IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

In re *Inter Partes Review* of:	)	
U.S. Patent No. 8,728,091 B2	)	
Issued: May 20, 2014	)	Attorney Docket No. 68890-286960
Inventors: Doug Hakala, et al.	)	
Application No. 14/079,463	)	
Filed: Nov. 13, 2013	)	FILED ELECTRONICALLY
For: SHOCKWAVE CATHETER SYSTEM WITH ENERGY CONTROL	)	PER 37 C.F.R. § 42.6(b)(1)

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PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,728,091

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 ("IPR") of claims 1-14 of U.S. Patent No. 8,728,091 (the "'091 Patent," Exhibit 1001), assigned to Shockwave Medical, Inc. ("SMI"). Payment of $30,500 for the fees specified by 37 C.F.R. §42.15(a)(1)(2)&(4)—comprising the $15,500.00 request fee and $15,000.00 post-institution fee—is effected together with the filing of this petition.

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LIST OF EXHIBITS

Exhibit 1001:	U.S. Patent No. 8,728,091
Exhibit 1002:	Declaration of Dr. Morten Olgaard Jensen
Exhibit 1003:	U.S. Patent Appl. Publ. No. 2009/0312768, by Hawkins, et al.
Exhibit 1004:	U.S. Patent Appl. Publ. No. 2006/0221528, by Li, et al.
Exhibit 1005:	U.S. Patent Appl. Publ. No. 2003/0176873, by Chernenko, et al.
Exhibit 1006:	U.S. Patent Appl. Publ. No. 2013/0041355, by Heeren, et al.
Exhibit 1007:	Cleveland, Robin O. et al, "Design and characterization of a research electrohydraulic lithotripter patterned after the Dornier HM3," Review of Scientific Instruments, vol. 71, no. 6, at 2514-2525.
Exhibit 1008:	Manousakas, I. et al., "A High-Voltage Discharging System for Extracorporeal Shock-Wave Therapy," IFMBE Proceedings ICBME 2008, Vol. 23 at 706-707.
Exhibit 1009:	Broyer, P. et al., "High-efficiency shock-wave generator for extracorporeal lithotripsy," Med. & Biol. Eng. & Comput., vol. 34 at 321-328, published September 1996.
Exhibit 1010:	Prosecution History U.S. Appl. No. 14/079,463 issued as U.S. Patent No. 8,728,091 ("File Wrapper").
Exhibit 1011:	U.S. Patent No. 5,116,227
Exhibit 1012:	European Patent No. 0571306
Exhibit 1013:	Japanese Unexamined Patent Application Publication, Publ. No. S62-275446
Exhibit 1014:	German Patent Application No. DE 3038445 A1
Exhibit 1015:	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 1016: Nisonson I, Witus WS, Madorsky ML, Weems WS. Ambulatory extracorporeal Millman J, Grabel A. Microelectronics Second Edition International Edition: McGraw-Hill, Inc. International Editions; 1987. p. 1001.

Exhibit 1017: 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 1018: Grocela JA, Dretler SP. Intracorporeal lithotripsy. Instrumentation and development. Urol Clin North Am. 1997;24(1):13-23.

Exhibit 1019: 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 1020: 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.

I. INTRODUCTION

Surgical electrohydraulic lithotripsy ("EHL") is a procedure in which an electrical spark is applied within a fluid to produce a mechanical shockwave. Applying the shockwave to calcified buildups within a patient's artery can help disrupt the buildup to clear the passage for improved blood flow. As discussed herein, before the purported invention date of the '091 Patent (Ex. 1001), the techniques of EHL were known, including generating the electrical spark by a pulse of voltage, for example, as disclosed within Hawkins (Ex. 1003). The '091 Patent allegedly discovered that terminating voltage pulses at a threshold current could limit excessive sparking. Yet, this is a standard feedback control scheme that was known from each of the prior art references Li (Ex. 1004) and Heeren (Ex. 1007), not previously before the Office. Furthermore, the Chernenko reference (Ex. 1006) was addressed during prosecution, but was critically misunderstood to lack control of individual voltage pulses due to Patent Owner's misleading arguments. In truth, Chernenko expressly teaches feedback control of individual pulses based on threshold current.

Moreover, design features such as specific thresholds and delay times were commonly known in feedback control, including in over-current protection arrangements important to EHL. As discussed herein, with proper appreciation of the control schemes already known within the prior art, the claims of the '091 Patent fails to recite patentable subject matter.

II. OVERVIEW OF CHALLENGES

A. Identification of Challenges

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claims 1-14 of the '091 Patent as unpatentable as follows:

Ground	35 U.S.C. § 103(a)	Challenged Claims
1	**Hawkins in view of Li**	**1-14**
2	**Hawkins in view of Chernenko**	**1-3, 10**
3	**Hawkins in view of Chernenko & Li**	**1-14**
4	**Hawkins in view of Heeren**	**1-14**

B. Identification of the Prior Art

As identified hereinafter, the prior art of concern in this proceeding includes the following:

- Hawkins, et al., U.S. 2009/0312768, published December, 2009 ("Hawkins") (Ex. 1003).
- Li, et al., U.S. 2006/0221528, published October 5, 2006 ("Li") (Ex. 1004).
- Chernenko, et al., U.S. 2003/0176873, published September 18, 2003 ("Chernenko") (Ex. 1005).

- Heeren, et al., U.S. 2013/0041255, filed August 11, 2011 ("Heeren") (Ex. 1006).

- Cleveland, Robin O. et al, "Design and characterization of a research electrohydraulic lithotripter patterned after the Dornier HM3," Review of Scientific Instruments, vol. 71, no. 6, at 2514-2525, published June 2000 ("Cleveland") (Ex. 1007).

- Manousakas, I. et al., "A High-Voltage Discharging System for Extracorporeal Shock-Wave Therapy," IFMBE Proceedings ICBME 2008, Vol. 23 at 706-707 ("Manousakas") (Ex. 1008).

- "Dual Full Bridge PWM Motor Driver," by Texas Instruments, published July 2011 ("TI Datasheet") (Ex. 1009).

- Broyer, P. et al., "High-efficiency shock-wave generator for extracorporeal lithotripsy," Med.&Biol. Eng. &Compute., vol. 34, 321-328, published September 1996 ("Broyer") (Ex. 1010).

According to their issuance or publication dates, each of Hawkins, Li, Chernenko, Cleveland, Manousakas, the TI Datasheet, and Broyer are prior art under 35 U.S.C. §102(b) as being patented or published more than one year before the presumed effective filing date of the '091 Patent (i.e., before the presumed effective filing date of September 13, 2012). Heeren is prior art under at least 35

U.S.C. §102(e) as a published U.S. Patent application effectively filed, naming another inventor, before the presumed effective filing date of the '091 Patent.

Li, Heeren, Cleveland, Manousakas, TI Datasheet, and Broyer were not cited or applied by the examiner during prosecution of the '091 Patent. Although Hawkins and Chernenko were addressed at prosecution, the Office has not previously considered these references applied as presented in Petitioner's challenges, for example, in combination in substantially the same manner and/or with the same prior art as presented herein. Indeed, as reviewed in detail herein, the prosecution history of the '091 Patent indicates that the Examiner critically misunderstood the teachings of the prior art considered at that time. 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 an ordinary artisan in consideration of these prior art references.

III. THE '091 PATENT

A. Overview of the '091 Patent

The '091 Patent is directed to conventional catheters for generating shockwaves within an angioplasty balloon to remove or reduce calcified stenotic lesions in blood vessels. *See, e.g.,* '091 Patent (Ex. 1001) at Title; Abstract; 2:55-3:4. In the described embodiments, a shockwave generator in the form of an arc (spark) generator includes at least one electrode pair positioned within a conventional fluid-filled angioplasty balloon. When high voltage pulses are applied to the electrodes, a spark is created between the electrodes resulting in the generation of a mechanical shockwave in the fluid. The shockwave is transmitted through the fluid and the balloon to a calcified stenotic lesion in the blood vessel to break or crack the calcified lesion, and thus restore normal blood flow. In controlling its voltage pulses, the '091 Patent monitors the current levels at the electrodes. The '091 Patent describes terminating voltage pulse upon detection of high current flow.

But monitoring current to control voltage pulsed devices was known before the alleged invention of the '091 Patent. *See, e.g.* Ex. 1003, Hawkins; Ex. 1004, Li; 1006, Chernenko; Ex. 1007, Heeren. For example, Li teaches a simple current protection for pulsed voltage devices that protects the device from current conditions exceeding a predetermined threshold. *See* Ex. 1004, Li. Furthermore, others controlled voltage pulses by monitoring current levels specifically for ***surgical devices***, to provide the same function, in the same manner, as claimed in the '091 Patent. *See, e.g.* Ex. 1003, Hawkins; Ex. 1006, Chernenko; Ex. 1007, Heeren. Indeed, manipulating these electrical variables is among the foundational principles of EHL, first used to address kidney stones and similar concretions, but that has also long been known for disrupting calcified lesions in blood vessels. Ex. 1002 ("Jensen"), ¶¶61-63.

The ‘091 Patent attempted to sidestep the well-known technique of monitoring current levels to control electrically pulsed devices by emphasizing routine features such as (i) controlling individual pulses and/or (ii) delay time in the control arrangements. However, the prosecution history illustrates that such routine features issued in the ‘091 Patent due to an incomplete understanding of the prior art, compounded by misdirection within the applicant’s remarks. Moreover, prior art not considered during prosecution also demonstrates that these common feedback techniques were readily known to provide their associated benefits in electrical pulse control.

With a clear understanding of the prior art control arrangements, the subject matter of the challenged claims was known both generally in electrical pulse control and specifically in electrically-pulsed surgical devices. Although the challenged claims should have been denied over the art applied during prosecution, additional references Li and Heeren emphasize that current-based feedback controls were readily known to improve control function, and that specific power levels and delay times were merely routine features recognized by the prior art and well-known to the artisan.

B. Level of Ordinary Skill

A person of ordinary skill in the art at the time of the alleged invention of the ‘091 Patent (a “POSITA” or “ordinary artisan”) 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, Electrical Engineering, Biomedical Engineering, or equivalent, and between three and five years of practical experience, including familiarity with the various medical devices and techniques for angioplasty lithotripsy, and/or familiarity with electro-pulsed surgical devices generally. Specific study and/or experience conditions may be met by equivalent experience, education, or training. Jensen, ¶¶34-38.

