Trials@uspto.gov
Tel: 571-272-7822

Paper 75
Date: July 8, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.,
Petitioner,

v.

SHOCKWAVE MEDICAL, INC.,
Patent Owner.

IPR2019-00409
Patent 8,728,091 B2

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

ROSS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Petitioner's Motion to Exclude
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a); 37 C.F.R. § 42.64

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed herein, we determine that Cardiovascular Systems, Inc., ("Petitioner") has shown, by a preponderance of the evidence, that claims 1–14 ("the challenged claims") of U.S. Patent No. 8,728,091 B2 (Ex. 1001, "the '091 patent") are unpatentable.

A. Procedural History

Petitioner filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–14 of the '091 patent. Petitioner relies on the declaration testimony of Dr. Morten Olgaard Jensen (Ex. 1002) to support its positions. Shockwave Medical, Inc., ("Patent Owner") filed a Preliminary Response to the Petition (Paper 11, "Prelim. Resp."). Pursuant to 35 U.S.C. § 314(a), on July 11, 2019, *inter partes* review was instituted on the following grounds:

Claim(s) Challenged	**35 U.S.C. §**	**Reference(s)/Basis**
1–14	103	Hawkins[1] and Li[2]
1–3, 10	103	Hawkins and Chernenko[3]
1–14	103	Hawkins, Chernenko and Li
1–14	103	Hawkins and Heeren[4]

[1] Hawkins, et al., US 2009/0312768 A1, published December 17, 2009 (Ex. 1003).
[2] US 2006/0221528 A1, published October 5, 2006 (Ex. 1004).
[3] US 2003/0176873 A1, published September 18, 2003 (Ex. 1005).
[4] US 2013/0041355 A1, published February 14, 2013 (Ex. 1006).

See Paper 14 ("Inst. Dec.").

Subsequent to institution, Patent Owner filed a Patent Owner Response (Paper 34, "PO Resp."), along with a Declaration of Daniel W. van der Weide, Ph.D. (Ex. 2100) to support its positions. Petitioner filed a Reply (Paper 48, "Pet. Reply") to the Patent Owner Response, along with a Supplemental Declaration of Dr. Jensen (Ex. 1200), and Patent Owner filed a Sur-Reply (Paper 55, "Sur-Reply").

Petitioner filed a Motion to Exclude certain exhibits. Paper 62 ("Pet. MTE"). Thereafter, Patent Owner filed an Opposition to Petitioner's Motion to Exclude (Paper 65, "PO MTE Opp.").

Patent Owner also filed a Motion to Exclude certain exhibits. Paper 61 ("PO MTE"). Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 63, "Pet. MTE Opp.").

An oral hearing was held on April 16, 2020. A transcript of the hearing is included in the record. Paper 74 ("Tr.").

B. 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 partes* 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.

C. 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.

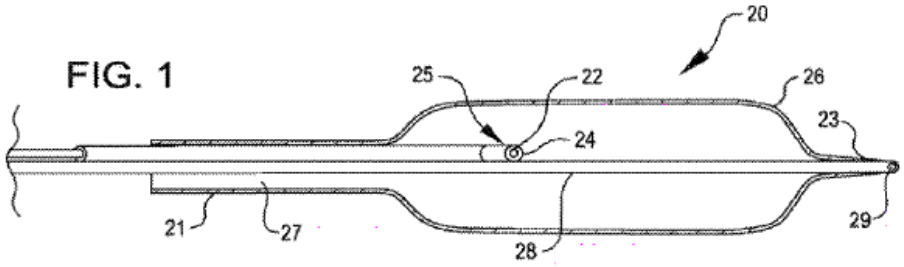

Figure 1 shows an angioplasty balloon catheter 20 including hollow sheath 21, dilating balloon 26, and guidewire 28. *Id.* at 7:34–40. The catheter includes shock wave generator 25, i.e., at least one pair of electrodes 22 and 24, within balloon 26 to generate a high voltage arc across the electrodes. *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.

D. 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. *Id.* at 11:59–12:12, 12:41–61 (claim 14 requiring a "delay timer" to trigger the timer in response to the current sensor signal).

II. ANALYSIS

A. Applicable Law

To prevail in its challenges to the patentability of the claims, Petitioner must demonstrate by a preponderance of the evidence that the challenged claims are unpatentable. 35 U.S.C. § 316(e) (2018). "In an [*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 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. An obviousness analysis "need not seek out precise

teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements," but "must instead articulate specific reasoning, based on evidence of record" to support an obviousness determination. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016). Petitioner also must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

At this final stage, we determine whether a preponderance of the evidence of record shows that the challenged claims would have been rendered obvious in view of the asserted prior art. We analyze the asserted grounds of unpatentability in accordance with these principles.

B. Level of Ordinary Skill in the Art and Dr. Jensen's testimony

1. 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* Ex. 1002 ¶¶ 36–37.

Patent Owner disagrees and contends that the level of ordinary skill in the art requires:

> (1) a masters or doctorate degree in electrical engineering or related field of study or an equivalent understanding of the relevant aspects of the generation and management of electrical arcs; and (2) at least two years' experience in electrohydraulic shockwave devices or an equivalent understanding of the relevant aspects of generation and management of shockwaves and pulsed signals.

