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Paper 14
Entered: July 11, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.
Petitioner,

v.

SHOCKWAVE MEDICAL, INC.,
Patent Owner.

Case IPR2019-00409
Patent 8,728,091 B2

Before MITCHELL WEATHERLY, RICHARD MARSCHALL, and AVELYN M. ROSS, *Administrative Patent Judges.*

ROSS, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Cardiovascular Systems, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–14 of U.S. Patent No. 8,728,091 B2 (Ex. 1001, "the '091 patent"). Shockwave Medical, Inc. ("Patent Owner") filed a Preliminary Response to the Petition (Paper 11, "Prelim. Resp.").

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons discussed below, after considering the parties' submissions and the evidence of record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one claim of the '091 patent. Thus, we institute *inter partes* review.

A. Related Proceedings

Petitioner states that it "is not aware of any judicial or administrative matter that would affect, or be affected by, a decision in the proceeding." Pet. 64. Patent Owner identifies concurrently filed petitions for *inter parties* review, IPR2019-00405 and IPR2019-00408, as related proceedings. Paper 3, 2. In addition, Patent Owner identifies several issued U.S. patents and applications as related matters. *Id.* at 2–3.

B. The '091 Patent

The '091 patent "relates to a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is used to cross a lesion in order to dilate the lesion and restore normal blood

flow in the artery." Ex. 1001, 1:15–18. Figure 1 below illustrates a simplified view of an angioplasty balloon catheter.

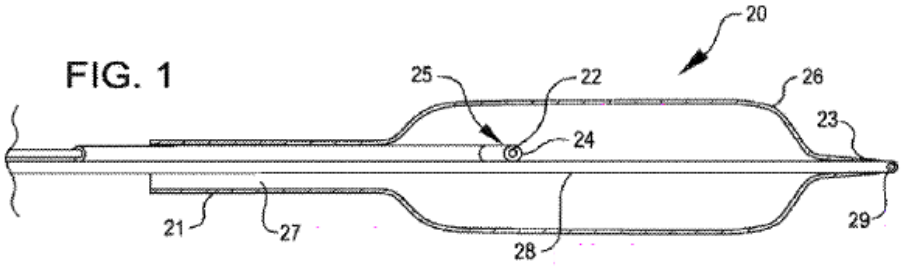

Figure 1 shows an angioplasty balloon catheter 20 including hollow sheath 21, dilating balloon 26, and guidewire 28. *Id.* at 7:34–40. The catheter includes shock wave generator 25, i.e., at least one pair of electrodes 22 and 24, within balloon 26 to generate a high voltage arc across the electrodes. *Id.* at 1:45–51. "The arc in turn causes a steam bubble to form" and "[e]ach steam bubble has the potential of producing two shock waves, a leading edge shock wave as a result of bubble expansion and a trailing edge wave as a result of bubble collapse." *Id.* at 1:56–62. Through use of repeated shockwaves, the calcified lesions can be broken up without damaging the surrounding tissue. *Id.* at 1:53–54. Because the trailing edge shock waves exhibit highly variable and greater energy levels, the '091 patent describes using the leading edge shock waves to create the steam bubble. *Id.* at 2:8–10. Even though the leading edge shock waves exhibit lower energy levels, these shock waves are a more consistent energy level. *Id.*

The '091 patent explains that "it has been learned that to sustain a leading edge shock wave, it is not necessary to sustain the high voltage throughout the shock wave" because it does not produce a shock wave of greater intensity and the heat produced by the steam bubbles may damage

tissue. *Id*. at 2:21–29. Therefore, "there is a need to control the applied energy to assure appropriate bubble and shock wave formation while at the same time conserving electrode material and assuring tissue safety." *Id.* at 2:49–52. The '091 patent explains that problems may be avoided and certain advantages are achieved by including a power source with a current sensor that sends signals to terminate the high voltage supply when current flow reaches a predetermined limit. *Id.* at 3:1–10, 8:20–40.

C. Illustrative Claims

Petitioner challenges claims 1–14 of the '091 patent. Independent claims 1 and 10 are illustrative of the challenged claims and are reproduced below:

> 1. A balloon catheter for delivering shockwaves to a calcified lesion comprising:
>
> an elongated carrier;
>
> a flexible balloon mounted on the elongate carrier, said balloon being fillable with a conductive fluid;
>
> a pair of electrodes on the elongated carrier within the balloon; and
>
> 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;
>
> 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.

Ex. 1001, 11:28–46.

> 10. A method for delivering shockwaves to a calcified lesion comprising:
>
> advancing a balloon catheter to a calcified lesion wherein the balloon catheter includes an elongated carrier, a flexible balloon, and a pair of electrodes on the elongated carrier within the balloon, wherein the electrodes are connected to a power source;
>
> activating the power source to supply one or more voltage pulses to the electrodes such that during each pulse, an arc is generated in the balloon and a current flows between the electrodes producing a shockwave;
>
> detecting when the current reaches a predetermined value during each pulse; and
>
> terminating the voltage supplied to the electrodes after the current reaches the predetermined value for that pulse.

Id. at 12:19–33. The remaining independent claims, claims 6 and 14, differ primarily in that each additionally requires termination of the voltage supply at a *predetermined time* after the current has reached a predetermined threshold. Ex. 1001, 11:59–12:2, 12:41–62 (claim 14 requiring a "delay timer" to trigger the timer in response to the current sensor signal).

D. The Asserted Grounds of Unpatentability

Petitioner contends claims 1–7 of the '453 patent would have been obvious in view of the following grounds of unpatentability (Pet. 4):

References	Basis	Claims Challenged
Hawkins[1] and Li[2]	§ 103	1–14
Hawkins and Chernenko[3]	§ 103	1–3, 10

[1] Hawkins, et al., US 2009/0312768 A1, published December 17, 2009 (Ex. 1003).
[2] US 2006/0221528 A1, issued October 5, 2006 (Ex. 1004).
[3] US 2003/0176873 A1, issued September 18, 2003 (Ex. 1005).