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"). Further, statements about the invention as a whole, such as those found in the Abstract and Summary of the Invention, are given particular weight. *E.g., Silicon Graphics, Inc., v. ATI Techs., Inc.*, 607 F.3d 784, 793 (Fed. Cir. 2010). Claim terms must also be interpreted in light of the problem intended to be solved. *CVI/Beta Ventures, Inc. v.*

Tura LP, 112 F.3d 1146, 1160 (Fed. Cir. 1997). "The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." *Phillips*, 415 F.3d at 1315 (internal quotations omitted); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings,* 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention.").

For the purposes of this proceeding, Petitioner believes that it is unnecessary to provide a specific construction for every term or phrase from the claims of the '091 Patent. Nevertheless, Petitioner has proposed constructions for select terms and phrases for this proceeding as set forth below. Constructions of other claim terms, such that the manner that the challenged claims are to be construed, can be appreciated from their overall discussion herein.

1. "predetermined value"

The ordinary artisan would understand the phrase "predetermined value" in the challenged claims, to mean a value set in advance. Jensen, ¶47. The specification of the '091 Patent does not set forth any particular definition of this phrase. In general, the specification uses this phrase to refer to a current limit, for example, 50 amps or amperes. *See e.g.*, 9:6-10. First, the inclusive mention of 50 amperes as an example of an acceptable predetermined limit indicates that the particular value may be set according to the design of the system because there is no indication that 50 amperes is the only possible value. Second, the more general term "value" instead of "limit" does not appear to have material effect on the plain meaning of "predetermined," which is defined as "determined in advance." Accordingly, the phrase "predetermined value" as recited in the challenged claims is best construed to mean a value set in advance.

2. "predetermined delay time"

The ordinary artisan would understand the phrase "predetermined delay time" in the challenged claims, to mean an amount of delay time set in advance. Jensen, ¶48. The specification of the '091 Patent does not set forth any particular definition of this phrase and never actually uses the exact phrase "predetermined delay time" in so many words. In general, the specification refers to a delay time, for example, 100 nanoseconds or more, after which the command signal is issued to operate a control loop. *See e.g.*, '091 Patent, 10:30-49. In particular, the specification indicates that the delay time of 100 nanoseconds is applied to counteract the response delay of the switch which executes voltage termination. *Id.*, 11:3-13. Thus, the specification does not appear to indicate that a "predetermined delay time" must be particularly limited to 100 nanoseconds but rather can be selected based on the design of the system. Jensen, ¶48. The terms "delay," "delay time," and their variants as used in the specification do not appear to have material effect on the plain meaning of "predetermined" to mean determined in advance. Moreover, the proposed construction for "predetermined delay time" comports with the construction of "predetermined value" as discussed above. Accordingly, the phrase "predetermined delay time" as recited in the challenged claims is best construed to mean a delay time set in advance.

IV. CLAIMS 1-14 OF THE '091 PATENT ARE UNPATENTABLE

A. There Is Nothing New About Monitoring Current To Control Shockwave Devices.

As discussed above, angioplasty catheters generating shockwaves to treat calcified plaque are not new. For example, more than two years before the presumed effective filing date of the '091 Patent, Hawkins 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, ¶3. In the described embodiments, a shockwave generator defined by an electrode pair is positioned within a conventional fluid filled angioplasty balloon. When high voltage pulses are applied by the shockwave generator, a plasma (i.e. spark) is created between the electrodes generating a shockwave. The shockwave is transmitted through the fluid and the balloon, to break or crack a calcified stenotic lesion in the blood vessel.

In applying pulsed electric power to generate shockwaves, power conditions must exist that can be hazardous on their own, let alone, when applied internally within a surgical patient's body. Jensen, ¶76. Indeed, in generating shockwaves for such treatment, it was known to monitor the current flow because a current spike occurs as the spark is generated. *Id.* These sparks are produced on the nanosecond scale making early spark detection and response key aspects to adequate and safe operation. *Id.*

As reviewed in detail below, the prior art teaches observing current to provide pulse control as a common manner of restricting current to appropriate levels in pulsed voltage devices. Moreover, it was known in electro-pulsed devices that when the current jumps, the onset of a spark is indicated. Applying these known principles of monitoring current and responsively controlling pulses, the sparks can be better managed to reduce risk of harm to the device and user alike. These common feedback schemes were likewise known in surgical devices to enhance electrical effectiveness while reducing the risk patient harm. Jensen, ¶77.

V. HAWKINS IN VIEW OF LI

As reviewed with particularity below, Hawkins teaches an EHL catheter that provides voltage pulses at its electrodes to generate an electrical spark and resultant shockwave. Hawkins acknowledges voltage, current, and control factors as common variables in EHL procedures. Li compliments Hawkins' electrical considerations by teaching over-current protection arrangements which can protect against overly intense current conditions, providing safe and reliable operation.

A. Independent Claim 1 is Obvious over Hawkins in view of Li.

Hawkins in view of Li achieves all features as recited in claim 1.

As discussed below, Hawkins discloses all features of claim 1, except it may not expressly disclose directly sensing current to control voltage pulses. Yet, Li's current protection arrangements illustrates that such feedback control is common place within pulsed voltage systems to avoid hazardous over-current conditions that can damage the device itself and/or cause trauma to the user or the subject.

[1a] A balloon catheter for delivering shockwaves to a calcified lesion comprising:

Although the preamble does not appear to limit claim 1, Hawkins, nevertheless, teaches such a balloon catheter. *See* Ex. 1003, Title. Hawkins discloses a shockwave balloon catheter capable of addressing a calcified lesion. *See e.g., id.*, ¶¶2 (legion is calcified), 38, 42, 45, 46, 51, 53, 56-62, Figs. 10, 11, 11b, 12, 13. For example, Hawkins discloses that its shockwaves can be "conducted … to the calcified lesion." *Id.*, ¶51. Accordingly, to the extent that it may be limiting, Hawkins discloses the balloon catheter as recited in the preamble of claim 1.

[1b] *__an elongated carrier;__*

Hawkins teaches an elongated carrier. *See e.g.*, Hawkins, Abstract ("elongated carrier"), ¶¶3, 10, 19, 50, claims 1, 9, & 14, Figs. 2, 4-8, & 9. For example, in at least one embodiment, Hawkins discloses that "the catheter 20 includes an elongated carrier, such as a hollow sheath 21." *Id.*, 50. Accordingly, Hawkins discloses the elongated carrier as recited in claim 1.

[1c] *__a flexible balloon mounted on the elongate carrier, said balloon being fillable with a conduction fluid;__*

Hawkins discloses a flexible balloon as recited in claim 1. Jensen, ¶82. For example, Hawkins discloses a balloon 26 mounted on its hollow sheath 21 (elongate carrier). *See e.g.,* Hawkins, ¶¶3, 5, 10, 14, 19, 50-55, Figs. 1, 2, 4-9, 10A-C, 11A, 12-13, 15; *see also e.g.*, ¶¶ 56, 58, 64, Figs. 7-10, 15 (balloons 66, 76, 86, 116). Hawkins discloses that its balloon is flexible. *See* Hawkins, ¶¶5, 61, 64, claims 3 and 4 (both compliant and non-compliant material can flex); *id.*, ¶49 (non-compliant expanded), ¶¶10, 59, 60, 62, (inflated/expanded). Hawkins' balloon is fillable with a conduction fluid. *Id.*, ¶¶8, 10, 17, 48-51, 60, 61, 64; *see also* Jensen, ¶82. Accordingly, Hawkins discloses the flexible balloon of claim 1.

[1d] *__a pair of electrodes on the elongated carrier within the balloon;__*

Hawkins discloses the electrodes as recited in claim 1. Jensen, ¶83. For example, Hawkins discloses electrodes 22, 24 within the balloon. *See e.g.*, Hawkins, ¶50, Figs. 2 & 4. Hawkins also discloses electrodes 42,44, 62, 64, 72, 74, 82, 84 within its balloon. *See id.*, ¶¶54-58, Figs. 5-9. Hawkins discloses its electrodes to be located on the elongated carrier at least as the electrodes are within the annular channel 27 formed between the balloon 26 about the sheath 21 (and equivalently located in arrangements having other numerals). *See id.*, ¶50, Fig. 2, 4, 5-9; Jensen, ¶83. Accordingly, Hawkins discloses the pair of electrodes of claim 1. Jensen, ¶83.

> *[1e] <u>a power source coupled to the electrodes for supplying voltage pulses to the electrodes, each voltage pulse generating an arc in the fluid within the balloon and causing current to flow between the electrodes and producing a shockwave;</u>*

Hawkins discloses the recited power source. *See* Hawkins, Figs. 2, 4, 5-9. Hawkins discloses that its power source 30 is coupled with the electrodes to generate reproducible current arcs (sparks) between the electrodes within the fluid to ultimately produce shockwaves. *See id.*, ¶¶50, 52, 53; Jensen, ¶84. Hawkins discloses its shockwaves to address calcified plaque in patient arteries. *Id.*, 51.

> *[1f] <u>wherein the power source includes a current sensor for detecting the current flow between the electrodes during each voltage pulse; and wherein when the current reaches a predetermined value during each voltage pulse, the sensor generates a signal that causes the power source to terminate the voltage supplied to the electrodes for that pulse.</u>*

Hawkins discloses embodiments including a reflected energy sensor 85 for providing feedback regarding its shockwaves. *See* Hawkins, ¶¶6, 15, 22, 37, 58, claims 6 & 17, Fig. 9. As Dr. Jensen explains, reflected energy indicates the effectiveness of the shockwave resultant from the current flow and is analogous to current sensing. *See id.*, ¶¶57-58; Jensen, ¶85. Thus, Hawkins considers current flow by analogy, but lacks explicit mention of current sensors and the current-based feedback for voltage termination as recited in claim 1.

