exact size, shape and relative surface area of the reflector or the coaxial conductors are design choices that may be modified without altering the function of generating a shockwave. Not surprisingly, utilizing a serial connection and different relative surface areas for the electrodes in a pair 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. Ex. 1002 at ¶ 53-64, 72-74.

B. Claim 1 is Obvious In View of Hawkins '020 and In Further View of Hawkins '768 and Kunis

Independent claim 1 recites:

[1a] A device comprising:

an axially extending elongate member

[1b] a balloon surrounding a portion of the elongate member, said balloon being fillable with a conductive fluid

[1c] a first electrode pair having first and second spaced apart electrodes and a second electrode pair having first and second spaced apart electrodes

[1d] said electrode pairs being located within and spaced from the balloon, said electrode pairs being mounted on the elongate member and within the conductive fluid and wherein the electrode pairs are configured to produce shock waves that propagate through the liquid

[1e] *and wherein one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair*

[1f] and a high voltage source connectable to the first electrode of first electrode pair and with the second electrode of first electrode pair being connected to the first electrode of the second electrode pair, and with the second electrode of the second electrode pair being connectable to the high voltage source

[1g] and wherein when a high voltage pulse is supplied to the first and second electrode pairs, a first arc is generated in the conductive fluid allowing current to flow across the first electrode pair and a second arc is

generated in the conductive fluid allowing current to flow across the second electrode pair, *thereby creating a series connection running from the first electrode in the first electrode pair to the second electrode of the second pair*

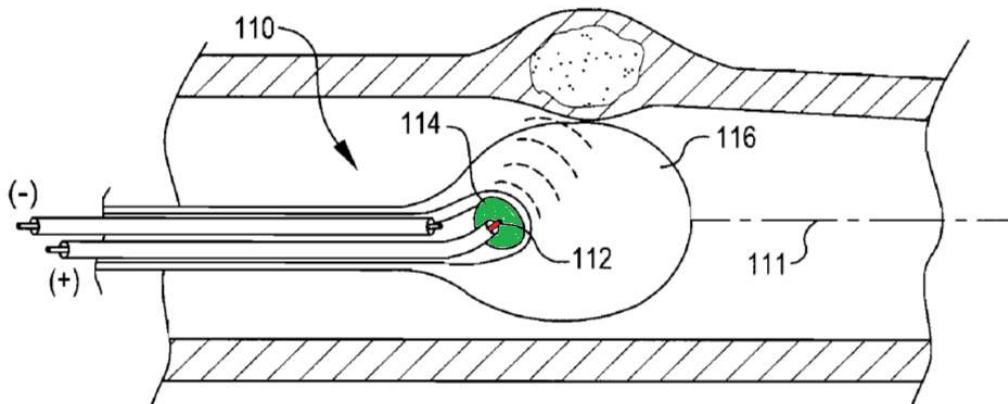
(Emphasis added). As previously discussed, and as shown in the claim chart below, Hawkins '020 expressly discloses the non-italicized portion of claim 1. With respect to the italicized portions, the combination of Hawkins '020 and Hawkins '768 discloses the claim limitation “*one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair*” and Hawkins '020 in combination with the skill and background knowledge possessed by a person having ordinary skill in the art discloses the claim limitation “*creating a series connection running from the first electrode in the first electrode pair to the second electrode of the second pair.*”

- 1. The combination of Hawkins '020 and Hawkins '768 discloses the claim limitation “one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair.”**

This relative surface area limitation was added by amendment to overcome a prior art rejection. Nothing in the prosecution history suggests that the examiner appreciated or understood that the prior art already expressly disclosed this limitation. Indeed, after the amendment adding this limitation, the prosecution history is silent with respect to this limitation, and the claim was allowed.

Regardless, the prior art expressly discloses this limitation. In particular, Hawkins '768 discloses an electrode pair having different relative surface areas. Hawkins '768 discloses that one of the electrodes of the electrode pairs may be a parabolic reflector (Ex. 1003, Fig. 15 (114), 0064 "a parabolic reflector 114 acting as one electrode inside a fluid filled compliant balloon 116. The other electrode 112 is located at the coaxial center of the reflector 114."

FIG. 15



It is readily apparent that the reflector/electrode 114 (shown in green) has a different surface area than the other electrode 112 (shown in red). Moreover, because the electrode pair in Hawkins '768 (Ex. 1003, Fig. 15, 114, 112) are coaxial, similar to the coaxial electrode pairs of Hawkins '020 (Ex. 1004, Fig. 3, 37, 39 and 33, 35), one of ordinary skill in the art would have known that these electrodes were interchangeable design choice and would have the skill and

background knowledge to modify the electrode of Hawkins '020 with the electrode of Hawkins '768 to provide for the relative surface area limitation.²

2. The combination of Hawkins '020 and Kunis along with the background knowledge of a POSITA discloses the claim limitation “creating a series connection running from the first electrode in the first electrode pair to the second electrode of the second pair.”

As previously discussed and recognized during the prosecution of the '673 patent, although Hawkins '020 expressly discloses that the plurality of electrode pairs are connected to the high voltage power supply, Hawkins '020 may not expressly disclose whether the electrodes are connected in series or parallel. Hawkins '020 teaches that the electrodes are connected in a manner to produce timed shockwaves and can be synchronized to concurrently impinge upon both sides of the leaflets to maximize the effectiveness of breaking the calcium deposit. Ex. 1004, 0027 (“Each chamber 24 and 26 may contain an electrode (as shall be seen subsequently) that can produce electrical arcs to deliver timed shockwaves. The shockwaves can be synchronized to concurrently impinge upon both sides of the leaflets to maximize the effectiveness of breaking calcium deposits.”) In view of the schematic of Figure 3, with two pairs of electrodes connected to a single

² It should be noted that Hawkins '768, which is based on application Ser. No. 61/061,170 (Ex. 1003) was incorporated by reference in Hawkins '020. *See* Ex. 1003, 0028 (“High voltage pulses from power supply 30 are applied to the electrode pairs 34 and 36 in a manner as described in the aforementioned application Ser. No. 61/061,170 to create shockwaves within the fluid within the chambers 24 and 26 of the balloon 22.”)

power source, it would have been obvious to a POSITA to try either a series or parallel connection between the two pairs of electrodes. Ex. 1002 at 53-64, 76-79. Indeed, series and parallel connections are the two known methods for connecting adjacent and commonly driven electrode pairs. Ex. 1002 at 53-64, 76.

Accordingly, utilizing a serial connection to connect the electrode pairs to a common power source to provide the same and predictable result of synchronizing the generation of shockwaves to concurrently impinge on the calcium deposit was well within the range of design choices brought by the experience and knowledge of the POSITA. Ex. 1002 at ¶ 53-64, 76.