References	Basis	Claims Challenged
Hawkins, Chernenko and Li	§ 103	1–14
Hawkins and Heeren[4]	§ 103	1–14

In support of its obviousness arguments, Petitioner relies on the declaration testimony of Dr. Morten Olgaard Jensen. Ex. 1002.

II. ANALYSIS

A. Applicable Law

"In an IPR [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a) (3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review). Furthermore, a petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of

[4] US 2013/0041355 A1, published February 14, 2013 (Ex. 1006).

the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Consideration of the *Graham* factors "helps inform the ultimate obviousness determination." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc), *cert. denied*, 138 S. Ct. 420 (2017). To prevail in an *inter partes* review, Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable.

At this preliminary stage, we determine whether the information presented shows a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been obvious over the proposed prior art.

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We review the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time of the invention. *Graham*, 383 U.S. at 17. Petitioner submits that the ordinarily skilled artisan would have

> 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.

Pet. 7; *see also* Ex. 1002 ¶¶ 36–37 (same).

Patent Owner does not disagree with Petitioner's description of the level of ordinary skill in the art. *See generally* Prelim. Resp. Neither Petitioner nor Patent Owner indicates that the outcome of any arguments made in this case would change depending on the level of ordinary skill in the art.

For purposes of this Decision, and based on the record currently presented, we accept Petitioner's definition.[5] Further, we find that the prior art of record reflects the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). We will make a final determination as to the level of ordinary skill in the art, however, based on the full trial record.

C. Claim Construction

In an *inter partes* review filed after November 13, 2018, we construe claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b);[6] *see Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

[5] For purposes of this Decision, we find that Dr. Jensen is qualified to opine as to the knowledge of a person of ordinary skill in the art at the time of the invention. Ex. 1002 ¶¶ 8–13 (statement of qualifications), Appendix A (curriculum vitae).

[6] On October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340

Petitioner provides proposed constructions for the terms "predetermined value" (Pet. 8) and "predetermined delay time" (*id.* at 9). Petitioner asserts "predetermined value" means "a value set in advance" and "predetermined delay time" means "a delay time set in advance." *Id.* at 9–10. Patent Owner does not propose any express construction for any claim language. *See generally* Prelim. Resp.

At this stage, none of the constructions proffered for the terms identified by the Petitioner is argued as dispositive of the issue of whether to institute *inter partes* review. Accordingly, we need not resolve the meaning of terms "predetermined value" or "predetermined delay time" at this time. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

D. Obviousness in view of Hawkins and Li

Petitioner contends the subject matter of claims 1–14 would have been obvious over the combined disclosures of Hawkins and Li. Pet. 12–35.

1. Hawkins

Hawkins discloses a treatment system for the dilation of calcified lesions or plaque in an artery wall. Ex. 1003 ¶ 2. According to Hawkins, the invention includes a catheter comprising an elongated carrier, a dilating balloon, and an arc generator comprising at least one electrode within the

(Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). This rule change applies to petitions filed on or after November 13, 2018. *Id*.

balloon. *Id.* ¶ 3. The arc generator is connected to a power source and forms shockwaves within the balloon that are used to break up the calcified lesion. *Id.* ¶¶ 10, 51. One exemplary embodiment is shown below in Figure 15.

FIG. 15

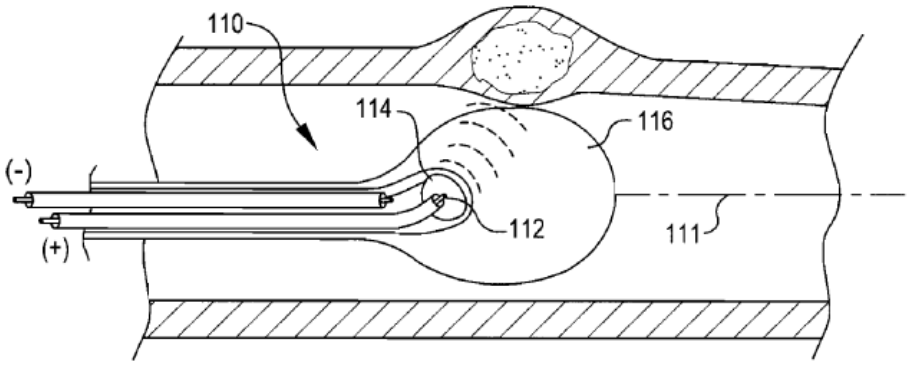

Figure 15 illustrates a dilation catheter 110 with a balloon 116. Ex. 1003 ¶ 64. The catheter includes a parabolic reflector 114, which acts as an electrode, and electrode 112 between which an arc is formed that generates a shockwave focused on the calcified lesion. *Id.* Catheter 110 may be equipped with a sensor, located on the distal end on one electrode, to sense reflected energy. Ex. 1003 ¶¶ 6, 58.