However, Li discloses arrangements for providing controlled voltage pulses while protecting against high current conditions by sensing current and terminating voltage appropriately. For example, Li discloses a current limiter arrangement which terminates voltage upon reaching a threshold current level on a pulse-by-pulse basis. Jensen, ¶86. As indicated by its Title, Li discloses systems and methods for providing over-current protection in a switching (pulsed) power supply. Li detects threshold current levels and terminates its voltage pulses to limit excessive current flow which can harm the device and the subject. *See* Li, ¶¶13-14, 24-28; Jensen, ¶¶86-87.

More specifically, Li senses a threshold current level and shortens (narrows) each voltage pulse to limit current. As shown in Fig. 2, below, Li discloses an over-current protection circuit 26 communicating with a current sense circuit 24 to detect threshold current levels.[1]

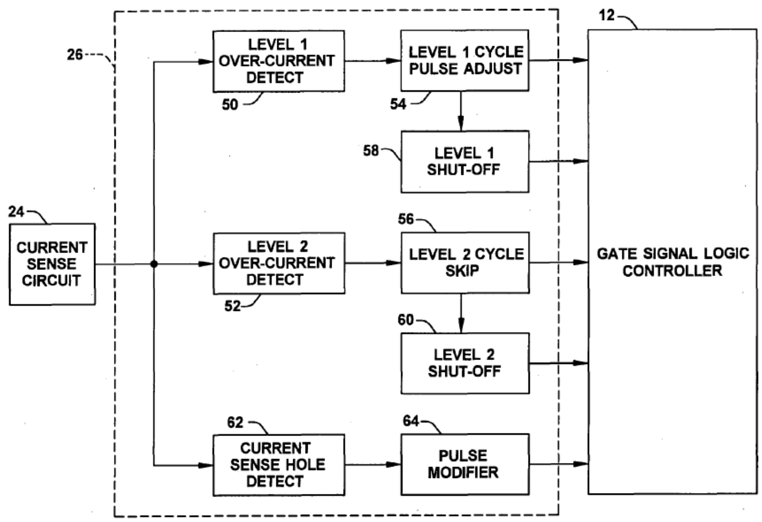

FIG. 2

Li teaches that its current sense circuit 24 forms a current sensor that measures the current in any variety of suitable manner. Li, ¶19. For example, Li's current sense circuit 24 can include a current sense resistor. *Id.* Li's current sense circuit 24 "provides the measured current to [the] over-current protection circuit 26."). *Id.*, 20.

When the sensor detects the threshold current level, Li narrows (terminates) the voltage pulse to limit the amount of current applied. *Id.*, 24 ("The gate signal

[1] Although Li suggests that additional threshold levels can be considered, it instructs that these different thresholds can be individually and/or exclusively applied. *See* Li, ¶27. Thus, for the purposes of clarity only a signal current threshold need be considered.

logic controller 12 could thus begin narrowing pulses or deactivating pulses early on the signal PWM_GD (not shown) that is used to control the switching supply 10."). Li's narrowed pulse terminates the voltage for each pulse. Li, ¶13 ("cycle-by-cycle narrowing of a pulse-width of the PWM signal, for example, by deactivating the pulse early during the current cycle or by narrowing subsequent pulses."); Jensen, ¶92. Thus, each of Li's pulses is terminated responsive to detection of the current threshold.

Li's threshold current level is a predetermined current level, for example, the level 1 current threshold set in advance. Li, ¶20 ("It is to be understood that the predetermined thresholds can be programmed to any desired values."). In its example, Li's threshold level 1 is a lower threshold. *Id.* And upon exceedance of the level 1 threshold, the over-current protection circuit sends a control signal to the logic controller to "begin narrowing the pulses of the signal PWM_GD on a cycle-by-cycle basis." *Id.*, ¶21. Accordingly, Li's level 1 threshold is a predetermined current level and causes termination of the voltage for each pulse. Jensen, ¶¶93-94.

Li teaches that its pulse narrowing provides the advantages of avoiding excessive current conditions. *See* Li, ¶¶13, 21; Jensen, ¶95. The ordinary artisan would have appreciated that limiting the current below an excessive threshold can reduce the risk of shock to the user and the subject, as well as the device itself.

Jensen, ¶¶95-96 (discussing excessive current generating shock risk). By reducing shock risk, practical advantages can be realized. For example, reducing shock can enhance device lifetime by reducing the exposure of device circuitry to higher current levels than desired. Similarly, reducing exposure to undesirably high current can provide corollary benefits such as enhanced device reliability and/or reduced warrantee issues. *Id.* These advantages would have been readily ascertained by the ordinary artisan in considering electronic control regimes for voltage pulsed devices. *Id.*

The benefits of current limitation are even more apparent in electro-surgical devices. Jensen, ¶97. Of course, avoiding high current in surgical applications using electricity could avoid risk of electric shock to the patient, the surgeon, and the device itself. Yet, in terms of surgical devices which apply intracorporeal (patient internal) electrical pulses, the hazards of over-current are exacerbated. *Id.* For example, the ordinary artisan would appreciate that intracorporeal procedures often take place in a highly conductive environment that is susceptible to unpredictable power transmittance. Moreover, such risks are enhanced in anesthetized patients who cannot consciously respond to confirm or deny the extent of trauma from wayward electrical power transmittance. *Id.*

Particular to lithotripsy devices which characteristically employ open electrical sparks, the need for current flow limitations is manifest. The ordinary artisan would have appreciated that the spark must exist for some period of time and at a sufficiently high voltage to cause the shockwave. Yet, equally apparent is that reducing excess electrical power (as taught by Li) to the minimum necessary for each spark to generate a shockwave reduces the patient exposure to unnecessary duration and intensity of open sparks. Jensen,¶98.

Thus, Li's current-limiting voltage control represents a practical manner of implementing known feedback techniques. In application to Hawkins, Li's feedback techniques merely serve to optimize electrical parameters already known for control in lithotripsy shockwave generation. *See* Hawkins, ¶50 ("The magnitude of the shockwave can be controlled by controlling the magnitude of the pulsed voltage, the current, the duration, and repetition rate."). Indeed, the incorporation of feedback control based on known control factors is the epitome of obviousness as merely a predictable use of prior-art elements according to their established functions. *See Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 558 F.3d 1341, 1351-52 (Fed. Cir. 2009) (finding known feedback control providing safety protections as ample motivation to combine, and obvious as a predictable use of prior-art elements). Accordingly, the artisan would have modified Hawkins to have Li's pulse narrowing control as discussed above, achieving all features as recited in combination in claim 1.

Furthermore, Li discloses its protection circuit to include a level 1 shut-off circuit 58 as an overriding current protection that independently meets the current sensing arrangements of claim 1. Li's level 1 shut-off circuit 58 "issues a shut-off command" to cease the voltage pulse responsive to the level 1 threshold current. Li, ¶25. More specifically, while Li's pulse narrowing control is processing, Li's shut-off circuit initiates a delay timer. "Upon the timer reaching a predetermined time, the level 1 shut-off circuit 58 could issue the shut-off command" which can be "reset" once the pulse is terminated. *Id.*; Jensen, ¶101 (resetting after current falls below the threshold which includes pulse termination). Li teaches that its level 1 shut-off circuit can be employed together with the pulse narrowing of its current limiter to provide overriding over-current protection. *Id.*

Li's overriding current protection is distinct from its current limiter protection because the overriding protection uses its delay timer for governing pulse termination and avoids additional logic processing. Li, ¶25; Jensen, ¶102. Upon expiration of the timer, no other determination must be made. *Id.* Li's overriding current protection provides a direct, fixed and predetermined period for pulse termination on exceeding the level 1 threshold. As Dr. Jensen explains, Li's overriding current protection can address instances in which the narrowing control process may act too slowly to properly address high current process conditions, and provides additional reliability in pulse termination. Jensen, ¶103. Applied individually, Li's overriding protection can reduce processing requirements, avoid response lag-time, and provide reliably-timed voltage termination. Yet, applied collectively with Li's pulse narrowing control, Li's overriding protection provides an additional layer of reliability in current protection. *Id.*, ¶¶103-104. The ordinary artisan would have appreciated that Li's overriding current protection would afford similar reliability advantages to Hawkins' EHL device and would constitute merely a predictable use of prior art arrangements according to their established function for over-current protection. *Id.*

Li's current limiter arrangements and overriding current protection arrangements are complimentary to each other but are divisible. Jensen, ¶105. For the purposes of this proceeding, Li's current limiter arrangement would constitute the pulse-by-pulse operation as recited in claim 1, whether applied alone or collectively with Li's overriding current protection arrangements. Yet, alternatively, Li's overriding current protection applied alone constitutes the pulse-by-pulse operation as recited in claim 1 providing fixed and direct voltage termination control, independent from further logical process implementation, improving high current protection reliability. Jensen, ¶106. Accordingly, either of Li's current limiter and overriding current protection arrangements would have been incorporated into Hawkins for their respective benefits, and/or collectively as enhancing their individual benefits. *Id.*

Therefore, for at least these reasons, the POSITA could and would have modified Hawkins to include Li's current limiter arrangement, including a current sensor for detecting current flow between Hawkins' electrodes during each voltage pulse, and wherein when the current reaches a predetermined value during each voltage pulse, the sensor generates a signal that causes the power source to terminate the voltage supplied to the electrodes for that pulse, in order to provide protection from high current conditions to the patient, the surgeon, and the device itself and the corresponding benefits as discussed above; and/or as a predictable use of feedback control arrangements of the prior-art according to their established functions and yielding no more than predictable results of protecting against high current. Further, the POSITA could and would have alternatively and/or additionally modified Hawkins to include Li's overriding current protection arrangement to enhance current protection reliability and/or a predictable use of feedback control arrangements of the prior-art according to their established functions and yielding merely predictable results of protecting against high current. For at least these reasons, Hawkins in view of Li achieves all features as recited in combination in claim 1.

Although Li is not specific to lithotripsy devices, the ordinary artisan would have looked to Li in considering pulsed voltage devices. Li is from the same field of control arrangements for electrically pulsed devices as is the focus of the '091

Patent. Moreover, Li's current protection arrangements are reasonably pertinent to EHL devices. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (analogous); *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398,402 (2007) (having same field and/or reasonably pertinent); *see also In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007) (commending itself to the inventor's attention); Jensen, ¶108.