In addition, a POSITA would have been motivated to utilize (or at least consider) a series connection. It is well understood to the skilled artisan that there is a desire to minimize the diameter of intravascular devices to allow for the device to be able to navigate the tortuous blood vessels to reach the area of treatment. Ex. 1002 at ¶ 58. In fact, this was the same problem that applicant identified during prosecution as the reason for using a series connection. Ex. 1008 at p. 466 (“The subject invention is related to approaches for increasing the number of electrode pairs located in the balloon while minimizing the number of conductors that must run between the high voltage pulse generator and the electrode pairs. As can be appreciated, the most basic design would require two conductors for each pairs. However, as the number of conductors is increased, the stiffness of the catheter is

also increased, making it difficult to steer the catheter to the desired location in the vasculature. One approach to address this problem is illustrated in Figure 12 with the equivalent electrical circuit shown in Figure 13. This embodiment includes three electrode pairs, essentially connected in series.”³ This problem and solution has been known to the POSITA for many years prior to the effective filing date of the ‘673 patent and is a primary design consideration for intravascular medical devices, together with minimizing cross-sectional profile. For example, Kunis taught an ablation catheter arranged for intravascular translation, having multiple electrodes mounted on the catheter in wired communication with an external power source. Ex. 1005, Fig. 17b; 5:18-37. Kunis also taught that the multiple electrodes “can be electrically connected in parallel, in series, individually, or combinations thereof.” Ex. 1005, 25:38-42. One reason for selecting either parallel or series connections to connect multiple electrodes is to control the bulk and stiffness of the catheter due to the number of wires. Ex. 1005, 25:59-67 (“In configurations with large number of electrodes, individual pairs of wires for each electrode may be

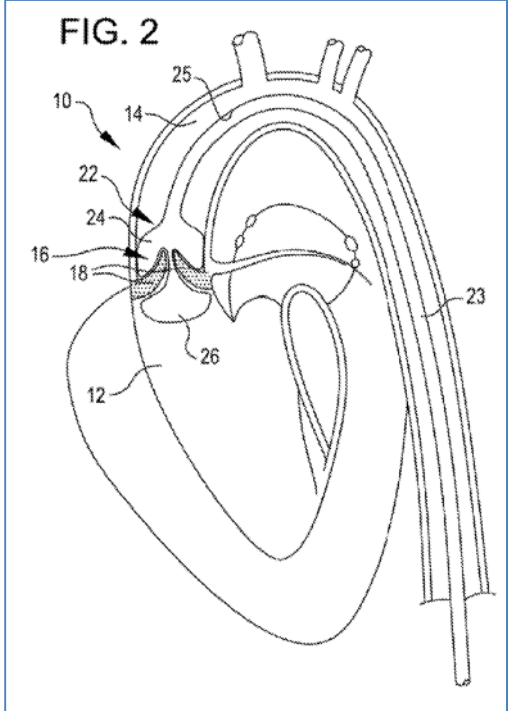
³ The ‘673 patent specification does not identify this problem or suggest series connection as this solution. In fact, the ‘673 patent specification is silent as to providing a preference for series, parallel or combination. Instead, the ‘673 patent specification indicates that the electrode pairs could be arranged in series or in parallel or a combination. Ex. 1001, 4:1-10. In addition, the ‘673 patent provides multiple embodiments of the invention including parallel connection (*e.g.* Fig. 8), series connection (*e.g.* Fig. 13) and combination (*e.g.* Fig. 14), and leaves it to the design choice of the POSITA to decide which type of circuitry is appropriate for a given device.

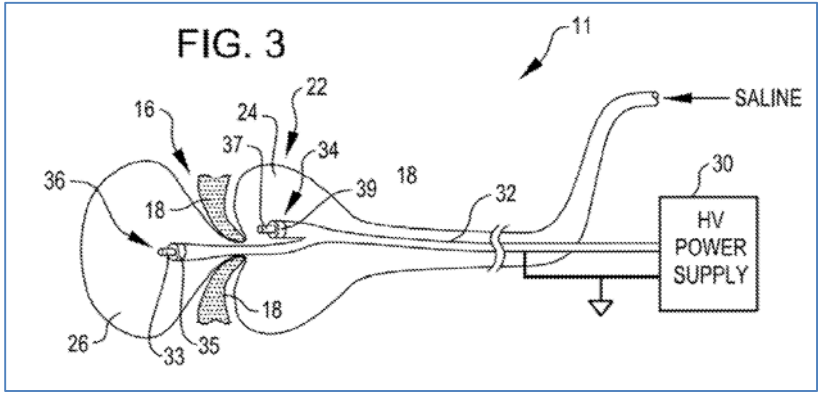
bulky and compromise the cross-sectional profile of the ablation catheter. In an alternative embodiment, one or more electrodes, connected in series fashion such that a reduced number of wires, such as two wires, can be attached to two or more electrodes, include switching means such that while a first electrode is powered, the remaining electrodes do not transmit ablative energy.”) Accordingly, applying the teachings of Kunis, utilizing a series connection would have been an obvious design choice for the POSITA to minimize the bulk and cross-sectional profile, as well as minimizing the stiffness, of the intravascular device. Using a series connection was a known solution to address the known problems associated with connecting multiple electrodes for intravascular devices. Moreover, there is nothing in the specification setting forth any reason why the series connection of the claims would result in a different function and unexpected result.

It would have been obvious to a POSITA to implement the features of Hawkins ‘768 and Kunis and utilized the background knowledge of one of ordinary skill in the art to provide the serial connection and relative surface area limitations to the shockwave balloon catheter with multiple shockwave sources system described by Hawkins ‘020. One of ordinary skill in the art would have readily known how to implement the serial connection and differential relative surface areas for the electrodes in this manner as discussed above. Ex. 1002 at 79. In view of these teachings and the rationales provided above, the combination of

Hawkins '020 with Hawkins '768 and Kunis, along with the background

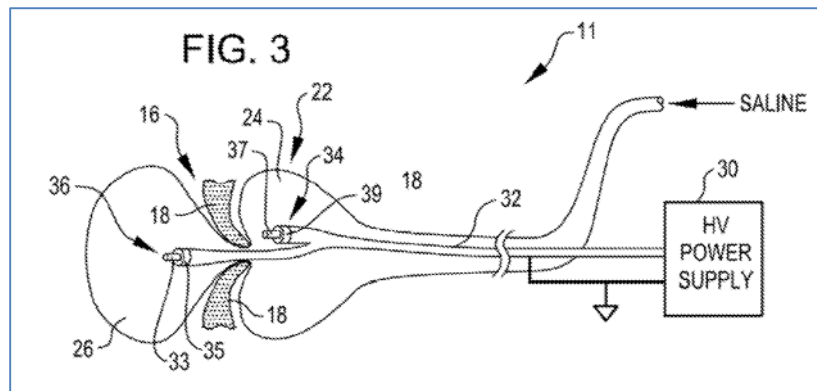
knowledge of the POSITA renders claim 1 obvious.