2. Li

Li discloses a system and method for "providing over-current protection in a switching power supply." Ex. 1004 ¶ 2. According to Li, the switching power supply may include a current sense circuit and a shut-off circuit. *Id.* ¶ 5. For example, when the over-current protection circuit receives a measured current value from the current sense circuit, the "over-current detector 50 determines that the measured current is between a first

predetermined over-current threshold and a second predetermined over-current threshold, then the level 1 over-current detector 50 activates the level 1 cycle pulse adjust circuit 54." *Id.* ¶ 24. The gate logic controller then begins "narrowing pulses or deactivating pulses." *Id.* The cycle pulse adjust circuit may also be connected to a shut-off circuit where "[t]he level 1 shut-off circuit 58 monitors the activity of the level 1 cycle pulse adjust circuit 54 and issues a shut-off command . . . upon the occurrence of a level 1 predetermined threshold condition." *Id.* ¶ 25. The shut-off circuit may include a timer where "[u]pon the timer reaching a predetermined time, the level 1 shut-off circuit 58 could issue the shut-off command." *Id.*

3. Analysis

Petitioner argues that "Hawkins discloses all the features of claim 1, except it may not expressly disclose directly sensing current to control voltage pulses." Pet. 12. Petitioner asserts that Hawkins describes balloon catheter that includes an elongated carrier, a flexible balloon, a pair of electrodes within the balloon, and a power source to generate current arcs within the fluid to produce shockwaves. Pet. 12–14 (citing Ex. 1003 ¶¶ 2, 3, 10, 14, 19, 38, 42, 45, 46, 49–55, 56–62, 64, 72, 82, 84 and Figs. 2–15; Ex. 1002 ¶¶ 79–83). Relevant to the claimed current sensor, Petitioner argues that Hawkins describes a sensor located on the distal end of one electrode to detect reflected energy signals. *Id.* at 15 (citing Ex. 1003 ¶¶ 6, 15, 22, 37, 57–58, Fig. 9; Ex. 1002 ¶ 85). In particular, Dr. Jensen testifies that because the reflected energy indicates effectiveness of the shockwave resultant from the current flow, it is analogous to current sensing. *Id.* at 15; *see also* Ex. 1002 ¶ 84 (same).

Additionally, Petitioner asserts that Li describes a current sense circuit that detects current levels and provides the measured current to the over-current protection circuit. *Id.* at 16. "When the sensor detects the threshold current level, Li narrows (terminates) the voltage pulse to limit the amount of current applied" for each pulse. *Id.* at 16–17 (citing Ex. 1004 ¶¶ 24). Petitioner reasons that the person of ordinary skill in the art would have reason to combine Hawkins and Li to "reduce the risk of shock to the user and the subject, as well as the device itself." *Id.* at 17 (citing Ex. 1002 ¶¶ 95–96). Dr. Jensen testifies that, in addition to the practical advantage of avoiding electric shock, reducing shock risk provides advantages such as enhanced device lifetime, enhanced device reliability, and reduced warranty issues. Ex. 1002 ¶¶ 95–98; *see also* Pet. 18–19 (same).

Petitioner also argues that Li's level 1 shut-off circuit independently meets the current sensing requirements of claim 1 alone or together with Li's current sense circuit. Pet. 20. Petitioner explains that the shut-off circuit initiates a delay timer once a threshold current is sensed. *Id.* When the delay timer reaches a predetermined time, the shut-off circuit issues a shut-off command to terminate the pulse. *Id.* Petitioner reasons that when applied individually, the shut-off circuit "reduce[s] processing requirements, avoid[s] response lag-time, and provide[s] reliably-timed voltage termination." *Id.* at 20–21; *see* Ex. 1002 ¶¶ 103–104. When applied in combination with the current sense circuit, Petitioner asserts "Li's overriding protection provides an additional layer of reliability in current protection." *Id.* at 21 (citing Ex. 1002 ¶¶ 103–105).

Petitioner asserts that "Li is from the same field of control arrangements for electrically pulsed devices" and is "reasonably pertinent to

EHL [electrohydraulic lithotripsy] devices." Pet. 22–23. In particular, Petitioner states that the '091 patent describes problems with controlling the energy levels of its pulses, which is not unique to surgical environments. *Id.* at 23. Therefore, "[t]he 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." *Id.*

Patent Owner does not dispute Petitioner's allegations regarding the teachings of Hawkins, but instead focuses its argument on whether Petitioner has shown the modification of Hawkins to include the Li current sensor would have been obvious to one of skill in the art. At this stage in the proceeding, Petitioner's evidence is sufficient to show all elements of claim 1 of the '091 patent except for a current "sensor [that] generates a signal that causes the power source to terminate the voltage supplied to the electrodes for that pulse." Ex. 1001, 11:40–46; Pet. 12–14. Below, we address whether Li teaches the requisite current sensor, which Patent Owner disputes.

Patent Owner first argues that Li is not analogous and therefore, the person of ordinary skill in the art would not have applied Li to Hawkins. In particular, Patent Owner argues that "Li describes a Texas Instruments switching power supply (such as might have been used with a laptop computer) that is not suitable for high-voltage plasma arc applications which operate in the kilovolt range," and therefore, is not relevant to the same field of endeavor. Prelim. Resp. 19 (citing Ex. 2007, 33–37, Ex. 2020).

Although Patent Owner's argument that Li is non-analogous may ultimately have some merit, it is not currently supported by evidence and may be based on an impermissibly narrow interpretation of the claim.

Claim 1 of the '091 patent is broad and does not require any particular voltage level. *See* Ex. 1001, 11:27–46. Furthermore, even if we were to limit claim 1 to high voltage applications, Li is silent about whether it is useful in either of high or low voltage applications, much less laptop computers, as Patent Owner alleges. *See generally* Ex. 1004. Lastly, Patent Owner fails to cite evidence connecting Li with the Texas Instruments low-voltage power supplies identified by Patent Owner. *See* Prelim. Resp. 19 (relying on Ex. 2007, 33–37).

Patent Owner further argues that the combination of Hawkins and Li must fail because Petitioner has failed "to explain how Li's low voltage current sensor arrangement would need to be modified so that it would function for use in Hawkins' high-voltage application." Prelim. Resp. 23. Patent Owner contends that the Texas Instruments device operates at 20V where Hawkins operates up to 3,000V. *Id.* at 22–23. Patent Owner cites no evidence to support this contention.