The '091 Patent asserts that it addresses the problems of controlling the amount of energy applied from its voltage pulses. '091 Patent, 2:30-53 ("There is a need to control the energy applied to the electrodes."). But electrical power control in pulsed-devices is not unique to surgery. *See* Hawkins, ¶50; Jensen, ¶108. The ordinary artisan, having recognized that the amount of applied current is an important aspect of EHL, would look to solutions of others facing high current problems. *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1573–74 (Fed. Cir. 1983) (*citing Weathering Engineering Corp. of America v. United States*, 204 USPQ 41 (Ct.Cl. tr. div. 1979), aff'd, 208 USPQ 939 (1980)). Li's generic implementation of current-based pulse control would have been ripe for consideration in pulsed devices generally, and more so in applications desiring closely controlled electric power. Jensen, ¶108. Accordingly, Li's solutions to high current conditions in the area of pulsed voltage operations would have been appropriately considered by the POSITA for combination with Hawkins.

B. Dependent Claim 2 is Obvious over Hawkins in view of Li.

[2] <u>The balloon catheter of claim 1, wherein the predetermined value is 50 amps</u>.

The discussions above regarding Hawkins in view of Li as applied to claim 1 are incorporated here as to claim 2. Additionally, selecting a predetermined current threshold for Li's application to shockwave generation is no more than an optimization of a result-effective variable involving merely routine skill to the ordinary artisan. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1296 (Fed. Cir. 2012) ("“[D]iscovery of an optimum value of a result effective variable ... is ordinarily within the skill of the art..") (citations omitted). The artisan would have understood current as an important variable in shockwave generation of lithotripsy devices. *See* Hawkins, ¶50; Jensen, ¶109; File Wrapper, 50. And treating calcified lesions with at least 50 amps of current was known and routine at the time of alleged invention. *See e.g.*, Chernenko, claim 5; Jensen, ¶109 (range of at least 16.7-66.6 amps). Accordingly, setting the current threshold at 50 amps in combining Hawkins and Li, as discussed above, is merely a design choice within the routine skill of the artisan and does not patentably distinguish claim 1 over the cited art.

C. Dependent Claim 3 is Obvious over Hawkins in view of Li.

[3] <u>The balloon catheter of claim 1, wherein the carrier has a guidewire lumen</u>.

The discussions above regarding Hawkins in view of Li as applied to claim 1 are incorporated here as to claim 3. In addition, Hawkins discloses the claimed guidewire lumen. *See* Hawkins, ¶9 ("The catheter may further include a lumen for receiving a guidewire. The lumen may be defined by the catheter."); *see also id.*, ¶¶18, 23, 51, claims 8, 13, 18. Notably, Hawkins recognizes that the balloon catheter having a guidewire lumen was a "typical prior art over the wire angioplasty balloon catheter." Adding a dependent claim reciting a well-known feature of the prior art, to perform the same function, in the same manner, to provide the same expected result does not provide any patentable distinction. Moreover, the ordinary artisan would have understood to use a guidewire within the carrier of Hawkins to guide the catheter into position. Jensen, ¶110.

D. Dependent Claim 4 is Obvious over Hawkins in view of Li.

[4] The balloon catheter of claim 1, wherein the power source further includes a delay timer with a predetermined delay time, the delay timer being triggered in response to the sensor signal and wherein the voltage supplied to the electrodes is terminated after the predetermined delay time has expired.

The discussions above regarding Hawkins in view of Li as applied to claim 1 are incorporated here as to claim 4. Indeed, as demonstrated above, Hawkins teaches all features of claim 1, except may not explicitly disclose sensing current to control voltage pulses. However, Li remedies these features in Hawkins by teaching over-current protection arrangements including its current limiter and/or its overriding current protection arrangements. Although circuitry systems naturally include predetermined response delays (Jensen, ¶112), Hawkins as modified by Li achieves all features as recited in claim 4.

Hawkins as modified to limit current as taught by Li achieves the delay timer of claim 4 because narrowing pulses to limit current sets a predetermined delay time for pulse termination—the delay time being the pulse duration itself. Li's pulse narrowing arrangement includes the claimed delay timer embodied as its protection circuit and controller which determine the duration of each narrowed pulse. This can include the hardware and/or programming to achieve this pulse-narrowing operation. Jensen, ¶112. As discussed above regarding claim 1, Li's controller 12 determines the desired (narrowed) pulse duration. Li, ¶21. The controller 12 and protection circuit 26 terminate the pulse voltage after expiration of the narrowed duration. *Id.* Li's narrowed pulse duration is thus itself a delay time set by the controller. Jensen, ¶112.

Li's pulse time is set in advance. For example, Li institutes its pulse narrowing during the present pulse or for subsequent pulses—in both instances, Li's pulse termination time is set in advance by its controller. Li, ¶¶13, 21; Jensen, ¶114. Accordingly, Li's protection circuit and controller form a delay timer with a delay time as the pulse duration that is predetermined by its controller. Jensen, ¶114.

Li's delay timer is initiated in response to the sensor signal of threshold current and causes termination of voltage after expiration of its delay time. For example, upon exceedance of the level 1 threshold, Li's protection circuit activates its controller to "begin narrowing the pulses." *Id.*, ¶21. Li's voltage supply for each pulse is terminated after the predetermined pulse duration has expired because completion of the pulse duration terminates the pulse. Jensen, ¶115.

Thus, Hawkins as modified to include Li's pulse narrowing control achieves the additional limitations of claim 4 providing the same benefits as mentioned above regarding claim 1. Yet, Li's overriding protection arrangement, additionally and/or alternatively, meets the limitations of claim 4.

As discussed above, Li's overriding protection arrangement includes a shut-off circuit having a delay timer that causes a shut-off command to terminate pulse voltage. *See supra,* Part V(A); Li, ¶25; Jensen, ¶117. Dr. Jensen explains that Li's level 1 overriding protection arrangement provides a direct approach to pulse termination that operates without additional control processing. *Id.* Applied individually, Li's overriding protection can reduce processing requirements, avoid response lag-time, and generally provide reliably-timed voltage termination. Yet, applied collectively with Li's pulse narrowing control, Li's overriding protection provides an additional layer of reliability in current protection. *Id.* Accordingly, the POSITA would have employed Li's overriding protection individually or collectively with the pulse narrowing controls to provide reliable override protection and/or as a predictable use of prior art elements according to their established function. *Id.*; *see also Monolithic Power Sys., Inc.*, 558 F.3d at 1351-52.

Accordingly, the POSITA could and would have modified Hawkins to include Li's current limiter arrangement including its pulse narrowing control based on a predetermined current threshold forming a delay timer to terminate the voltage supplied to the electrodes for each pulse after a predetermined delay time, in order to provide protection from over-current conditions to the device itself, the patient, and the surgeon, and the corresponding benefits as discussed above regarding claim 1; and/or as a predictable use of feedback control arrangements of the prior-art according to their established functions and yielding no more than predictable results including protecting against high current levels. Further, the POSITA could and would have alternatively and/or additionally modified Hawkins to include Li's overriding current protection arrangement including its delay timer and predetermined delay time to enhance reliable current protection and/or a predictable use of feedback control arrangements of the prior-art according to their established functions and yielding no more than predictable results of protecting against high current. Accordingly, Hawkins as modified by Li achieves the delay timer having predetermined delay time as recited in claim 4.

E. Dependent Claim 5 is Obvious over Hawkins in view of Li.

[5] The balloon catheter of claim 4, wherein the predetermined delay time is 100 nanoseconds or more.

The discussions above regarding Hawkins in view of Li as applied to claims 1 and 4 are incorporated here as to claim 5.

Additionally, selection of a particular delay time is merely an optimization of a result-effective variable recognized within the prior art and having no patentable significance. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (holding optimization of result-effective variables is not inventive). As discussed above, the predetermined delay time was known within the prior art as taught by at least Li (as well as Heeren, discussed below) promoting programmable control arrangements to protect against high current conditions.

The '091 Patent indicates that this 100 nanoseconds delay time is merely the result of the natural response delay of the control scheme. '091 Patent, 10:60-11:9 ("Since it takes 100 nanoseconds for the switch to turn off and since 100 nanoseconds are timed before the turn-off signal is applied to the switch, 200 nanoseconds will pass before the applied voltage to the electrodes is actually terminated."). Thus, the claimed delay time is merely a complimentary design choice based on the selection of particular components, such as switches, having no patentable distinction from a different switch and delay time.

Moreover, the background art illustrates that delays of 100 nanoseconds or greater were within the known range of operational times. Indeed, the background article Broyer indicates a pulse duration of about 200 nanosecond, corresponding to the 200 nanosecond total delay duration mentioned by the '091 Patent. *Compare*, '091 Patent, 10:60-11:9 (200 nanoseconds) with Ex. 1010, Fig. 4; Jensen, ¶121 (about 200 nanoseconds). Further, Chernenko, also as a background reference, exhibits this feature by indicating pulse durations of 250-5000 nanoseconds, preferably 500-3000 nanoseconds, each of which exceed the claimed 100 nanoseconds. Chernenko, ¶59. Accordingly, the particular value of 100 nanoseconds was within the range of times well-known to the prior art and the artisan.

Therefore, the specific minimum delay times as claimed merely represent an optimized condition and/or a relative dimension (timing) for a given (and known) circuity implementation. Jensen, ¶122. The claimed delay time would have been routinely applied in either of the pulse narrowing and/or overriding protection controls as taught by Li as being within the known design criteria. *Id.* For at least these reasons, the claimed predetermined delay time of claim 5 is merely an optimization of a result-effective variable recognized within the prior art, a recitation of a relative dimension (timing), and/or a routine design choice lacking patentable significance. *Id.*

F. Independent Claim 6 is Obvious over Hawkins in view of Li.

The discussions above regarding Hawkins in view of Li as applied to claims 1 and 4 are incorporated here as to claim 6. For at least those same reasons discussed above regarding claims 1 and 4, Hawkins in view of Li achieves all features as recited in claim 6.

Claim 6 is identical to claim 1 regarding the initial recitation of the elongated carrier, flexible balloon, and pair of electrodes. Claim 6 also initially recites "a power source" which is identical to that recited in claim 1, except indicating that arc generation is performed "in the balloon" rather than "in the fluid." For the purposes of this proceeding, the asserted prior art discloses these aspects of the power source for similar reasons that the prior art discloses arc generation in the fluid. *See supra*, Part V(A); Jensen, ¶124. Moreover, there is no patentable distinction between arc generation performed "in the balloon" as opposed to "in the fluid" because the balloon is inflated with a conductive fluid and therefore being "in the balloon" necessarily includes being "in the fluid."