Claim	Exemplary Disclosures of Hawkins '020 and Hawkins '768
<p>[1a]. A device comprising: an axially extending elongate member</p>	<p>Hawkins discloses an axially extending elongate member. Hawkins Fig. 2:</p>  <p>“The system may further comprise an elongated tube.” Fig. 2, element 23; 0027 “The balloon, as seen in Fig. 2, is at the distal end of an elongated tube 23.”</p>
<p>[1b] a balloon surrounding a</p>	<p>Hawkins '020 teaches a balloon (22) surrounding a portion of the elongate member (23), said balloon (22) fillable with</p>

<p>portion of the elongate member, said balloon being fillable with a conductive fluid</p>	<p>a conductive fluid (Ex. 1004, Abstract “The balloon is inflatable with a liquid”, 0027 “The chambers 24 and 26 are inflated with saline/contrast mixture, for example”). <i>See also</i>, Hawkins ‘020 Fig. 3:</p> 
<p>[1c] a first electrode pair having first and second spaced apart electrodes and a second electrode pair having first and second spaced apart electrodes</p>	<p>Hawkins ‘020 teaches a first electrode pair (36) having first and second spaced apart electrodes (33 and 35) and a second electrode pair (34) having first and second spaced apart electrodes (37 and 39).</p>
<p>[1d] said electrode</p>	<p>Hawkins ‘020 teaches that said electrode pairs being located</p>

pairs being located within and spaced from the balloon, said electrode pairs being mounted on the elongate member and within the conductive fluid and wherein the electrode pairs are configured to produce shock waves that propagate through the liquid

within and spaced from the balloon (fig. 3):

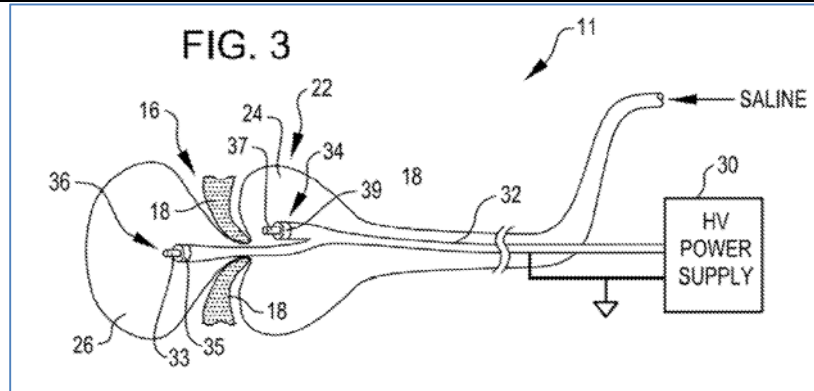


wherein the electrode pairs are configured to produce shockwaves that propagate through the liquid (Ex. 1004, 0027 “Each chamber 24 and 26 may contain an electrode (as shall be seen subsequently) that can produce electrical arcs to deliver timed shockwaves. The shockwaves can be synchronized to concurrently impinge upon both sides of the leaflets to maximize the effectiveness of breaking calcium deposits.”); Abstract “The balloon is inflatable with a liquid”; 0027 “The chambers 24 and 26 are inflated with saline/contrast mixture, for example”.

[1e] and wherein one electrode in each pair has a

Hawkins ‘020 discloses that one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair. For example, Fig. 3:

surface area larger
 than the surface area
 of the other
 electrode in the pair

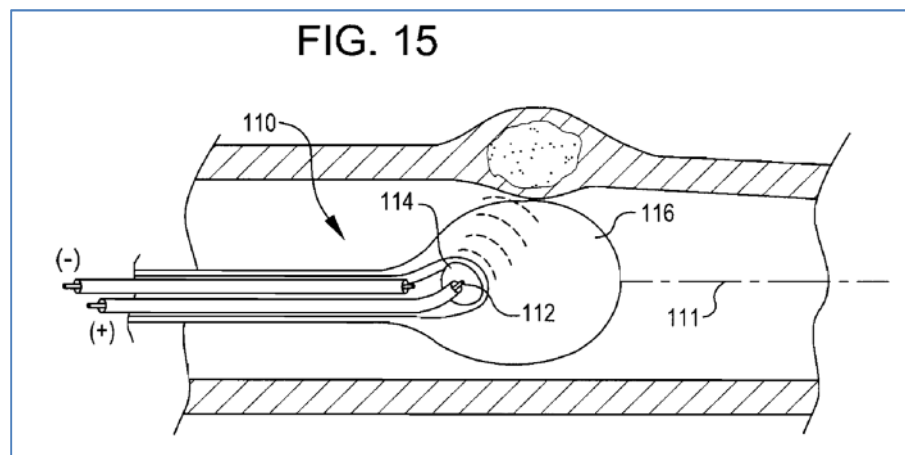


“electrode pair 36 is at the distal end of a first cable and comprises a center conductor 33 and an outer conductive shield 35. Similarly, electrode pair 36 is at the distal end of a second cable and comprises a center conductor 33 and an outer conductive shield 35.” Ex. 1004, 0028. Moreover, Hawkins ‘020 discloses high voltage catheters with the electrode pairs arranged coaxially. The outer conductive shields are insulated from the inner conductors. That insulation causes a certain distance to exist between the outer surface of the center (/inner) conductors and the inner surface of the outer conductive shields. Since the area of these surfaces increase with the distance from the center of the catheter, the center conductors and outer conductive shields will necessarily have different surface areas. In

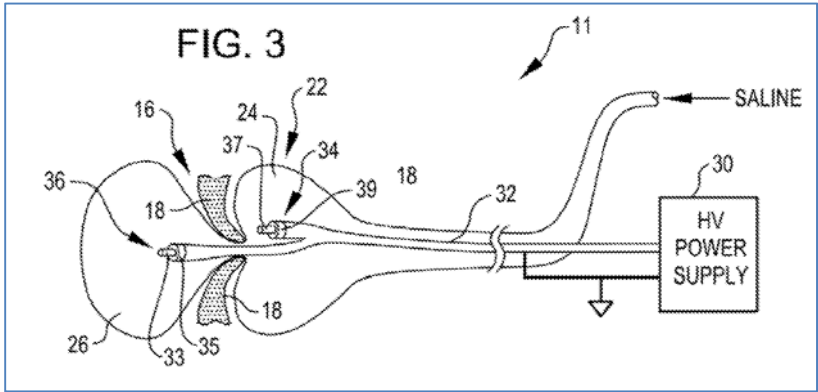
other words, the inner areas of the outer conductive shields must be larger than the outer areas of the center conductors.

Ex. 1002 at ¶71.

To the extent that Hawkins '020 does not expressly teach this limitation, Hawkins '768 does teach that one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair. *See* Fig. 15, 114 and 112.



Hawkins '768 discloses that one of the electrodes of the electrode pairs may be a parabolic reflector (Ex. 1003, Fig. 15 (114), 0064 “a parabolic reflector 114 acting as one electrode inside a fluid filled compliant balloon 116. The other electrode 112 is located at the coaxial center of the reflector 114.). It is readily apparent that the

	<p>reflector/electrode 114 has a different surface area than the other electrode 112. Ex. 1002 at ¶ 72-73.</p>
<p>[1f] and a high voltage source connectable to the first electrode of first electrode pair and with the second electrode of first electrode pair being connected to the first electrode of the second electrode pair, and with the second electrode of the second electrode pair being connectable to the high voltage source</p>	<p>Hawkins '020 discloses a high voltage source (30) connectable to the first electrode of first electrode pair (36), and with the second electrode of first electrode pair (36) being connected to the first electrode of the second electrode pair (34), and with the second electrode of the second electrode pair (34) being connectable to the high voltage source (30). <i>See, e.g.,</i> Ex. 1004, Fig. 3:</p>  <p>FIG. 3</p>
<p>[1g] and wherein</p>	<p>Hawkins '020 discloses that when a high voltage pulse is</p>