As detailed above, the evidence of record does not support Patent Owner's allegations. Neither Li nor claim 1 are limited to either high-voltage or low-voltage applications. And, the record does not establish any relationship between Texas Instruments low-voltage power supplies and those described by Li.

Patent Owner also contends that "Li includes a current sensor that is used to monitor the current level flowing through a transistor P1 in the pulse width modulation circuit 16 to prevent the transistor from being destroyed, *not across the output terminals to protect the device or object to which the output voltage is applied*." Prelim. Resp. 25 (emphasis in original). Referring to Fig. 1, Patent Owner explains that current sense circuit 24 is

associated with P1 and therefore "protect[s] the circuit itself, not the item to which the output voltage is applied." *Id.* Furthermore, Patent Owner argues that the approach in Li measures current within the pulse generation circuit as opposed to at the load, i.e., across the electrodes. *Id.* at 26. Patent Owner reasons that applying Li to Hawkins would result in the current sensor being placed "*within Hawkins variable HV source* to protect it from damage, *not at the output (electrodes) as required by the claims.*" *Id.* Furthermore, Patent Owner contends that "Petitioner does not offer any reason why, in the combined system of Hawkins and Li, the current would [be] monitored [between Hawkins electrodes] instead of the location specifically suggested in Li (i.e., at the waveform generation module)." *Id.* at 27.

We are not persuaded by Patent Owner's arguments because they rest on bodily incorporation. In particular, Patent Owner asserts that Li's sensors, if used in Hawkins, would be placed in the location described in Li. Bodily incorporation is not the standard for obviousness analysis. *See In re Mouttet*, 686 F.3d 1322, 1332–33 (Fed. Cir. 2012); *see also MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015) ("[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference" (citation omitted)), *cert. denied*, 137 S. Ct. 292 (2016). "Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted). Dr. Jensen testifies that a person skilled in the art would have modified Hawkins to include "a current sensor for detecting current *flow between Hawkins' electrodes* during each voltage pulse." Ex. 1002 ¶106. Petitioner proposes substituting the Hawkins sensor—located at the

distal end of one electrode—for that of Li, therefore, the sensor would be positioned to detect current flow *across* the electrodes. Pet. 19, 22; Ex. 1002 ¶106. Further, Dr. Jensen testifies that "the need for current flow limitations is manifest" and 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." Pet. 18–19 (citing Ex. 1002 ¶ 98); *see also* Ex. 1002 ¶ 97 ("The need for tightly controlled current flow is readily apparent because of the open nature of the electrical arc in proximity to the highly conduction patient-internals.").

Lastly, Patent Owner contends that there is no reason to combine Hawkins and Li. Prelim. Resp. 30. According to Patent Owner, Petitioner fails to articulate a reason to include Li's current sensor in Hawkins because Li's sensing has not been shown to be superior to that of "Hawkins' sensing of current 'by analogy.'" *Id.* Patent Owner urges that merely because Li provides an alternative technique for monitoring current it is insufficient to show obviousness. *Id.* Patent Owner also contends that the proffered reason to combine—protection from high current conditions—omits analysis of "how a skilled artisan would have known what the minimum necessary spark length was." *Id.* at 32.

We are not persuaded by Patent Owner's arguments. While Hawkins may "by analogy" describe a current sensor, a showing of superiority is not required for obviousness. A claim is obvious where it '"simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (quotes and citation omitted); *In re Mayne*, 104 F.3d 1339, 1340 (Fed. Cir.

1997) ("Because the applicants merely substituted one element known in the art for a known equivalent, this court affirms [the rejection for obviousness]."). Furthermore, Petitioner explains that Li provides voltage control features that Hawkins recognizes as beneficial. *See* Pet. 19 (citing Ex. 1003 ¶ 50) ("The magnitude of the shockwave can be controlled by controlling the magnitude of the pulsed voltage, the current, the duration, and repetition rate.")). Dr. Jensen testifies that the ordinarily skilled artisan would have understood that circuitry operating at current levels in excess of design parameters can result in short-circuiting, overheating, and component wear. Ex. 1002 ¶ 94. In addition, Dr. Jensen testifies that "in the context of surgical devices, reducing risk of undesirable electrical shock in the device can likewise reduce the risk of shock to the surgeon and/or patient . . . . would have been readily ascertained by the ordinary artisan in considering current protection regimes for voltage pulsed devices." *Id.* ¶¶ 95; 98.

Accordingly, at this stage of the proceeding, Patent Owner's arguments are unpersuasive. In view of the foregoing, Petitioner has demonstrated a reasonable likelihood that claim 1 of the '091 patent would have been obvious over the combined disclosures of Hawkins and Li. We have considered Petitioner's and Patent Owner's arguments as to independent claim 14, and we similarly determine that Petitioner has shown sufficiently, for purposes of this Decision, that there is a reasonable likelihood that all the limitations recited in claim 14 are suggested by the Hawkins/Li combination. *See* Pet. 20–23, 26–29, 35 (citing Ex. 1004 ¶¶ 13, 21, 25; Ex. 1002 ¶¶ 101–106, 112, 114–115, 117, 134–136).[7] Patent Owner

[7] By way of example, claim 14 additionally recites a delay timer that is triggered by the current sensor signal and causes the power source to

does not challenge Petitioner's allegations as to independent claims 6 and 10 or dependent claims 2–5, 7–9, and 11–13 separate from the arguments advanced for claims 1 and 14. Based on our independent review of the Petition and cited evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it will prevail at trial in showing that the subject matter of claims 2–13 was suggested by the combined teachings of Hawkins and Li prior to the application leading to the '091 patent.

E. Obviousness in view of Hawkins and Chernenko

Petitioner contends the subject matter of claims 1–3 and 10 would have been obvious over the combined disclosures of Hawkins and Chernenko. Pet. 36–43.