Claim 6 recites "wherein the power source includes a current sensor configured to detect current flow between the electrodes during each pulse." Thus, claim 6 recites "configured to detect current flow" in lieu of "for detecting the current flow" as recited in claim 1. For the purposes of this proceeding, the asserted prior art discloses these aspects of the current sensor of claim 6 for similar reasons that the prior art discloses the current sensor of claim 1. *See supra*, Part V(A); Jensen, ¶125.

Claim 6 further recites "wherein the power source is configured to terminate the voltage supply a predetermined delay time after the current has reached a predetermined value during each voltage pulse." For the purposes of this proceeding, the asserted prior art discloses these aspects of the power source of claim 6 for similar reasons that the prior art discloses the power source of claim 4. *See supra*, V(A); Jensen, ¶126.

For at least these reasons, Hawkins in view of Li achieves all features as recited in claim 6.

G. Dependent Claims 7-9 are Obvious over Hawkins in view of Li.

The references and arguments applied to claims 2, 3, and 5 are incorporated here regarding claims 7-9, respectively. For the purposes of this proceeding, the additional "predetermined delay time" feature included within independent claim 6, and included in claims 7 and 8 based on their dependency from claim 6, does not materially affect the analysis regarding the "50 amps" of claim 7 and the "guidewire lumen" of claim 8, compared with that of claims 2 and 3, respectively. Jensen, ¶128. For at least these reasons, Hawkins in view of Li achieves all features as recited in each of claims 7-9.

H. Independent Claim 10 is Obvious over Hawkins in view of Li.

The discussions above regarding Hawkins in view of Li as applied to claim 1 are incorporated here as to claim 10. For at least similar reasons discussed above, Hawkins in view of Li achieves all features as recited in claim 10.

Claim 10 recites "a method for delivering shockwaves to a calcified lesion" which is disclosed by the prior art combinations as applied to claim 1. The combinations of cited art as discussed above relative to claim 1 disclose each of advancing a balloon catheter, activating the power source, detecting a predetermined current value, and terminating the voltage, as recited in claim 10.

For example, Hawkins discloses the claimed balloon catheter including elongated carrier, flexible balloon, pair of electrodes, and power source. *See supra*, Part V(H). The ordinary artisan would have appreciated that Hawkins likewise teaches advancing its balloon catheter to the calcified lesion. Jensen, ¶130. Hawkins discloses activating its power source to produce one or more voltage pulses providing a current arc between the electrodes and producing a shockwave. *See* Hawkins, Figs. 2, 4, 5-9; *See also e.g.*, *id.*, ¶¶50-53; Jensen, ¶130.

As discussed above, Hawkins discloses at least reflected energy sensors which detect current by analogous sensing of reflected energy. *See supra*, Part V(A). However, to the extent that Hawkins may not expressly disclose terminating the voltage supplied to the electrodes after the current reaches the predetermined value for that pulse, Li discloses this feature to provide current protection to its voltage pulses and the benefits associated therewith. *See supra*, Part V(A&D); Jensen, ¶131.

For at least these reasons, Hawkins in view of Li achieves all features as recited in claim 10.

I. Dependent Claims 11-13 are Obvious over Hawkins in view of Li.

The references and arguments applied to claims 2, 4, and 5 are incorporated here regarding claims 11-13, respectively. For at least these reasons, Hawkins in view of Li achieves all features as recited in each of claims 7-9.

J. Independent Claim 14 is Obvious over Hawkins in view of Li.

The references and arguments applied to claims 1, 4, 6, 10, and 12 are incorporated here as to claim 14. For the same reasons as discussed above regarding claims 1, 4, 6, 10, and 12, Hawkins in view Li achieves all features as recited in claim 14.

Claim 14 is identical to claim 1 regarding the initial recitation of the elongated carrier, flexible balloon, and pair of electrodes. Claim 14 initially recites "a power source" which is identical to that recited in claim 1, except indicating that the power source is coupled to the electrodes for supplying a voltage to the electrode "to generate an arc in the fluid within the balloon and causing current to flow between the electrodes and producing a shockwave." Moreover, claim 14 includes a current sensor which generates a signal upon current reaching a predetermined value causing voltage termination, and a delay timer including a predetermined delay time that is triggered by the sensor signal and expires before termination of the voltage.

For the purposes of this proceeding, the asserted prior art discloses these aspects of the power source of claim 14 for the same reasons that the prior art discloses the (power source) operation of claims 4, 6, and 12. *See supra*, Part V(A&D); Jensen, ¶¶134-136. For at least these reasons, Hawkins in view of Li achieves all features as recited in claim 14.

VI. HAWKINS IN VIEW OF CHERNENKO

A. Independent Claim 1 is Obvious over Hawkins in view of Chernenko.

As discussed above and incorporated here, Hawkins discloses all features of claim 1, except may not expressly disclose sensing current to control voltage pulses. However, Chernenko teaches using current sensors in lithotripsy devices to terminate voltage pulses at threshold current levels. The examiner considered Chernenko during prosecution of the '091 Patent, but Chernenko's control of individual pulses was overlooked due to Patent Owner's misleading arguments.

Chernenko discloses an electro-hydraulic lithotripsy device providing shockwaves for addressing arterial calculi. Chernenko, Title & Abstract; Jensen, ¶144; Ex. 1011, ("File Wrapper"), p. 50. Chernenko teaches that "[i]gniting of spark discharge between the electrodes is used for destroying an object 150, residing at the work location." Chernenko, ¶56. Chernenko discloses a feedback control arrangement including a current sensor for terminating voltage supply to the electrodes. For example, Chernenko discloses current sensors 490,491 and control circuit 495. Chernenko, ¶¶71-72; *see also e.g.*, Fig. 4a. As discussed below, the ordinary artisan would have appreciated Chernenko's current sensor arrangement to afford early and reliable detection of sparks at the onset of dielectric breakdown. *See* Chernenko, ¶¶20, 38; claims 7 & 8 ("onset"); Jensen, ¶¶145.

While Chernenko was addressed during prosecution of the '091 Patent, the examiner misunderstood its control scheme over Patent Owner's arguments. Chernenko suggests that a series of pulses can generate a single spark. However, Chernenko also indisputably teaches using single pulses to each generate a spark. For example, Chernenko expressly states that "[t]he pulses can be applied ***either*** as onetime impulses ***or*** as repeating impulses."). Chernenko, ¶60; *see also id.*, ¶62 ("[E]ven after applying a signal impulse or a few impulses it is possible to destroy effectively various calculi."). Even in describing that its pulse count is adjustable, Chernenko again acknowledges that a signal pulse can be applied amid a range of 1-99 pulses. *See id.*, 81. Thus, Chernenko expressly teaches using individual pulses to each create a spark. Jensen, ¶151. Yet, as reviewed below, the examiner misunderstood Chernenko to exclude this teaching due to Patent Owner's misleading remarks.

During prosecution, Patent Owner amended the independent claims to include voltage <u>*pulses*</u>, attempting to circumvent Chernenko. Ex. 1011, 32. In its Remarks, Patent Owner explicitly acknowledged that Chernenko discloses current sensor 491 which senses threshold current (producing sparks) and thereafter responsively signals for voltage termination. *Id.*, 36-37; Jensen, ¶¶148-152. However, Patent Owner misleadingly directed the Examiner to consider switch 450, arguing that "[s]ince the delivery of pulses is triggered by 'non-controllable' switch 450, the Chernenko circuit cannot terminate a pulse." *Id.*, 37. Patent Owner's argument is not only false because Chernenko expressly teaches pulse termination, but it is also misleading because non-controllable switch 450 is irrelevant to Chernenko's normal control.[2]

Indeed, it is Chernenko's ***controllable*** switch 451 which is germane to its current sensors 490, 491 and control circuit 495. Chernenko, ¶71 ("The schematic comprises also a controllable switch 451, couple of current sensors 490,491 and a control circuit 495, provided with a pulse counter, indictor of pulse generation mode, and indicator of breakdown mode."); *see also id.*, Fig. 4a (current sensors 490,491 connected with control circuit 495); Jensen, ¶148 ("This 'breakdown' is the dielectric breakdown occurring upon arced current flow between the electrodes as the principal operation of electrohydraulic shockwave generation."). Using its current sensors, Chernenko terminates voltage upon either of two different operating scenarios: (i) reaching a numerical limit of voltage pulses, and (ii) sensing current of any pulse sufficient to provide dielectric breakdown forming a spark. *Id.*, ¶72 ("Both sensors are connected to the control circuit, which controls operation of the charging means and terminates it as soon as either a preset amount

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[2] As Dr. Jensen explains, the "non-controllable switch" 450 likely represented a safety or maintenance feature having no bearing on its normal surgical operations. Jensen, ¶150;

of pulses has been generated or the breakdown occurs."); Jensen, ¶148 (explaining that even a numerical limit of more than one pulse would terminate voltage on current threshold given routine power settings). Thus, although Chernenko can also halt voltage at a pulse limit, Chernenko undeniably teaches to terminate individual voltage pulses responsive to sensing a predetermined current threshold. *Id.*, ¶148.

Despite Chernenko's overt teaching to terminate each pulse on threshold current, Patent Owner misleadingly argued that the "non-controllable" switch 450 prevented Chernenko from operating exactly as disclosed. Ex. 1011, ¶37. Indeed, the Interview Summary from March 11, 2014 illustrates Patent Owner's ploy to ignore Chernenko's teachings noting that "the applicant stated that Chernenko terminates voltage after a group of pulses whereas applicant's invention focuses on pulse control." File Wrapper, 28.

However, as reviewed above, Chernenko's control includes termination after "onetime impulses." *See* Chernenko, ¶60 ("The pulses can be applied either as onetime impulses or as repeating impulses."), *see also id.*, ¶¶62, 81. Chernenko even touts its current-based individual pulse control having the advantages of reduced risk of unnecessary energy release and achieving short, but intense pulses. *Id.*, ¶¶20, 59; *compare id.*, claims 2 & 3; Jensen, ¶¶151-152. Indeed, Chernenko even contemplates giving the surgeon accessing a pedal to guide treatment pulse-by-pulse. Chernenko, ¶¶81-83; Jensen, ¶152.