<p>when a high voltage pulse is supplied to the first and second electrode pairs, a first arc is generated in the conductive fluid allowing current to flow across the first electrode pair and a second arc is generated in the conductive fluid allowing current to flow across the second electrode pair, thereby creating a series connection running from the first</p>	<p>supplied to the first and second electrode pairs, a first arc is generated in conductive fluid allowing current to flow across the first electrode pairs, a first arc is generated in the conductive fluid allowing current to flow across the first electrode pair and a second arc is generated in the conductive fluid allowing current to flow across the second electrode pair (Ex. 1004, 0012, 0013, and 0027).</p> <p>Moreover, Hawkins '020 teaches that the electrodes are connected in a manner to produce timed shockwaves and can be synchronized to concurrently impinge upon both sides of the leaflets to maximize the effectiveness of breaking the calcium deposit. Ex. 1004, 0027 (“Each chamber 24 and 26 may contain an electrode (as shall be seen subsequently) that can produce electrical arcs to deliver timed shockwaves. The shockwaves can be synchronized to concurrently impinge upon both sides of the leaflets to maximize the effectiveness of breaking calcium deposits.”) In view of the schematic of Figure 3, with two pairs of electrodes connected to a single power</p>
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<p>electrode in the first electrode pair to the second electrode of the second pair</p>	<p>source, it would have been obvious to a POSITA to try either a series or parallel connection between the two pairs of electrodes. Ex. 1002 at 53-64, 76-79. Indeed, series and parallel connections are the two known methods for connecting adjacent and commonly driven electrode pairs in synchrony. Ex. 1002 at 53-64, 76. Accordingly, utilizing a serial connection to connect the electrode pairs to a common power source to provide the same and predictable result of synchronizing the generation of shockwaves to concurrently impinge on the calcium deposit was well within the range of design choices brought by the experience and knowledge of the POSITA. Ex. 1002 at ¶ 53-64, 79.</p> <p>In addition, a POSITA would have been motivated to utilize a series connection. It is well understood to the skilled artisan that there is a desire to minimize the diameter of intravascular devices to allow for the device to be able to navigate the tortuous blood vessels to reach the area of treatment. Ex. 1002 at ¶ 58. For example, for many years prior to the effective filing date of the '673 patent, Kunis</p>
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taught an ablation catheter arranged for intravascular translation, having multiple electrodes mounted on the catheter in wired communication with an external power source. Ex. 1005, Fig. 17b; 5:18-37. Kunis also taught that the multiple electrodes “can be electrically connected in parallel, in series, individually, or combinations thereof.” Ex. 1005, 25:38-42. One reason for selecting either parallel or series connections to connect multiple electrodes is to control the bulk and stiffness of the catheter due to the number of wires. Ex. 1005, 25:59-67 (“In configurations with large number of electrodes, individual pairs of wires for each electrode may be bulky and compromise the cross-sectional profile of the ablation catheter. In an alternative embodiment, one or more electrodes, connected in series fashion such that a reduced number of wires, such as two wires, can be attached to two or more electrodes, include switching means such that while a first electrode is powered, the remaining electrodes do not transmit ablative energy.” Accordingly, applying the teachings of Kunis, utilizing a series connection would have been an obvious

	design choice for the POSITA to minimize the bulk and cross-sectional profile of the intravascular device.
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C. Claim 2 Is Obvious In View of Hawkins ‘020 in Further View of Hawkins ‘768 and Kunis

[2] *A device as recited in claims 1 further including a third electrode pair having first and second spaced apart electrodes, with the second electrode of the second electrode pair being connectable to the first electrode of the third electrode pair and with the second electrode of the third electrode pair being connectable to the high voltage source.*

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

Claim 2 adds a third electrode pair to the device of Claim 1 in the same manner as the first two electrode pairs. This is nothing more than the mere duplication of parts and thus would have been obvious to the POSITA. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (1960). Indeed, nowhere in the specification of the ‘673 patent, nor the prosecution history, does the applicant provide any support that the addition of a third electrode pair (or any other number of electrode pairs) produces new and unexpected result. There is no disclosure of any modification that is needed, other than the duplication of parts, to add additional electrode pairs, or how the addition of electrode pairs does anything more than generate a shockwave in the same manner and for the same purpose as the other

electrode pairs. The third electrode pair added by Claim 2 would perform the same function (i.e. generate a shockwave) in the same manner and for the same purpose as the other electrode pairs from Claim 1. Ex. 1002 ¶ 81. The POSITA would know how to connect the third electrode pair, or any other number of electrode pairs, to Hawkins '020 utilizing a series connection. Ex. 1002 ¶ 53-64, 81. Moreover, the applicant ignored this rejection when raised by the examiner during prosecution, thus conceding that the limitation did not make the claim patentable over the prior art of record.

In addition, one of ordinary skill in the art would know that the treatment area is often much wider and/or longer than what can be covered by one electrode pair. Accordingly, it has been known for several decades that utilizing multiple electrodes to cover the entire size or length of the target area is an obvious solution to more efficiently and effectively treat these elongated lesions. For example, Kunis teaches an ablation catheter for treating vascular atherosclerotic plaque lesions, with multiple electrodes mounted along the length of the catheter axis on the catheter in wired communication with an external power source. Ex. 1005, Fig. 17b; 5:18-37. Kunis also teaches that the electrodes may be configured to deliver multiple types of energies, including RF, acoustic, ultrasound, electrical, magnetic, microwave, thermal, chemical, light, mechanical radiation and combinations thereof. Ex. 1005, 25:25-36. Moreover, these elements “can be electrically

connected in parallel, in series, individually, or combinations thereof.” Ex. 1005, 25:38-42. One reason for selecting either parallel or series connections to connect multiple electrodes is to control the bulk and stiffness of the catheter due to the number of wires. Ex. 1005, 25:59-67 (“In configurations with large number of electrodes, individual pairs of wires for each electrode may be bulky and compromise the cross-sectional profile of the ablation catheter. In an alternative embodiment, one or more electrodes, connected in series fashion such that a reduced number of wires, such as two wires, can be attached to two or more electrodes, include switching means such that while a first electrode is powered, the remaining electrodes do not transmit ablative energy.”) Accordingly, applying the teachings of Kunis, it would have been obvious to one to utilize multiple electrodes in a series connection to provide more efficient and effective coverage of the treatment area and to minimize the bulk and cross-sectional profile of the intravascular device. Ex. 1002, at ¶82.

An advantage of including multiple shockwave generators within a balloon for a valvuloplasty or angioplasty system is the ability to control the location of the shockwave generator relative to the treatment area to more effectively break calcium deposits. Ex. 1004, 0028 (“As previously described, shockwaves will impinge upon opposite sides of the leaflets 18 to more effectively break calcium deposits in the valve leaflets 18.”).

It is known that the treatment area is often much wider and/or longer than what can be covered by one electrode pair. Ex. 1002, at ¶ 48. Incorporating multiple electrodes to cover the entire size or length of the target area is an obvious solution that has been in use for several decades. *Id.* at 48-50. It has long been known that the intensity of the shockwave is reduced inversely as the square of its distance from the source. Ex. 1042, p. 44 (“Since the energy emitted from a point source spreads out in all directions its intensity reduces significantly with distance. The intensity of any wave is proportional to the square of the amplitude. For spherical waves, the amplitude varies as the wavefront travels (see Figure 14). Due to this, the wave intensity is reduced inversely as the square of its distance from the source.”). It is also known that plaque buildup within the vessels are elongated. Ex. 1002, ¶ 82; Ex. 1005, 2:43-46; 5:14-18; 6:20-32; Ex. 1006, 0038-0039; Ex. 1007, 3:25-49. Accordingly, the intensity of the shockwave originating from a single shockwave generator may vary across an elongated treatment area. Ex. 1002, ¶ 82. This is a similar problem faced by ablation devices where a single electrode is not capable of treating the entire treatment area without the need to reposition the ablation device. Ablation devices solved this problem by incorporating multiple electrodes to cover the entire size or length of the target area. Ex. 1002, ¶ 48-50, 82; Ex. 1005 – 1007.