1. Chernenko

Chernenko is directed to systems and methods of intracorporeal lithotripsy using electro-hydraulic destruction or electro-impulse destruction to disintegrate or destroy stones and other calculi. Ex. 1005 ¶¶ 1, 55–58. Chernenko explains that "[i]t has been found, that by virtue of the present invention that even after applying of a single impulse or a few impulses it is possible to destroy efficiently various calculi." *Id.* ¶ 62. Chernenko's system includes current sensors "connected to the control circuit, which controls operation of the charging means and terminates it as soon as either a preset amount of pulses has been generated or the breakdown occurs, whatever comes first." *Id.* ¶ 72.

terminate after a predetermined time. Ex. 1001. 12:57–61. Petitioner alleges that Li describes a delay timer. Pet. 20–21, 26–27, 35 (citing Ex. 1004 ¶¶ 13, 21, 25; Ex. 1002 ¶¶ 101–104, 112, 114–117, 134–136).

2. Analysis

Petitioner argues that "Hawkins discloses all features of claim 1, except [Hawkins] 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." Pet. 36. Petitioner asserts that Chernenko describes spark generation through the application of "*either* as onetime impulses *or* as repeating impulses." *Id.* at 37 (citing Ex. 1005, ¶¶ 60, 62). According to Petitioner, Chernenko's sensor "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.* at 38 (citing Ex. 1005 ¶¶ 72, 148). Petitioner contends that the skilled artisan would have reason to modify Hawkins to include Chernenko's current sensors "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, [and] to increase treatment reliability." *Id.* at 42 (citing Ex. 1002 ¶ 159); *see also id.* at 39–41 (citing Ex. 1005 ¶¶ 20, 37–39, 59; Ex. 1002 ¶¶ 151–158).

Consistent with Patent Owner's practice in addressing the combination of Hawkins and Li (above), Patent Owner here does not dispute Petitioner's allegations regarding the teachings of Hawkins, but rather centers its argument on whether Petitioner has shown that the modification of Hawkins to include the Chernenko current sensor would have been obvious.

First, Patent Owner contends that "Chernenko's circuit cannot prematurely terminate a pulse because the circuit is incapable of selectively terminating the pulse once a pulse has started." Prelim. Resp. 34. Patent Owner explains its position with reference to modified Figure 4(b)[8], reproduced below.

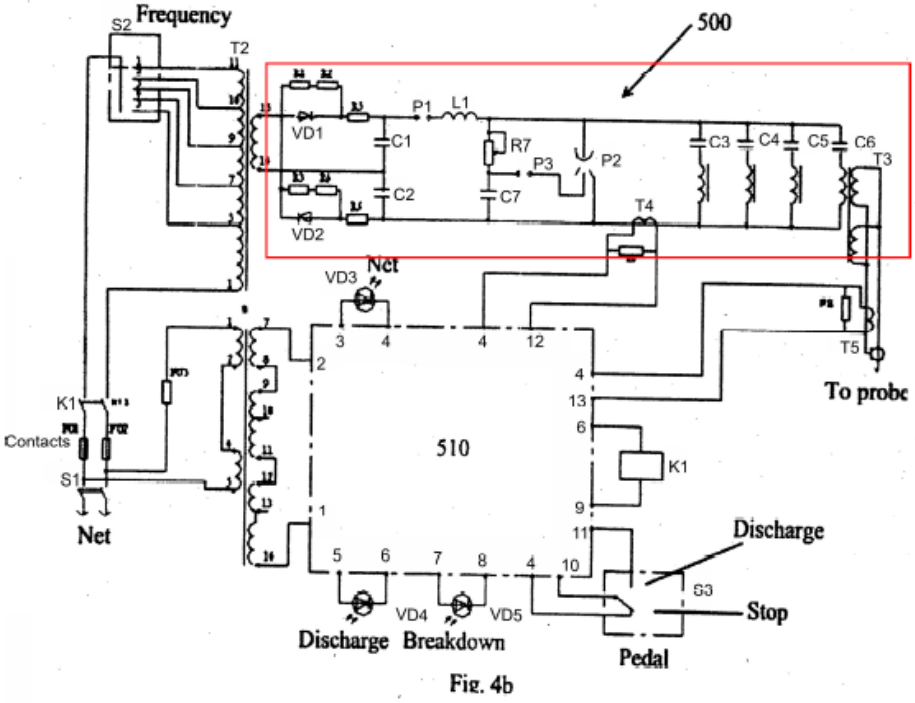

Fig. 4b

Modified Figure 4b depicts schematics of the pulse generator for Chernenko's lithotripter. Ex. 1005 ¶¶ 50, 51. Patent Owner argues that transformers T4 and T5 detect voltage spikes and are connected to a control circuit which controls operation of the charging means and terminates voltage when either a preset number of pulses has occurred or a dielectric breakdown occurs. Prelim. Resp. 39–40 (citing Ex. 1005 ¶¶ 72, 75, 79, 83). Patent Owner states that in operation, Chernenko's circuit builds up charge

[8] Figure 4(b) is modified to "include more legible reference numerals or letters." Prelim. Resp. 39–40 n2.

in capacitor bank C3/C4/C5/C6. *Id.* (citing Ex. 1005 ¶¶ 74–77). Therefore, Patent Owner argues,

> shutting off the voltage generator 430 only prevents the formation of later pulses by preventing <u>re</u>charging of the capacitor bank C3/C4/C5/C6. *There is simply no means in Chernenko to stop the discharge of a capacitor bank C3/C4/C5/C6 once it has started. Thus, there is no mechanism in Chernenko to terminate a pulse once it has started.*

Id. at 42.