Thus, although unrecognized during prosecution, Chernenko teaches to achieve high intensity pulses with reduced patient-impact by terminating each individual pulse upon threshold current. Jensen, ¶¶153-155. Whatever the source of the Examiner's confusion, it was only under a partial (and misguided) view of Chernenko that the '091 Patent was allowed—a view which ***directly conflicts*** with Chernenko's specific control arrangement that terminates individual pulse voltage in response to threshold current.

With this more accurate understanding of Chernenko's teachings, the final amendments to the challenged claims to recite voltage *pulses* assuredly did not transform common current-based feedback control for shockwaves into patentable subject matter. Ex. 1011, 32-34. Moreover, Chernenko's options for single or multiple pulses evidences that individual pulse control (and application) is merely routine optimization, design choice, and/or predictable use of known elements for their expected function. *Id.*

As mentioned above, Chernenko teaches the benefits of its current-based control to provide tight impulses having high intensity that use short rise and duration and increase the probability of spark formation. Chernenko, ¶59 (up to 20 kV). Chernenko teaches that its high intensity, short duration pulses can enhance calculi breakup in intracorporeal (internal) lithotripsy, preferably using a rectangular pulse wave. *Id.* As Dr. Jensen explains, this high intensity rectangular wave focuses the pulse energy to apply electric power for minimal duration by reducing the ramping times during which less-than-effective powers are applied. Jensen, ¶155.

In the context of pulses for the lithotripsy devices of Hawkins and Chernenko, this means that nearly the full duration of the rectangular pulse can provide the desired current level, reducing the patient's exposure to excess power. Although ideal rectangle pulse conditions are likely unattainable, Chernenko teaches to pursue rectangular waveforms of its current-based pulse control to reduce ramp times and enhance the shockwave generation while reducing trauma to the patient. *Id.*,¶¶156-157 Conversely, the artisan would appreciate that using less-than-rectangular waveforms might require higher currents than necessary for the same energy transfer as a rectangular waveform. *Id.*

Chernenko also teaches that its approach can enable control of calcified fragments during treatment, increase patient safety, and increase treatment reliability. *Id.*, ¶¶37-39, 109; Jensen, ¶158. Additionally, the POSITA would have appreciated that current-based control of voltage pulses merely applies prior art techniques according to their known functions to achieve expected results, and/or represents merely routine design choice. *See* Chernenko, ¶112 (noting that inductive, capacitive, resistive sensors could provide similar control); *see also* Hawkins, ¶50; Jensen, ¶158.

Therefore, the POSITA would have modified Hawkins to include a current sensor as taught by Chernenko for detecting current between the electrodes during each voltage pulse, and when the current reaches a predetermined value during each voltage pulse, the sensor generates a signal that causes the power source to terminate the voltage supplied to the electrodes for that pulse to provide tight control of intensely pulsed shockwaves to increase the probability of spark formation for each pulse, to reduce trauma from unnecessarily high current, to enable control of fragments, to increase patient safety, to increase treatment reliability, as a predictable use of known techniques yielding merely expected results, and/or as routine design choice. Jensen, ¶159. Accordingly, the combination of Hawkins and Chernenko renders claim 1 obvious.

B. Dependent Claim 2 is Obvious over Hawkins in view of Chernenko.

The discussions above regarding Hawkins in view of Chernenko as applied to claim 1 are incorporated here as to claim 2. Additionally, selecting the predetermined current threshold for Chernenko's breakdown indication is no more than an optimization of a result-effective variable involving merely routine skill to the ordinary artisan. Jensen, ¶160; File Wrapper, 50. The prior art recognizes current as an important shockwave variable of lithotripsy devices. *See e.g.*, Hawkins, ¶50 ("The magnitude of the shockwave can be controlled by controlling the magnitude of the pulsed voltage, the current, the duration, and repetition rate."); *see also* Chernenko, ¶112. And treating lesions with at least 50 amps of current was known at the time of alleged invention. *See e.g.*, Chernenko, claim 5; Jensen, ¶160 (range of 16.7-66.6 amps). Accordingly, the use of 50 amps as the current threshold is within routine skill and does not patentably distinguish claim 1 over the cited art.

C. Dependent Claim 3 is Obvious over Hawkins in view of Chernenko.

The discussions above regarding Hawkins in view of Chernenko as applied to claim 1 are incorporated here as to claim 3. In addition, Hawkins discloses the claimed guidewire. *See* Hawkins, ¶9 ("The catheter may further include a lumen for receiving a guidewire. The lumen may be defined by the catheter."); *see also id.*, ¶¶18, 23, 51, claims 8, 13, 18. Notably, Hawkins recognizes that the balloon catheter having a guidewire lumen was a "typical" angioplasty balloon catheter." Hawkins, ¶49. Adding a dependent claim reciting a well-known feature of the prior art, to perform the same function, in the same manner, to provide the same expected result does not provide any patentable distinction. Moreover, the ordinary artisan would have understood to use a guidewire within the carrier of Hawkins to guide the catheter into position. Jensen, ¶161.

D. Dependent Claim 10 is Obvious over Hawkins in view of Chernenko.

The discussions above regarding Hawkins in view of Chernenko as applied to claim 1 are incorporated here as to claim 10. Additionally, the comparison between the language of claim 10 and claim 1 regarding Hawkins and Li is likewise also here. *See supra*, Part V(H). For at least similar reasons discussed above, Hawkins in view of Chernenko achieves all features as recited in claim 10. Jensen, ¶162.

VII. HAWKINS AS MODIFIED BY CHERNENKO FURTHER IN VIEW OF LI

A. Independent Claim 1 and Dependent Claims 2 & 3 are Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins in view of Chernenko as applied to claims 1-3 are incorporated here as to claims 1-3.

As discussed above, Hawkins discloses all features of claim 1, except may not expressly disclose current sensing to provide voltage control, which Chernenko discloses to tightly control voltage pulses. Additionally, Li provides more specific control implementations, further motivating modification of Hawkins to include a current sensor providing voltage control as a practical implementation of active control feedback in its current protection. *See supra*, Parts V(A&D).

More specifically, Li provides further encouragement that individual pulse control can provide the advantage of protection from hazardous over-current conditions which can damage the device. Li, ¶4. The ordinary artisan would have appreciated that Li's current limiter and/or overriding current protection arrangements implemented in Hawkins' lithotripsy device (modified to use Chernenko's current sensors) can also avoid risks of (excessive) electrical shock and provide corresponding benefits to the patient, surgeon, and device as discussed above, and/or can provide consistent and reliable pulse control. Jensen, ¶165. Furthermore, implementing Li's known feedback control routines to achieve the recognized over-current protection results constitutes a predictable use of the prior-art according to their established functions and yielding merely predictable results of protecting against high current conditions. *See Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 558 F.3d at 1351-52 (Fed. Cir. 2009) (finding implementation of known feedback control providing safety protections obvious as a predictable use of prior-art elements).

Accordingly, Hawkins as modified by Chernenko and further in view of Li, achieves all features as recited in claims 1-3.

B. Dependent Claims 4 is Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins in view of Chernenko as applied to claim 1, and Hawkins as modified by Chernenko further in view of Li as applied to claim 1, are incorporated here as to claim 4. Hawkins discloses all features of claim 1, except may not expressly disclose current sensing to provide voltage control, which Chernenko discloses to tightly control voltage pulses, and for which Li provides more particular control implementations to provide high current protection. Li's control implementations includes a delay timer having predetermined delay time as recited in claim 4.

Having appreciated Chernenko's teachings to monitor current to control lithotripsy pulses, Li discloses a practical implementation of active feedback control for current protection. More specifically, Li teaches pulse narrowing which includes a delay timer having a predetermined delay time as the remaining pulse duration set in advance for each narrowed pulse. *See supra*, Parts V(A); Jensen, ¶167. Li discloses triggering its delay time, as its narrowed pulse duration, in response to threshold current levels. *Id.; see also* Li, ¶¶24-28. Upon sensing a threshold current level, Li responsively implements predetermined delay time to narrow (deactivate) each pulse to limit high current conditions. *Id.*, 21.

Li teaches that its pulse narrowing control arrangements provide the advantage of protection from hazardous high current conditions which can affect the device. Moreover, the ordinary artisan would appreciate that Li's current limiter implemented in Hawkins' lithotripsy device (modified to use Chernenko's current sensors) can likewise reduce the risk of electrical shock to the patient and the surgeon. *See supra*, Parts V(A). Furthermore, implementing Li's known feedback control routines to achieve the recognized over-current protection results constitutes a predictable use of the prior-art according to their established functions and yielding simply predictable results of limiting current. *See Monolithic Power Sys., Inc.*, 558 F.3d at 1351-52 (Fed. Cir. 2009).

Additionally and alternatively, Li's over-current protection provides an overriding current protection for voltage termination after a predetermined time delay from a delay timer meeting the limitations of claim 4. *See supra*, Parts V(D). Li teaches that on detection of the level 1 threshold current its shut-off circuit initiates a delay timer and issues the shut-off command to terminate voltage after the predetermined time expires. Li, ¶25. Li's overriding current protection provides a fixed and direct voltage termination independent from logical control implementation, improving high current protection reliability. Jensen, ¶169. Moreover, applying Li's overriding current protection to Hawkins' EHL device is merely a predictable use of the prior-art according to their established functions and yielding only predictable results of avoiding high current conditions. *Monolithic Power Sys., Inc.*, 558 F.3d at 1351-52 (Fed. Cir. 2009).

Accordingly, Hawkins as modified by Chernenko and further in view of Li, achieves all features as recited in claim 4.

C. Dependent Claim 5 is Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins as modified by Chernenko further in view of Li as applied to claims 1 and 4 are incorporated here as to claim 5. Additionally, selection of a particular delay time is merely an optimization of a result-effective variable recognized within the prior art and having no patentable significance. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (holding optimization of result-effective variables is not inventive). As discussed above, using a predetermined delay time was known within the prior art at least as taught by Li. Notably, Chernenko expressly meets this claim limitation by indicating pulse durations of 250-5000 nanoseconds, preferably 500-3000 nanoseconds, each of which exceed the claimed 100 nanoseconds. Chernenko, ¶59.