Accordingly, it would have been obvious to one of ordinary skill in the art to add more electrodes or shock generators to the system to provide sufficient coverage over the treatment area. This is the same solution that has been employed by the skilled artisan for decades to treat elongated lesions (Ex. 1004; Kunis, Ex. 1005; Lesh, Ex. 1006; Janssen, Ex. 1007). Moreover, the skilled artisan has the skill and knowledge of implementing any number of electrodes or shock generators in this manner, to provide this known and desired function, in a predictable and intended manner. Ex. 1002, ¶ 51.

It would have been obvious to a POSITA to implement the features of Kunis and utilize the background knowledge of one of ordinary skill in the art to provide a third electrode pair being serial connected to the other electrode pairs and the power source. Ex. 1002, at ¶ 83. A POSITA would have readily known how to implement the additional third electrode pair in this manner as discussed above. *Id.* Moreover, a POSITA would have been motivated to do so to provide more effective and efficient coverage over the treatment area, while also minimizing the size and bulk of the intravascular device. *Id.* In view of these teachings and the rationales provided above, the combination of Hawkins '020, Hawkins '768, Kunis, and along with the background knowledge of the POSITA renders claim 2 obvious.

D. Claim 3 Is Obvious In View of Hawkins '020 in Further View of Hawkins '768 and Kunis and Lesh

[3] *A device as recited in claims 1 further including a third electrode pair having first and second spaced apart electrodes and a fourth electrode pair having first and second spaced apart electrodes, with the second electrode of the third electrode pair being connected to the first electrode of the fourth electrode pair, said device further including a multiplexer for selectively connecting the high voltage source to either the first and second electrode pairs or the third and fourth electrode pairs.*

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

Claim 3 adds a third and fourth electrode pairs to the device of Claim 1 in the same manner as the first two electrode pairs. This is nothing more than the mere duplication of parts and thus would have been obvious to the POSITA. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (1960). Indeed, nowhere in the specification of the '673 patent, nor the prosecution history, does the applicant provide any support that the addition of a third electrode pair (or any other number of electrode pairs) produces new and unexpected result. There is no disclosure of any modification that is needed, other than the duplication of parts, to add additional electrode pairs, or how the addition of electrode pairs does anything more than generate a shockwave in the same manner and for the same purpose as the other electrode pairs. Moreover, the applicant ignored this rejection when raised by the

examiner during prosecution, thus conceding that the patentability of the limitation rested on the patentability of the independent claim.

In addition, as discussed above, one of ordinary skill in the art would know that the treatment area is often much wider and/or longer than what can be covered by one electrode pair. Accordingly, it has been known for several decades that utilizing multiple electrodes to cover the entire size or length of the target area is an obvious solution to more efficiently and effectively treat these elongated lesions. For example, Kunis teaches an ablation catheter for treating vascular atherosclerotic plaque lesions, with multiple electrodes mounted along the length of the catheter axis on the catheter in wired communication with an external power source. Ex. 1005, Fig. 17b; 5:18-37. Kunis also teaches that the electrodes may be configured to deliver multiple types of energies, including RF, acoustic, ultrasound, electrical, magnetic, microwave, thermal, chemical, light, mechanical radiation and combinations thereof. Ex. 1005, 25:25-36. Moreover, these elements “can be electrically connected in parallel, in series, individually, or combinations thereof.” Ex. 1005, 25:38-42. One reason for selecting either parallel or series connections to connect multiple electrodes is to control the bulk and stiffness of the catheter due to the number of wires. Ex. 1005, 25:59-67 (“In configurations with large number of electrodes, individual pairs of wires for each electrode may be bulky and compromise the cross-sectional profile of the ablation

catheter. In an alternative embodiment, one or more electrodes, connected in series fashion such that a reduced number of wires, such as two wires, can be attached to two or more electrodes, include switching means such that while a first electrode is powered, the remaining electrodes do not transmit ablative energy.”) Accordingly, applying the teachings of Kunis, it would have been obvious to one to utilize multiple electrodes in a series connection to provide more efficient and effective coverage of the treatment area and to minimize the bulk and cross-sectional profile of the intravascular device. Ex. 1002, at ¶82.

Moreover, Kunis teaches how to treat an elongated region with a series of electrodes. For example, Kunis discloses an ablation catheter arranged for intravascular translation, having multiple electrodes mounted on the catheter in wired communication with an external power source. Ex. 1005, Fig. 17b; 5:18-37. Kunis also taught that the multiple electrodes “can be electrically connected in parallel, in series, individually, or combinations thereof.” Ex. 1005, 25:38-42. In some embodiments disclosed in Kunis, multiple electrodes (46) are connected in series on multiple carrier arms (45). Accordingly, one carrier arm may comprise a first and second electrode pairs and another carrier arm may comprise a third and fourth electrode pair. Ex. 1002, ¶87. Moreover, because the electrode pairs are connected in series, the third electrode pairs would be connected to the fourth electrode pairs. The exact means of connection is a routine design choice and well

within the knowledge and skill of a POSITA and reasonably expected to be successfully implemented, including connecting the second electrode of the third electrode pair to the first electrode of the fourth electrode pair, which would provide the simplest and most direct connection between the third and fourth electrode pairs. *Id.* In addition, Kunis discloses an electrical connector (72) that is “configured to electrically connect to one or more of: an energy delivery unit. . . .” Ex. 1005, 13:12-17. Moreover, Kunis discloses that the multiple controls that can be connected via the electrical connector (72) can “activate energy delivery to one or more electrodes 46 or 58.” Ex. 1005, 12:10-18.

Claim 3 also adds a multiplexer for selectively connecting the high voltage source to either the first and second electrode pairs or the third and fourth electrode pairs. Lesh teaches a multiplexer for switching between various electrodes. Ex. 1006, 0114. Lesh is in the analogous field of controlling electrodes for intravascular devices. Ex. 1002 at ¶ 86. The POSITA would find it obvious to include a multiplexer connected to the high voltage source and the electrode pairs in order to act as a switching mechanism. *Id.* Using a multiplexer or switching device to selectively apply energy to one electrode or series of electrodes is known to the POSITA. *See, e.g.*, Ex. 1007 at 6:8-23. Nothing in Claim 3 or the specification of the ‘673 patent, indicates that the multiplexer is being used in a

manner that is different than its well-known and intended use to obtain the same and predictable result.