Patent Owner's argument may ultimately have some merit but it is currently unpersuasive as the impliedly expert analysis by Patent Owner's counsel of Chernenko and is not supported by appropriate evidence. The argument also relies upon an unrelated reference purportedly describing the function of circuits similar to that of Chernenko. *See* Prelim. Resp. 35–38 (citing Ex. 2018), 39 (stating that "[t]he operation of Chernenko's control circuit, which has the same functionality as Motisan's [Ex. 2018], will now be reviewed in detail").

Next, Patent Owner argues that "because Chernenko works on a fundamentally different principle than Hawkins, a skilled artisan would understand that the modified Hawkins device would not enjoy these advantages." Prelim. Resp. 44. Specifically, Patent Owner states that "Chernenko nowhere suggests that this advantage [i.e., increased probability of spark propagation] would be achieved when generating sparks in a liquid medium and Petitioner has made no such showing." *Id.* at 45–46. Patent Owner further argues that Petitioner failed to correlate the advantages of patient safety and reliability to the current sensors of Chernenko. *Id.* at 46.

At this stage in the proceeding, we do not find Patent Owner's arguments persuasive. Patent Owner's argument is based on the assertion

that "Chernenko works on a fundamentally different principle than Hawkins," that is, Chernenko electrodes directly contact the calcified lesions but Hawkins only indirectly contacts the lesions with shockwaves. Prelim. Resp. 44–45. However, we observe that Chernenko also describes transferring energy from the electrodes to the lesion through a liquid in Figure 6a, which we reproduce below. Ex. 1005, ¶¶ 5, 88.

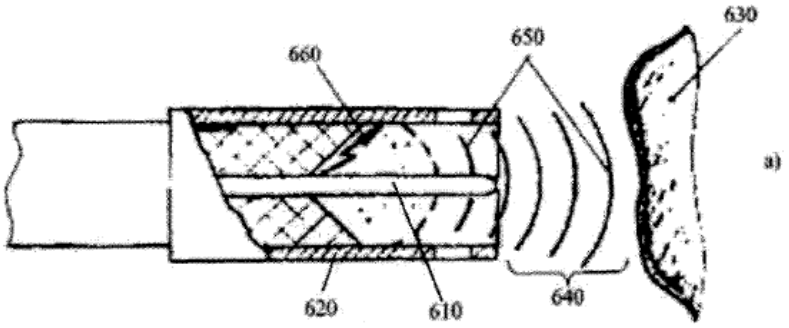

Figure 6a depicts schematically the electro-hydraulic lithotripsy methodology where a high voltage electrode 610 is surrounded by a second, annular electrode 620. *Id.* ¶¶ 53, 88. Chernenko discusses Figure 6a as follows:

> An object 630, e.g. a calculus . . . is distant from both electrodes and due to a gap 640 none of the electrodes is in immediate electrical contact with the calculus. Shock waves 650 produced by a spark discharge 660 propagate towards the calculus. No discharge channel is formed in the calculus.

Id. ¶ 88; *see also id.* ¶ 41 (same). Accordingly, at least one embodiment of Chernenko does not directly contact the calcified lesions. Furthermore, Petitioner expressly relates Chernenko's current-based control of voltage pulses to patient safety and reliability. Pet. 40–41 (relying on Ex. 1005 ¶¶ 37–39, 59, 109–110; Ex. 1002 ¶¶ 155–158). Dr. Jensen further testifies that "using a rectangular waveform pulse [would] thus enhance shockwave generation while reducing trauma to the patient by reducing excess power

exposure" and "enables control of fragments during treatment [which] increases patient safety, increases treatment reliability." Ex. 1002 ¶¶ 156–157.

Therefore, on this record, Petitioner has demonstrated a reasonable likelihood that it will prevail in showing the subject matter of claim 1 would have been obvious over Hawkins and Chernenko. Patent Owner does not present additional argument for claims 2, 3, and 10 separate from that argued for independent claim 1. *See generally* Prelim. Resp. 33–47. Based on our independent review of the Petition and cited evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it will prevail at trial in showing that the subject matter of claims 2, 3, and 10 was suggested by the combined teachings of Hawkins and Chernenko prior to the application leading to the '091 patent.

F. Obviousness in view of Hawkins, Chernenko, and Li

Petitioner contends the subject matter of claims 1–14 would have been obvious over the combined disclosures of Hawkins, Chernenko, and Li. Pet. 44–52. Petitioner argues that "Hawkins discloses all features of claim 1, except [that Hawkins] may not expressly disclose current sensing to provide voltage control, which Chernenko discloses to tightly control voltage pulses" and that "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." *Id.* at 44. Petitioner relies on the same arguments advanced in promoting the combination of Hawkins and Li and the combination of Hawkins and Chernenko when presenting its arguments for

the combination of Hawkins, Chernenko, and Li. *Compare* Pet. 12–44, *with id.* at 44–52.

Patent Owner, at this stage, argues that the Hawkins/Chernenko/Li combination "fails for substantially the same reasons set forth above in Section III (addressing the combination of Hawkins and Li) and Section IV (addressing the combination of Hawkins and Chernenko)." Prelim. Resp. 48. For the same reasons discussed above in addressing the combinations Hawkins/Li and Hawkins/Chernenko, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1–14 would have been obvious over the combined disclosures of Hawkins, Li, and Chernenko.

G. Obviousness in view of Hawkins and Heeren

Petitioner asserts the subject matter of claims 1–14 would have been obvious over the combined disclosures of Hawkins and Heeren. Pet. 52–63.