The '091 Patent indicates that this 100 nanoseconds delay time is merely the result of the natural response delay of the control scheme. '091 Patent, 10:60-11:9 ("Since it takes 100 nanoseconds for the switch to turn off and singe 100 nanoseconds are timed before the turn-off signal is applied to the switch, 200 nanoseconds will pass before the applied voltage to the electrodes is actually terminated."). Thus, the claimed delay time is merely a complimentary design choice based on the selection of particular components, such as switches, having no patentable distinction from a different switch and delay time.

Moreover, the background art illustrates that delays of 100 nanoseconds or greater were within the known range of operational times. Indeed, the background article Broyer indicates a pulse duration of about 200 nanosecond, corresponding to the 200 nanosecond total delay duration mentioned by the '091 Patent. *Compare*, '091 Patent, 10:60-11:9 (200 nanoseconds) with Ex. 1010, Fig. 4; Jensen, ¶174 (about 200 nanoseconds). Further, Chernenko also as a background reference exhibits this feature by indicating pulse durations of 250-5000 nanoseconds, preferably 500-3000 nanoseconds, each of which exceed the claimed 100 nanoseconds. Chernenko, ¶59. Accordingly, the particular value of 100 nanoseconds was within the range of delay times well-known to the prior art and the artisan.

Therefore, the specific minimum delay times as claimed merely represents an optimized condition and/or a relative dimension (timing) for a given (and known) circuity implementation. Jensen, ¶175. The claimed delay time would have been routinely applied in either of the pulse narrowing and/or overriding protection controls taught by Li as being within the known range of design criteria. *Id.* For at least these reasons, the claimed predetermined delay time of claim 5 is merely an optimization of a result-effective variable recognized within the prior art, a recitation of a relative dimension (timing), and/or a routine design choice lacking patentable significance. *Id.*

D. Independent Claim 6 is Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins in view of Chernenko as applied to claim 1, and regarding Hawkins as modified by Chernenko further in view of Li as applied to claims 1 and 4 are incorporated here at to claim 6. The comparison between the language of claim 6 and claim 1 regarding Hawkins and Li is likewise also here. *See supra*, Part V(F). For at least those same reasons discussed above regarding claims 1 and 4, Hawkins as modified by Chernenko and further in view of Li achieves all features as recited in claim 6.

E. Dependent Claims 7-9 are Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins as modified by Chernenko and further in view of Li as applied to claims 2, 3, and 5 are incorporated here regarding claims 7-9, respectively. For the purposes of this proceeding, the additional "predetermined delay time" feature included within independent claim 6, and included in claims 7 and 8 based on their dependency from claim 6, does not materially affect the analysis regarding the "50 amps" of claim 7 and the "guidewire lumen" of claim 8, compared with that of claims 2 and 3, respectively. Jensen, ¶177. For at least these reasons, Hawkins as modified by Chernenko and further in view of Li achieves all features as recited in each of claims 7-9.

F. Independent Claim 10 is Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins as modified by Chernenko as applied to claim 1, and regarding Hawkins as modified by Chernenko further in view of Li as applied to claim 1 are incorporated here as to claim 10. The comparison between the language of claim 10 and claim 1 regarding Hawkins and Li is also incorporated here. *See supra*, Part V(H). For at least similar reasons as discussed above regarding claims 1, Hawkins as modified by Chernenko and further in view of Li achieves all features as recited in claim 10.

G. Dependent Claims 11-13 are Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins in view of Chernenko and regarding Hawkins as modified by Chernenko further in view of Li, as applied to claims 2, 4, and 5 are incorporated here regarding claims 11-13, respectively. For at least these reasons, Hawkins as modified by Chernenko and further in view of Li achieves all features as recited in each of claims 11-13.

H. Independent Claim 14 is Obvious over Hawkins as Modified by Chernenko further in view of Li.

The discussions above regarding Hawkins in view of Chernenko at applied to claim 1, and regarding Hawkins as modified by Chernenko further in view of Li as applied to claims 1, 4, 6, 10, and 12 are incorporated here as to claim 14. The comparison between the language of claim 14 and claim 1 regarding Hawkins and

Li is likewise incorporated here. *See supra*, Part V(J). Additionally, claim 14 does not include a distinct recitation of voltage *pulses*, and therefore, these aspects of claim 14 would additionally be met by Chernenko's disclosure of voltage termination after a predetermined number of pulses at least as predictable use of known techniques yielding merely expected results. Jensen, ¶180. For at least these reasons, Hawkins as modified by Chernenko and further in view of Li achieves all features as recited in claim 14.

VIII. HAWKINS IN VIEW OF HEEREN

A. Independent Claim 1 is Obvious over Hawkins in view of Heeren.

Hawkins in view of Heeren achieves all features as recited in claim 1.

As discussed above and incorporated here, Hawkins discloses all features of claim 1, except may not expressly disclose sensing current to control voltage pulses. *See supra*, Part V(A). In the medical device arena, Heeren discloses control of pulsed-electric field (PEF) surgical devices, such as electrical tissue-cutting devices. *See e.g.*, Heeren, Abstract, ¶¶3-4. Heeren was not previously considered by the Office, but discloses a current sensor for detecting dielectric breakdown to control voltage pulses in surgical devices.

Heeren discloses electro-pulsed devices having a current sensor 126 to detect the onset of dielectric breakdown at the electrodes which causes sparking. *See e.g.*, Heeren, ¶¶17-18, 25-27; Jensen, ¶188. Although Heeren considers tissue-cutting tools, Heeren teaches how to control the negative effects of breakdown applicable to various surgical devices. For example, Heeren teaches to use its current sensors to "detect a dielectric breakdown right after it happens," providing early spark detection. Heeren, ¶27; Jensen, ¶188. Heeren explains that "a sudden increase of electric current" at the surgical site indicates dielectric breakdown. *Id.*

To perform detection, Heeren teaches to "compare the [current sensor data] to a threshold to determine … whether a dielectric breakdown has occurred." Heeren, ¶30. Heeren again explains that "[t]he threshold may correspond to an increase in current, which is predetermined." *Id.*

In implementing its current sensors, Heeren teaches to terminate voltage once reaching the current threshold. For example, Heeren teaches to dynamically adjust the pulse duration, upon reaching the current threshold. Heeren, ¶31 (dynamically adjusting any of pulse duty cycle, pulse duration, shape, and/or rise and fall time); *see also id.*, 32 ("If it is decided that the application of pulsed electric fields should not continue, pulsing of the electric fields is stopped."); Jensen, ¶190 (dynamic adjustment of pulse duration). Notably, Heeren expressly mentions reducing the pulse duration responsive to threshold current. Heeren, ¶33 ("reducing the strength, duration, and/or shape of the electric pulses delivered to the electrical site."). And, setting the pulse duration necessarily sets the pulse termination. Jensen, ¶190.

In application to Hawkins, the POSITA could and would have applied Heeren's current-threshold feedback control to each pulse. First, Heeren expressly teaches to reduce pulse duration on a pulse-by-pulse basis. Heeren, ¶¶33 (teaching that electrical pulses "may be adjusted in the middle of an electric pulse," or "between two electric pulses"); *see also id.*, ¶32. Moreover, the POSITA would have implemented Heeren's feedback control to each of Hawkins' pulses because Hawkins generates a spark with each pulse. Hawkins, ¶52; Jensen, ¶192. In controlling pulse duration for EHL devices which spark, the artisan would have applied Heeren's current-threshold feedback to each pulse (and spark) to avoid excessive amounts of spark current for each shockwave. Such pulse-by-pulse control provides efficient and safe operation for each open spark occurrence. Jensen, ¶193 (reducing pulse duration provides efficient control as well as protection).

Heeren teaches that its dynamic parameter adjustment provides the benefit of "reduce[d] damage from dielectric breakdown." *Id.*, ¶33. Specifically, Heeren teaches its dynamic pulse control to reduce damage to the patient from electrical-pulsed surgical devices, such as from excess heat, burns, or the like. Heeren, ¶¶33 (increasing the effectiveness of pulses without over-exposing the subject to damaging heat); *see also id.*, 4, 14, 24, 26. The POSITA considering Heeren would have appreciated that its dynamic control reduces excessive current flows that cause undue amounts of similar damage in shockwave devices, such as lithotripsy devices, because sparks are generated in the same fundamental way—through dielectric breakdown. Jensen, ¶194 (dielectric breakdown is manifestation of the onset of electrical spark).

The POSITA considering Heeren would have also appreciated its dynamic control to increase electrical efficiency of the device by applying only the threshold power required. Such efficiency can decrease component wear by reducing excessive power use and/or increase device versatility by allowing dynamic adjustment according to the particular parameters of the procedure. Jensen, ¶¶193-197. Notwithstanding these benefits, Heeren evidences that pulse-by-pulse voltage control on the basis of current was commonly known in electro-pulsed surgical devices at the time, and was merely a predictable use of prior art elements according to their established function. *Id.*, ¶196.

For at least these reasons, the POSITA could and would have modified Hawkins to include a current sensor and pulse-by-pulse voltage termination control based on a threshold current as recited in claim 1, to provide dynamic control of surgical shockwave generation to reduce ancillary damage and/or impact to the patient, to increase electrical efficiency, decrease component wear, increase device versatility, and/or as application of known elements according to their established function to yield merely predictable results. Accordingly, the combination of Hawkins and Heeren renders claim 1 obvious.

Although Heeren considers avoiding problems of dielectric breakdown, the ordinary artisan would have appreciated that Heeren's techniques apply equally to pulsed electrical devices in which controlled-dielectric breakdown is desirable. Jensen,¶198. As mentioned above, perhaps most evident is that spark generation, whether desirable or not, generally occurs based on the same fundamental phenomenon of dielectric breakdown. *Id*. Heeren, therefore, would have been readily considered by the ordinary artisan in designing control arrangements for electrically pulsed surgical devices. Indeed, control of the high current and voltage levels of lithotripsy devices would be particularly well-served by such feedback control where the risks of electrical shock are elevated. *Id.* As such, Heeren is within the field of endeavor of the '091 Patent and/or is reasonably pertinent to surgical devices using electrically pulsed energy. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (analogous); *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398,402 (2007) (having same field and/or reasonably pertinent); *see also In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007) (commending itself to the inventor's attention). Heeren's general teachings on the field of electrically-pulsed surgical devices would have readily been of interest in developing EHL devices. Heeren, ¶35; Jensen, ¶198.