Importantly, during prosecution, the Patent Owner admitted that they did not invent multiplexing. Ex. 1008 at 370 (“Applicants do not claim to have invented multiplexing.”).⁴ Moreover, the Patent Owner did not dispute any of the teachings of Lesh or that it would have been “obvious to one of ordinary skill in the art at the time of the invention to include a multiplexer connected to the high voltage source and the electrode pairs in order to act as a switching mechanism.” Ex. 1008, at 393; 370-371. The Patent Owner should not now be heard disputing the teachings of Lesh or that including a multiplexer connected to a high voltage source and the electrode pairs in order to act as a switching mechanism is not obvious to the POSITA. *Ex Parte A. James Smith Jr.*, 2010 WL 3269939, *4 (BPAI Aug. 17, 2010), citing *Hyatt v. Dudas*, 551 F.3d 1307, 1313-14 (Fed. Cir. 2008) (the Board may treat arguments appellant failed to make for a given ground of rejection as waived).

⁴ A multiplexer is a basic component used in circuitry design and well known to a POSITA to be used as a switching mechanism to connect electrode pairs to a power source. A common conductor is always employed to connect a plurality of elements or electrodes together. Ex. 1002 at ¶86; Ex. 1043-1045; Ex. 1007, 6:8-22; Ex. 1005, 12:10-18; and Ex. 1006, 0114.

In view of these teachings and the rationales provided above, the combination of Hawkins '020, Hawkins '768, Kunis, and Lesh and along with the background knowledge of the POSITA renders claim 3 obvious.

E. Claim 4 Is Obvious In View of Hawkins '020 and In Further View of Hawkins '768 and Kunis and Lesh

[4] *A device as recited in claim 3 wherein the second electrode of the second electrode pair and the second electrode of the fourth electrode pair are connectable to a common conductor providing a return path to the high voltage source.*

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

Claim 4 adds a third and fourth electrode pairs to the device of Claim 1 in the same manner as the first two electrode pairs. This is nothing more than the mere duplication of parts and thus would have been obvious to the POSITA. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (1960). Indeed, nowhere in the specification of the '673 patent, nor the prosecution history, does the applicant provide any support that the addition of a third electrode pair (or any other number of electrode pairs) produces new and unexpected result. There is no disclosure of any modification that is needed, other than the duplication of parts, to add additional electrode pairs, or how the addition of electrode pairs does anything more than generate a shockwave in the same manner and for the same purpose as the other electrode pairs. Moreover, the applicant ignored this rejection when raised by the

examiner during prosecution, thus conceding that the patentability of the limitation rested on the patentability of the independent claim. *Ex Parte A. James Smith Jr.*, 2010 WL 3269939, *4 (BPAI Aug. 17, 2010), citing *Hyatt v. Dudas*, 551 F.3d 1307, 1313-14 (Fed. Cir. 2008) (the Board may treat arguments appellant failed to make for a given ground of rejection as waived).

In addition, Kunis discloses an ablation catheter arranged for intravascular translation, having multiple electrodes mounted on the catheter in wired communication with an external power source. Ex. 1005, Fig. 17b; 5:18-37. Kunis also taught that the multiple electrodes “can be electrically connected in parallel, in series, individually, or combinations thereof.” Ex. 1005, 25:38-42. In some embodiments disclosed in Kunis, multiple electrodes (46) are connected in series on multiple carrier arms (45). Accordingly, one carrier arm may comprise a first and second electrode pairs and another carrier arm may comprise a third and fourth electrode pair. Ex. 1002, ¶87. Moreover, because the electrode pairs are connected in series, the third electrode pairs would be connected to the fourth electrode pairs. The exact means of connection is a routine design choice and well within the knowledge and skill of a POSITA and reasonably expected to be successfully implemented, including connecting the second electrode of the third electrode pair to the first electrode of the fourth electrode pair, which would

provide the simplest and most direct connection between the third and fourth electrode pairs. *Id.*

Moreover, Kunis discloses an electrical connector (72) (the claimed “common conductor”) that is “configured to electrically connect to one or more of: an energy delivery unit. . . .” Ex. 1005, 13:12-17. “Electrical connector 72 includes multiple connection points for multiple wires that travel within outer shaft 36 and connect to ablation elements and one or more sensors such as temperature sensors included in first carrier assembly 45 and second carrier assembly 55.” Ex. 1005, 13:7-12. The exact means of connection is a routine design choice and well within the knowledge and skill of a POSITA and reasonably expected to be successfully implemented, including connecting the second electrode of the second electrode pair and the second electrode of the fourth electrode pair to the electrical connector 72 (the claimed “common conductor”), which may be connected to an energy delivery unit. Ex. 1005, 13:12-17; Ex. 1002, ¶87. In addition, as discussed above, a common conductor is always employed to connect a plurality of elements or electrodes together, such as a plurality of electrodes to a multiplexer. Ex. 1002 at ¶86-87; Ex. 1043-1045; Ex. 1007, 6:8-22; Ex. 1005, 12:10-18; and Ex. 1006, 0114.

As discussed above in connection with the series connection limitation, it would have been obvious to the POSITA to try a series or parallel connection

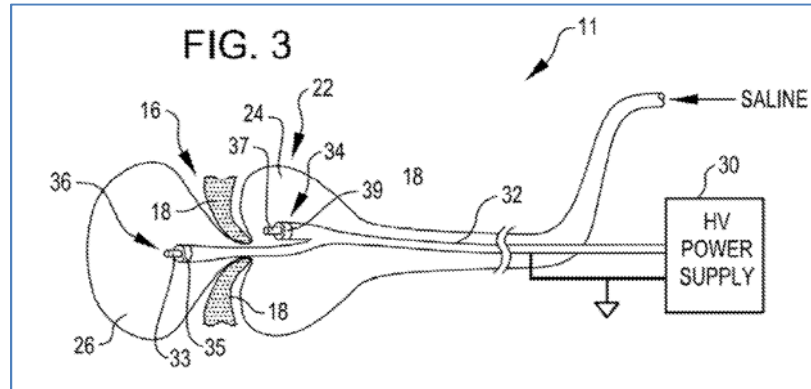
between two electrode pairs because they are the known methods for connecting adjacent and commonly driven electrodes pairs (i.e. connected to a common conductor and returning to the same high voltage source). Because there are only two fundamental ways for analogue connections, series and parallel, selecting between a series and parallel connection would be a functionally equivalent design choice and obvious to try by the POSITA. Ex. 1002 at ¶89. Similarly, it is well known to a POSITA that a common method for connect a plurality of electrodes to other components, such as a multiplexer is the use of a common connector. Ex. 1002 at ¶87; Ex. 1043-1045; Ex. 1007, 6:8-22; Ex. 1005, 12:10-18; and Ex. 1006, 0114. Indeed, these are basic principles of electrical circuit designs well known to the POSITA. No matter how many components or how complex the circuit is, it can always be dissected and observed as a combination of serial and/or parallel connections. Accordingly, designing a circuit that connects the electrodes of various electrode pairs together through a common conductor is a routine design choice well within the skill and knowledge of the POSITA. Moreover, the '673 patent does not provide that this configuration is different than or provides any unexpected result compared to the myriad of known connections. *Id.*

F. Claim 5 Is Obvious In View of Hawkins '020 and in Further View of Hawkins '768 and Kunis

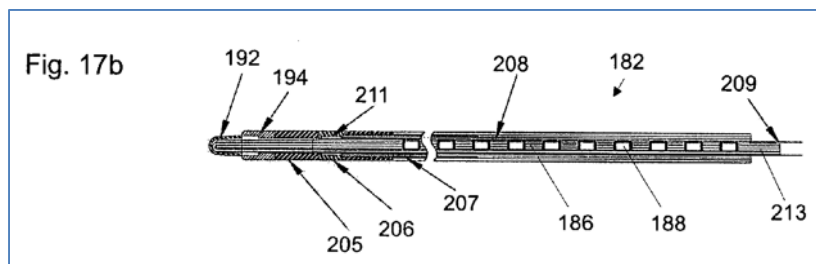
[5] *A device as recited in claims 1 wherein at least two of the electrode pairs are spaced longitudinally along the elongated member.*

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

Hawkins '020 teaches wherein at least two of the electrode pairs are spaced longitudinally along the elongated member. Ex. 1004, Fig. 3, coaxial electrode pairs 34 and 36 shown spaced apart longitudinally along the elongated member.