1. Heeren

Heeren is directed to "[a] pulsed-electric field (PEF) surgical device that can prevent or reduce damages caused by a dielectric breakdown." Ex. 1006 ¶ 5. The device includes "one or more sensors to detect an attribute characteristic of a dielectric breakdown." *Id.* ¶ 6. For example, "[a] current sensor at the tip of probe 114 can measure the strength of the electric current passing through probe 114 to detect a sudden increase of electric current" which may indicate dielectric breakdown. *Id.* ¶ 27. The sensor readings are fed to a transducer monitor which "is configured to compare the data collected by sensors 126 to a threshold to determine whether a dielectric breakdown is imminent or whether a dielectric breakdown has occurred." *Id.* ¶ 30. "Based on the sensor data and/or the

result of the comparison between the sensor data and one or more predetermined thresholds, transducer monitor 155 instructs pulse generator 170 to adjust the properties of the electrical pulses." *Id.* ¶ 31. Operational parameters such as pulse duration may be adjusted or the electric pulses may be turned off. *Id.* ¶ 33.

2. Analysis

Petitioner argues "Hawkins discloses all features of claim 1, except [that Hawkins] may not expressly disclose sensing current to control voltage pulses." Pet. 52. But, Petitioner alleges Heeren discloses "a current sensor 126 to detect the onset of dielectric breakdown at the electrodes which causes sparking." *Id.* (citing Ex. 1006 ¶¶ 17–18, 25–27; Ex. 1002 ¶ 188). Petitioner explains that Heeren compares current sensor data to a threshold value to determine whether a dielectric breakdown has occurred and dynamically adjusts the pulse duration when the threshold is met. *Id.* at 53 (citing Ex. 1006 ¶¶ 27, 30–32; Ex. 1002 ¶¶ 188, 190). Relying on the testimony of Dr. Jensen, Petitioner explains that "setting the pulse duration necessarily sets the pulse termination." *Id.* (citing Ex. 1002 ¶ 190). Petitioner also contends that Heeren describes "reduc[ing] pulse duration on a pulse-by-pulse basis" and that pulses may be adjusted mid-pulse. *Id.* at 54 (citing Ex. 1006 ¶¶ 32–33; Ex. ¶¶ 192–193). Petitioner explains that Heeren's dynamic pulse control "reduce[s] damage to the patient from electrical pulsed surgical devices, such as from excess heat, burns, or the like." *Id.* at 54 (citing Ex. 1006 ¶¶ 4, 14, 24, 33, 26). Petitioner reasons a person skilled in the art would realize Heeren's dynamic pulse control would reduce excessive current flows shockwave devices like Hawkins. *Id.* at 55 (citing Ex. 1002 ¶ 194). Therefore, the skilled artisan would have modified

Hawkins in view of Heeren to increase electrical efficiency which decreases component wear. *Id.* (citing Ex. 1002 ¶¶ 193–197).

Patent Owner does not dispute Petitioner's allegations related to Hawkins and instead raises two principal arguments related to the combination with Heeren—the combination does not disclose all elements of the claim and no reason exists to combine Hawkins and Heeren. *See* Prelim. Resp. 48–55. With respect to claim 1, Patent Owner argues Heeren "does not teach *termination* of an existing pulse based on the current sensed at the electrode tip." *Id.* at 49. Instead, Patent Owner asserts that Heeren teaches only *adjusting* the voltage mid pulse and turning off pulses completely. *Id.* at 49–50 (citing Ex. 1006 ¶ 33, Fig. 7). Patent Owner asserts that "Hereen [sic] at no time seeks to terminate a pulse and then permit the next pulse to resume at full power, as in the '091 patent." *Id.* at 50.

However, Figure 7, reproduced below, contradicts Patent Owner's assertion by illustrating examples of adjusting the operational parameters according to Heeren.

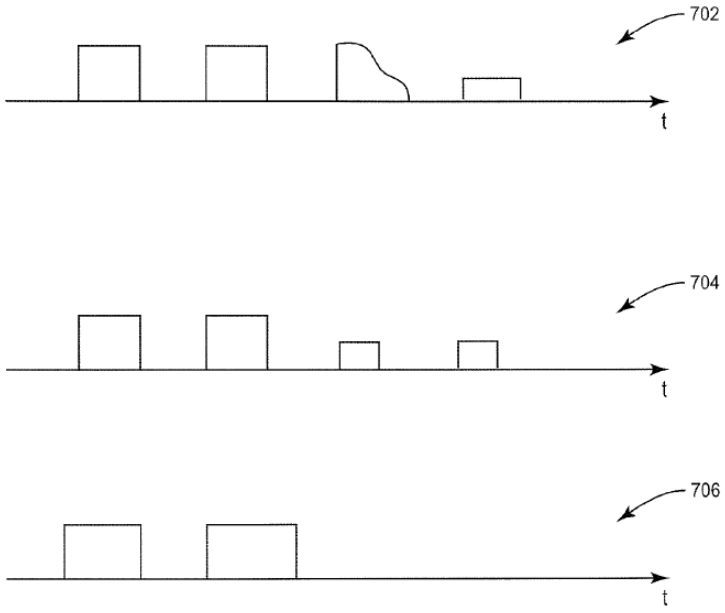

FIG. 7

Figure 7 "illustrates series of electric pulses with parameters adjusted during a dielectric breakdown." Ex. 1006 ¶ 13. Heeren explains that

> The operational parameters, such as the voltage of the pulses, may be adjusted in the middle of an electric pulse, as shown in diagram **702** in FIG. **7**. Alternatively, the operational parameters, such as the duration and voltage of the pulses, may be adjusted in between two electric pulses (diagram **704**). The electric pulses may be turned off completely as well (diagram **706**).

Id. ¶ 33. Dr. Jensen testifies that adjusting or reducing the pulse duration "necessarily sets the pulse termination as the end of the given pulse." Ex. 1002 ¶ 189. At this stage of the proceeding, Petitioner has shown sufficiently that the combination of Hawkins and Heeren suggests sensing current to control voltage.