B. Dependent Claim 2 is Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren applied to claim 1 are incorporated here as to claim 2. Additionally, selecting the predetermined current threshold indicating a spark sufficient to generate a shockwave is merely an optimization of a result-effective variable involving merely routine skill to the ordinary artisan. *See In re Applied Materials, Inc.*, 692 F.3d at 1295. The prior art recognizes current as an important variable in shockwave generation of lithotripsy devices. *See* Hawkins, ¶50; File Wrapper, 50; Jensen, ¶199. And treating calcified lesions with at least 50 amps of current was known at the time of alleged invention. *See e.g.*, Chernenko, claim 5; Jensen, ¶199 (range including at least 16.7-66.6 amps). Accordingly, the use of 50 amps is within routine skill and does not patentably distinguish claim 1 over the cited art.

C. Dependent Claim 3 is Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren applied to claim 1 are incorporated here as to claim 3. In addition, Hawkins discloses the claimed guidewire. *See* Hawkins, ¶9 ("The catheter may further include a lumen for receiving a guidewire. The lumen may be defined by the catheter."); *see also id.*, ¶¶18, 23, 51, claims 8, 13, 18. Notably, Hawkins recognizes that the balloon catheter having a guidewire lumen was a "typical prior art over the wire angioplasty balloon catheter." Adding a dependent claim reciting a well-known feature of the prior art, to perform the same function, in the same manner, to provide the same expected result does not provide any patentable distinction. Moreover, the ordinary artisan would have understood to use a guidewire within the carrier of Hawkins to guide the catheter into position. Jensen, ¶200.

D. Dependent Claim 4 is Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren as applied to claim 1 are incorporated here as to claim 4.

As reviewed in detail above, Hawkins discloses all features of claim 1, except may not expressly teach current sensing to effect voltage termination, which Heeren discloses to provide dynamic pulse control and its related benefits. As discussed below, Hawkins as modified by Heeren achieves the delay timer having predetermined delay timer as recited in claim 4 wherein Heeren's dynamic control sets the pulse duration as a delay time based on the threshold current.

As Dr. Jensen explains, Heeren's dynamic pulse control terminates individual pulses according to a predetermined delay time—i.e., the remaining duration of the individual pulse as determined by its processor. Jensen, ¶203; *see* Heeren, ¶¶32-33 (dynamic control including reducing pulse duration). And the ordinary artisan would have implemented Heeren's individual pulse modulation into Hawkins to increase pulse control accuracy and precision for a given spark event; reduce excessive power for each spark which can reduce trauma to the patient, decrease electrical shock risk to surgeon and device, provide efficient power usage, reduce component wear, and/or increase reliability; and/or as merely a predictable use of known current-based controls according to their establish functions and yielding only predictable results. *Id.*; *see supra*, Parts V(A&D).

Moreover, Heeren's dynamic controls applied in lithotripsy devices would have been recognized to provide optimization of spark generation. These optimizations apply to each pulse, but would also to the particulars of a given surgical procedure. For example, lithotripsy procedures may incur variation in any one or more of the conductivity of the dielectric, the acoustics of the balloon and/or arterial section, the efficiency of the electronics varied during its lifetime. Applying dynamic spark control can optimize the shockwave (and/or its generation) in consideration of these variations. Jensen, ¶204. Thus, the ordinary artisan would have applied Heeren's dynamic pulse control to Hawkins' lithotripsy device to optimize pulse control according to particular operating conditions—including in environments having varying electrical and shockwave conditions of Hawkins' shockwave balloon catheter. *Id.*

Therefore, the POSITA would have modified Hawkins' EHL device to include dynamic pulse control as taught by Heeren including its pulse duration control forming a delay timer having predetermined delay time as recited in claim 4, to provide increased pulse control accuracy and precision for a given spark event; reduced excess power for each spark which can reduce trauma to the patient, decreased shock risk to surgeon and device, efficient power usage, reduced component wear, and/or increased system reliability; and/or as merely a predictable use of prior art current-based controls according to their establish functions and yielding only predictable results.

Accordingly, Hawkins in view of Heeren achieves the delay timer as recited in claim 4.

E. Dependent Claim 5 is Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren applied to claim 4 are incorporated here as to claim 5.

Moreover, selection of a particular delay time is merely an optimization of a result-effective variable recognized within the prior art and without patentable significance. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (holding optimization of result-effective variables is not inventive). As discussed above, the predetermined delay time was known within the prior art at least as taught by Heeren (and also by Li as discussed above in Part V(A), *supra*).

The '091 Patent indicates that this 100 nanoseconds delay time is merely the result of the natural response delay of the control scheme. '091 Patent, 10:60-11:9 ("Since it takes 100 nanoseconds for the switch to turn off and singe 100 nanoseconds are timed before the turn-off signal is applied to the switch, 200 nanoseconds will pass before the applied voltage to the electrodes is actually terminated.”). Thus, the claimed delay time is merely complimentary design choice based on the selection of particular switches, having no patentable distinction from a different switch and delay time.

Moreover, the background art illustrates that delays of 100 nanoseconds or greater were within the known range of response delays. Indeed, Broyer indicates a pulse duration of about 200 nanosecond, corresponding to the 200 nanosecond total delay duration mentioned by the ‘091 Patent. *Compare*, ‘091 Patent, 10:60-11:9 (200 nanoseconds) with Ex. 1010, Fig. 4; Jensen, ¶210 (about 200 nanoseconds). Further, Chernenko, also as a background reference, exhibits this feature by indicating pulse durations of 250-5000 nanoseconds, preferably 500-3000 nanoseconds, each of which exceed the claimed 100 nanoseconds. Chernenko, ¶59. Accordingly, the particular value of 100 nanoseconds was within the range of delay times well-known to the prior art and the artisan.

Therefore, the specific minimum delay times as claimed merely represents an optimized condition and/or a relative dimension (timing) for a given (and known) circuity implementation. Jensen, ¶¶207-211. For at least these reasons, the claimed predetermined delay time of claim 5 is merely an optimization of a result-effective variable recognized within the prior art, a recitation of a relative dimension (timing), and/or a routine design choice lacking patentable significance. *Id.*

F. Independent Claim 6 is Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins as modified by Heeren as applied to claims 1 and 4 are incorporated here at to claim 6. The comparison between the language of claim 6 and claim 1 regarding Hawkins and Li is also incorporated here. *See supra*, Part V(F). For at least those same reasons discussed above regarding claims 1 and 4, Hawkins in view of Heeren, achieves all features as recited in claim 6.

G. Dependent Claims 7-9 are Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren as applied to claims 2, 3, and 5 are incorporated here as to claims 7-9, respectively. For the purposes of this proceeding, the additional "predetermined delay time" feature included within independent claim 6, and included in claims 7 and 8 based on their dependency from claim 6, does not materially affect the analysis regarding the "50 amps" of claim 7 and the "guidewire lumen" of claim 8, compared with that of claims 2 and 3, respectively. Jensen, ¶217. For at least these reasons, Hawkins in view of Heeren achieves all features as recited in each of claims 7-9.

H. Independent Claim 10 is Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren as applied to claim 1 are incorporated here as to claim 10. The comparison between the language of claim 10 and claim 1 regarding Hawkins and Li is likewise incorporated here. *See supra*, Part V(H). For at least similar reasons discussed above, Hawkins in view of Heeren discloses, teaches, and/or achieves all features as recited in claim 10. Jensen, ¶¶218-221.

I. Dependent Claims 11-13 are Obvious over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren as applied to claims 2, 4, and 5 are incorporated here at to claims 11-13, respectively. For at least these reasons, Hawkins in view of Heeren achieves all features as recited in each of claims 11-13. Jensen, ¶222.

J. Independent Claim 14 is Obvious Over Hawkins in view of Heeren.

The discussions above regarding Hawkins in view of Heeren as applied to claims 1, 4, 6, 10 and 12 are incorporated here as to claim 14. The comparison between the language of claim 14 and claim 1 regarding Hawkins and Li is likewise incorporated here. *See supra*, Part V(J). For at least similar reasons as discussed regarding claims 1, 4, 6, 10 and 12, Hawkins in view of Heeren achieves all features as recited in claim 14. Jensen, ¶¶223-224.

IX. MANDATORY NOTICES

A. Real Party-in-Interest

Cardiovascular Systems, Inc. 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. Counsel and Service Information

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D. Certification Of Grounds For Standing

Petitioner certifies pursuant to Rule 42.104(a) that the '091 Patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR on the grounds identified in this Petition.

X. CONCLUSION

Accordingly, as discussed hereinabove, the '091 Patent merely implements known feedback control techniques in a known lithotripsy device. In fact, the routine features which purportedly overcame certain prior art during prosecution were known within those prior art references, but appear to have been plainly misunderstood over misleading arguments by Patent Owner. Moreover, undiscovered art amply discloses controlling electrical pulses responsive to threshold currents and with delay timers, even within the specific area of surgical devices. With proper appreciation of the control schemes already known to the artisan, the challenged claims are unpatentable.

Accordingly, a reasonable likelihood exists that at least one of the challenged claims is unpatentable. Petitioner requests institution of review of all claims of the '091 Patent under 35 U.S.C. §314 and 37 C.F.R. §42.108, and that a final decision be entered canceling each of the challenged claims. Please charge any additional fees due in connection with the filing of this paper to our deposit account no. 505,196.

Respectfully submitted,

Dated: December 7, 2018

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

The undersigned certifies, pursuant to 37 C.F.R. §42.24(d) , that the word count for the foregoing Petition For Inter Partes Review Of U.S. Patent No. 8,728,091 Under 35 U.S.C. §312 AND 37 C.F.R. §42.104 totals 13,985, 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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CERTIFICATE OF SERVICE

The undersigned certifies that a complete true and correct copy of the Petition For *Inter Partes* Review Of U.S. Patent No. 8,728,091, and all supporting exhibits, 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 to the correspondence address of record as follows:

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