To the extent that the electrode pairs of Hawkins '020 are not considered to be spaced longitudinally along the elongated member, Kunis expressly discloses electrode pairs can be configured spaced longitudinally along the elongated member. *See, e.g.,* Ex. 1005, Fig. 17b.



See also Willneff Ex. 1010, Figs 2 and 3; p. 5 (“[A] shockwave 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

shockwaves are to be applied. . . .”); Fig. 1 (spark gap 16 arranged between two longitudinally displaced electrodes (not numbered elements) in operative communication with co-axial, flexible current supply (6)).

As previously discussed, one consideration for the skilled artisan when designing an intravascular device is minimizing the device’s diameter, while maximizing flexibility, to allow for the device to be able to navigate the tortuous blood vessels to reach the area for treatment. This is an important consideration to the skilled artisan as they consider the various design choices available to them in designing intravascular devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to try placing at least two of the electrode pairs spaced longitudinally along the elongated member as it would provide the most narrow cross sectional profile. In addition, longitudinally spacing the electrode pairs assist with minimizing the problems associated with varying energies of the shockwaves due to the distance from the origination to the point of the treatment area, when dealing with elongated treatment areas. Moreover, the skilled artisan has the skill and knowledge of implementing any number of electrodes or shock generators in this manner, to provide this known and desired function, in a predictable and intended manner. Ex. 1002, at ¶ 92-93.

G. Claim 6 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis

[6] *A device as recited in claims 1 wherein the elongated member comprises a guide wire lumen*

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

Hawkins ‘020 teaches wherein the elongated member comprises a guide wire lumen. Ex. 1004, 0011 (“The elongated tube may include a lumen.”). To the extent that the lumen of Hawkins ‘020 is not used as a guide wire lumen, Hawkins ‘768, which was incorporated by reference by Hawkins ‘020 (*see* Ex. 1004, 0027 and 0028 indicating that copending application No. 61/061,170 is incorporated herein in its entirety) unequivocally teaches an elongated member comprises a guide wire lumen. Ex. 1003, 0009 (“The catheter may further include a lumen for receiving a guide wire. The lumen may be defined by the carrier.”). *See, e.g.*, Kunis, Ex. 1005, 6:51-63 (“The catheters of the present invention may be configured to be advanced into the heart of a patient over a previously placed guidewire, such as a standard interventional 0.035” guidewire. The catheter may include an inner lumen for the majority of its length, through which the guidewire is inserted, or the catheter may include a relatively short sidecar near its distal end, where the guidewire inserted through a lumen of the sidecar. The placement over the guidewire allows simplified positioning and re-positioning by an operator. The

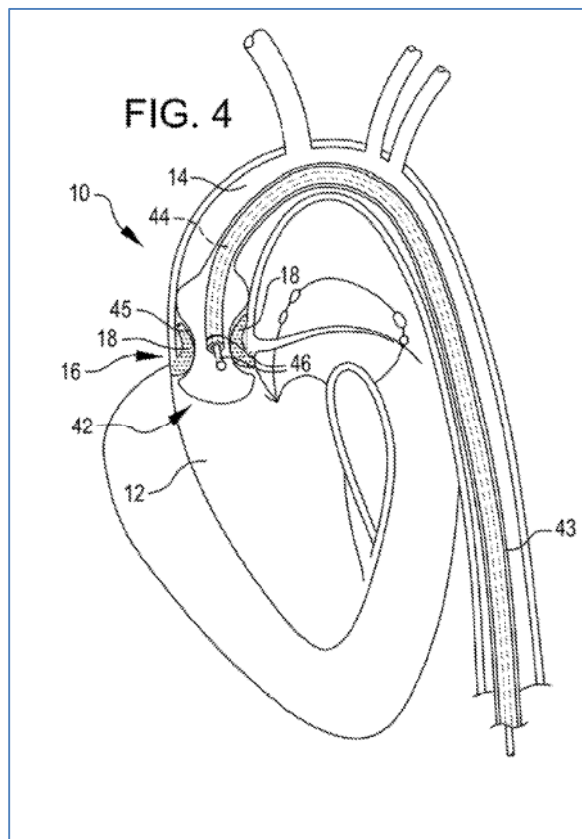
guidewire placement also provides stability such as to simplify maintaining the position of the catheter during energy delivery, typically 60 seconds.”).

H. Claim 7 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis

[7] *a device as recited in claims 1 wherein said balloon is a single chamber angioplasty balloon.*

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

Hawkins ‘020 teaches wherein said balloon is a single chamber angioplasty balloon. Ex. 1004, Fig. 4.



To the extent that the single chamber balloon of Hawkins ‘020 is not used as an angioplasty balloon, Hawkins ‘768, which was incorporated by reference by Hawkins ‘020 (*see* Ex. 1004, 0027 and 0028 indicating that copending application No. 61/061,170 is incorporated herein in its entirety) unequivocally teaches that said balloon is a single chamber angioplasty balloon. Ex. 1003, Figs. 2, 4-8; 0050 (“Fig. 2 is a view of a dilating angioplasty balloon catheter 20 according to an embodiment of the invention.”).

I. Claim 8 Is Obvious In View of Hawkins ‘020 in Further View of Hawkins ‘768 and Kunis

[8] *A device as recited in claims 1 wherein said balloon includes two chambers configured for valvuloplasty.*

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

Hawkins ‘020 teaches wherein said balloon includes two chambers configured for valvuloplasty. Ex. 1004, Fig. 3, 0027 (“The treatment balloon 22 has two longitudinally spaced chambers 24 and 26 that share a common inflation lumen 25 of the tube 23.”); 0008 (“In one embodiment, a valvuloplasty system comprises a balloon adapted to be placed adjacent leaflets of a valve, the balloon being inflatable with a liquid, and a shockwave generator within the balloon that produces shockwaves that propagates through the liquid for impinging upon the valve. The balloon may be adapted to be placed on opposite sides of the valve leaflets or within the valve annulus.”).

J. Claim 9 Is Obvious In View of Hawkins '020 and in Further View of Hawkins '768 and Kunis and Lesh

[9] A device comprising:

an axially extending elongate member;

a balloon surrounding a portion of the elongate member, said balloon being fillable with a conductive fluid;

a plurality of electrode pairs located within and spaced from the balloon, said electrode pairs being mounted on the elongate member and within the conductive fluid and wherein the electrode pairs are configured to produce shockwaves that propagate through the liquid and wherein one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair;

a high voltage source connectable to the electrodes; and

a multiplexer and wherein the plurality of electrode pairs include *a first set of two pairs of electrodes* with one electrode of one pair being connected to one electrode of the other pair, said electrode pairs further including *a second set of two pairs of electrodes* with one electrode of one pair being connected to one electrode of the other pair, and *wherein said multiplexer selectively connects the high voltage source to one or the other of the first and second sets of electrode pairs*, with the connected set operating in series

across an arc generated in the conductive fluid allowing current to flow across each pair of electrodes.