Second, Patent Owner argues that no motivation to combine Hawkins and Heeren exists. Prelim. Resp. 51. In addition to Patent Owner's argument (*infra* pp. 15–16) that Petitioner does not explain why the Hawkins

sensor is inadequate, Patent Owner asserts that, because of the differences in the way in which Heeren operates (direct contact with tissue) versus the way Hawkins operates (indirect contact with tissue through shockwaves), "the additional benefit provided by terminating a pulse mid-way, as opposed to just terminating the next pulse, is likely miniscule." *Id.* at 53. Patent Owner contends that the combination results in disadvantages, i.e., the necessity of "more pulses and generating more heat" and that "missing from Petitioner's analysis is how a skilled artisan would have known what the minimum necessary spark length was." *Id.* at 53–54. Patent Owner asserts that these omitted considerations are found only in the patented invention and, therefore, are the product of hindsight.

Here, Patent Owner's characterization of the benefits of the combination as "likely miniscule" and resulting in disadvantages, is argument unsupported by evidence. In contrast, Petitioner, through the testimony of Dr. Jensen, demonstrates that Heeren's dynamic pulse control will promote patient safely, reduces excessive current flow, and increases electrical efficiency. Pet. 54–55 (citing Ex. 1006 ¶¶ 4, 14, 24, 33, 26; Ex. 1002 ¶¶ 192–197). Therefore, on this record, we find that Petitioner has sufficiently shown that the person of ordinary skill in the art would have had reason to modify Hawkins to include Heeren's sensor and dynamic pulse control.

We have considered Petitioner's and Patent Owners arguments as to claim 1, and we determine that Petitioner has shown sufficiently, for purposes of this Decision, that there is a reasonable likelihood that all the limitations recited in claim 1 are suggested by the combination of Hawkins and Heeren. We have also considered Petitioner's and Patent Owner's

arguments as to independent claim 14, and we similarly determine that Petitioner has shown sufficiently, for purposes of this Decision, that there is a reasonable likelihood that all the limitations recited in claim 14 are suggested by the combination of Hawkins and Heeren. *See* Pet. 58–60, 63 (citing Ex. 1006 ¶¶ 32–33; Ex. 1002 ¶¶ 203–204, 223–224). Patent Owner does not challenge Petitioner's allegations as to dependent claims 2–13 separate from the arguments advanced for claims 1 and 14. Based on our independent review of the Petition and cited evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it will prevail at trial in showing that the subject matter of claims 2–13 was suggested by the combination of Hawkins and Heeren prior to the application leading to the '091 patent.

H. Secondary Indicia of Nonobviousness

Patent Owner argues that there exists substantial evidence of nonobviousness in the form of industry acclaim and commercial success. *See* Prelim. Resp. 13–18. By way of example, Patent Owner explains that it won the 2015 CRT award "bestowed by one of the world's leading interventional cardiology conferences." *Id.* at 14. In addition, industry publications have described the Patent Owner's shockwave technology as "revolutionary," "novel," "revolutionary," "amazing," and "space-age technology." *Id.* at 13, 15; *see also id.* at 59 (same). Patent Owner attributes its commercial success to its lithoplasty technology explaining that "its stock 'has appreciated an impressive 97% in the 3-4 weeks since going public and now carries almost a $1bln valuation despite generating only $12m in revenue last year.'" *Id.* at 16 (quoting Ex. 2016, 1); *see also id.* at 17 (describing analyst reports praising Patent Owner's products). Patent Owner

reasons that because it has only a single product, the industry praise and commercial success is fairly attributed to its patented lithoplasty technology. *Id.* According to the testimony of Mr. Stephens, Vice President of Research and Development at Shockwave Medical, "the Shockwave IVL system has practiced all features recited in the independent claims of the '091 patent." Ex. 2013 ¶ 6; *see also id.* at ¶¶ 7–10 (comparing the Shockwave IVL system to claims 1, 6, 10, and 14). Accordingly, Patent Owner argues that the requisite nexus between the secondary indicia of nonobviousness and the patented technology exists. *Id.*

Patent Owner contends that Petitioner failed to address objective evidence of nonobviousness despite knowing of such evidence prior to filing the Petition. *Id.* at 55. According to Patent Owner, because Petitioner is Patent Owner's primary competitor and the parties sell products in the same market, Petitioner "surely knew about most if not all of the objective evidence of nonobviousness discussed herein, especially the industry awards and clinical studies." *Id.*at 56. Therefore, Patent Owner urges that the petition should be denied. *Id.* at 56–59.

Here, although Patent Owner presents a supporting declaration and significant evidence of objective indicia of nonobviousness, that information was not considered in allowing the claims or in a related litigation. *See e.g.*, *Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche Inc.*, IPR2015-01792, slip op. at 17–18 (PTAB Mar. 11, 2016) (Paper 14) (declining to institute where the unrebutted evidence was "apparently relied on by the Examiner") and *Robert Bosch Tool Corp. v SD3, LLC*, IPR2016-01753, slip op. at 27–39 (PTAB Mar. 22, 2017) (Paper 15) (declining to institute where the Initial Determination of the ITC stated the evidence of objective indicia

of nonobviousness was "very strong"). Further, there is no persuasive evidence of record to suggest the Petitioner was in fact aware and should have responded to such evidence in the Petition. Thus, under the facts of this case and at a time when the trial record is not fully developed, we are not inclined to deny institution on the basis of Patent Owner's evidence alone.

III. CONCLUSION

For the reasons set forth above, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to each of its challenges to the claims of the '091 patent. Thus, we institute an *inter partes* review. Trial shall commence on the entry date of this Decision.

IV. ORDER

It is ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–14 of the '091 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that no other ground of unpatentability is authorized during the trial; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which will commence on the entry date of this Decision.

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