Claim 9 is identical to Claim 1 in all material respects except for the addition of the “multiplexer” limitation and the two sets of two pairs of electrodes shown in italics. The multiplexer limitation and the two sets of two pairs of electrodes limitation are identical in all material respects to Claim 3. Accordingly, all of the arguments related to Claim 1 and Claim 3 are incorporated herein.

K. Claim 10 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis and Lesh

[10] *A device as recited in claims 9 wherein one electrode in the first set of two pairs and one electrode in the second set of two pairs are connectable to a common conductor providing a return path to the high voltage source.*

The references and arguments applied to claim 9 are incorporated here.

Claim 10 adds that the third and fourth electrode pairs of Claim 9 are connectable to a common conductor providing a return path to the high voltage source in the same manner as in Claim 4. Accordingly, all of the arguments related to Claim 4 are incorporated herein.

L. Claim 11 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis and Lesh

[11] *A device as recited in claims 9 wherein at least two of the electrode pairs are spaced longitudinally along the elongated member.*

The references and arguments applied to claim 9 are incorporated here.

Claim 11 adds the same limitation to independent Claim 9 as Claim 5 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 5 are equally applicable and are incorporated by reference.

M. Claim 12 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis and Lesh

[12] *A device as recited in claims 9 wherein the elongated member comprises a guide wire lumen.*

The references and arguments applied to claim 9 are incorporated here.

Claim 12 adds the same limitation to independent Claim 9 as Claim 6 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 6 are equally applicable and are incorporated by reference.

N. Claim 13 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis and Lesh

[13] *A device as recited in claims 9 wherein said balloon is a single chamber angioplasty balloon.*

The references and arguments applied to claim 9 are incorporated here.

Claim 13 adds the same limitation to independent Claim 9 as Claim 7 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 7 are equally applicable and are incorporated by reference.

O. Claim 14 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘768 and Kunis and Lesh

[14] *A device as recited in claims 9 wherein said balloon includes two chambers configured for valvuloplasty.*

The references and arguments applied to claim 9 are incorporated here.

Claim 14 adds the same limitation to independent Claim 9 as Claim 8 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 8 are equally applicable and are incorporated by reference.

P. Claim 15 is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘786 and Kunis

[15] A device comprising: an axially extending elongate member;
a tubular member surrounding a portion of the elongate member, said *tubular member* being fillable with a conductive fluid;
a first electrode pair having first and second spaced apart electrodes and a second electrode pair having first and second spaced apart electrodes, said electrode pairs being located within and spaced from the *tubular member*, wherein the electrode pairs are configured to produce shockwaves that propagate through the liquid, and wherein one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair;
and a high voltage source connectable to the first electrode of first electrode pair, and with the second electrode of first electrode pair being connected to

the first electrode of the second electrode pair, and with the second electrode of the second electrode pair being connectable to the high voltage source, and wherein when a high voltage pulse is supplied to the first and second electrode pairs, a first arc is generated in the conductive fluid allowing current to flow across the first electrode pair and a second arc is generated in the conductive fluid allowing current to flow across the second electrode pair, thereby creating a series connection running from the first electrode in the first electrode pair to the second electrode of the second pair.

Claim 15 is identical to Claim 1 in all material respects except for the substitution of “a balloon” with “a tubular member” and elimination of the claim limitation “said electrode pairs being mounted on the elongate member and within the conductive fluid” that was present in Claim 1.⁵ Notably, the claim term “tubular member” is not mentioned anywhere in the specification. Moreover, the claim term “tubular member” was only mentioned during prosecution when claims 63-68 were added on November 15, 2016. Ex. 1008, pp. 364-367. Accordingly, the “tubular member” is the same as the balloon, and there no patentable

⁵ The elimination of the “said electrode pairs being mounted on the elongate member and within the conductive fluid and” limitation is the only substantive difference between Claim 1 and Claim 15. This is further evidence that this limitation was not sufficient to overcome the prior art.

distinction between a “tubular member” and a “balloon.”⁶ All of the arguments related to Claim 1 are equally applicable and are incorporated herein.

Q. Claim 16 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘786 and Kunis

[16] *A device as recited in claims 15 further including a third electrode pair having first and second spaced apart electrodes, with the second electrode of the second electrode pair being connectable to the first electrode of the third electrode pair and with the second electrode of the third electrode pair being connectable to the high voltage source.*

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

Claim 16 adds the same limitation to independent Claim 15 as Claim 2 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 2 are equally applicable and are incorporated by reference.

R. Claim 17 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘786 and Kunis and Lesh

[17] *A device as recited in claims 15 further including a third electrode pair having first and second spaced apart electrodes and a fourth electrode pair having first and second spaced apart electrodes, with the second electrode of the third electrode pair being connected to the first*

⁶ To the extent that the Patent Owner argues that the “tubular member” is different than the “balloon”, Petitioner argues that there is no written description support for the “tubular member” as used in Claim 15 other than as synonymous with a “balloon.”

electrode of the fourth electrode pair, said device further including a multiplexer for selectively connecting the high voltage source to either the first and second electrode pairs or the third and fourth electrode pairs.

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

Claim 17 adds the same limitation to independent Claim 15 as Claim 3 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 3 are equally applicable and are incorporated by reference.

S. Claim 18 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘786 and Kunis and Lesh

[18] *A device as recited in claim 17 wherein the second electrode of the second electrode pair and the second electrode of the fourth electrode pair are connectable to a common conductor providing a return path to the high voltage source.*

The references and arguments applied to claim 17 are incorporated here.

Claim 18 adds the same limitation to Claim 17 as Claim 4 added to Claim 3. Accordingly, the arguments with respect to Claim 4 are equally applicable and are incorporated by reference.

T. Claim 19 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘786 and Kunis

[19] *A device as recited in claim 15 wherein the first electrode pair and second electrode pair are spaced longitudinally along the elongated member.*

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

Claim 19 adds the same limitation to independent Claim 15 as Claim 5 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 5 are equally applicable and are incorporated by reference.

U. Claim 20 Is Obvious In View of Hawkins ‘020 and in Further View of Hawkins ‘786 and Kunis

[20] *A device as recited in claim 15 wherein the elongated member comprises a guide wire lumen.*

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

Claim 20 adds the same limitation to independent Claim 15 as Claim 6 added to Independent Claim 1. Accordingly, the arguments with respect to Claim 6 are equally applicable and are incorporated by reference.

VII. CONCLUSION

For the foregoing reasons, claims 1-20 of the ’673 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. 9,642,673, all supporting
exhibits (Exhibits 1001 through 1043), 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
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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

The undersigned certifies, pursuant to 37 C.F.R. §42.24(d) , that the word count for the foregoing Petition For Inter Partes Review Of U.S. Patent No. 9,642,673 Under 35 U.S.C. § 312 AND 37 C.F.R. § 42.104 totals 13,637, and within the 14,000 words allowed under 37 C.F.R. §42.24(a)(1)(i).

Date: December 7, 2018

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