PO Resp. 16 (quoting Ex. 2100 ¶ 71).

The parties' positions primarily differ in that Patent Owner suggests an advanced degree, i.e., "a masters or doctorate degree in electrical engineering" and two years of experience in electrohydraulic shockwave devices is required. *Id.* Petitioner, instead, explains that a bachelor's degree in mechanical engineering, electrical engineering, or biomedical engineering, with at least three years of experience in angioplasty lithotripsy or electro-pulsed surgical devices, is required though "[s]pecific study and/or experience conditions may be met by equivalent experience, education, or training." Pet. 7; Ex. 1002 ¶¶ 34–38.

On this record, the parties' positions are similar. On education, Petitioner includes other engineering disciplines in addition to electrical engineering and does not require an advanced degree as a basis for attaining ordinary skill. However, Petitioner contends that more experience in the field is needed to attain ordinary skill. *Id.* Based on the record, we adopt Patent Owner's definition of the ordinarily skilled artisan as consistent with

the level of skill necessary to address the problems encountered in this field.[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).

2. Dr. Jensen's Testimony

Patent Owner asserts that Dr. Jensen's testimony should be afforded little, if any weight. PO Resp. 14. Patent Owner contends that "Dr. Jensen … does not have this [requisite] level of skill even today." *Id.* at 16. Specifically, Patent Owner contends that Dr. Jensen did not understand the concepts of inductance and negative resistance nor did he understand certain figures from the prior art. *Id.* at 16–17. As a result, Patent Owner contends that "Dr. Jensen is not skilled in the relevant art [and] his opinions are entitled to little, if any, weight." *Id.* at 18.

Petitioner argues that the concept of negative resistance is not relevant to the case (Pet. Reply 6–10) and that "Chernenko purposefully did not disclose the details of various components in Fig. 4b" (*id.* at 18). Petitioner further asserts that "Dr. Jensen is qualified as an expert under either party's definition of a [person of ordinary skill in the art] [as] established in the Petition." *Id.* at 6.

We agree with Petitioner that Dr. Jensen's background and experience meets the level of skill in the art that we adopt in this case. *See* Ex. 1002

---

[5] Though we adopt Patent Owner's definition of the level of skill in the art, the outcome of our Decision would remain the same under Petitioner's proposed definition.

¶¶ 8–13 (statement of qualifications), Appendix A (curriculum vitae) (listing a bachelor's degree in electrical engineering, master's degree in biomedical engineering, and doctoral degrees in medical science). Furthermore, a declarant's expertise and experience need not match perfectly the experience and education of a person of ordinary skill in the art in order to provide testimony so long as there is an adequate relationship between the declarant's education and experience when compared to the claimed invention. *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010). Accordingly, we find that Dr. Jensen is qualified to testify about the perspective of one of ordinary skill in the art at the time of the invention.

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." *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,340, 51,358 (Oct. 11, 2018) (now codified at 37 C.F.R. pt. 42);[6] *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

[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.

1. "predetermined value" and "predetermined delay time"

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 "an amount of delay time set in advance." *Id.* at 9– 10. Patent Owner does not propose any express construction for any claim language. *See generally* PO Resp. Neither party argues that the construction of either term is dispositive of any issue presented in this *inter partes* review. Accordingly, we need not resolve the meaning of terms "predetermined value" or "predetermined delay 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.")).

2. "terminate the voltage supplied to the electrodes for that pulse"

The relevant claim language is reproduced below:

> 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*.

This rule change applies to petitions filed on or after November 13, 2018. *Id*.

Ex. 1001, 11:40–46 (emphasis added). Though neither party requested in their briefing that we construe the phrase "terminate the voltage supplied to the electrode for that pulse" (*see generally* Pet., PO Resp.; Tr. 71:17–72:4), the issue arises in Petitioner's reply brief where it addresses the relevance of "inductance and negative resistance" raised by Patent Owner in its Patent Owner Response.

According to Patent Owner, "[a] phenomenon known as 'negative resistance' is inherent in electric arc generation [and] . . . provides that at ambient pressure or above, when extinguishing a pulse the voltage must *increase* before current may decrease." PO Resp. 10 (citing Ex. 2100 ¶¶ 38–50, 151). Patent Owner explains that the "negative resistance phenomenon (and the associated delay) poses a significant hurdle in arc termination in the context of the device claimed in the '091 patent." *Id.* at 13 (citing Ex. 2100 ¶¶ 43, 45). Inductance similarly results in a delay that "prohibit[s] rapid and reliable termination of a voltage pulse," which "would also generally defeat any attempt to prematurely terminate a pulse that is generally 3 s or less." *Id.* at 15 (citing Ex. 2100 ¶¶ 37, 45, 50, 52). Patent Owner alleges that the delay caused by inductance together with negative resistance "pose[s] a significant challenge with respect to early termination of an arc-generating high voltage pulse in the context of the device claimed in the '091 patent." *Id.* (citing Ex. 2100 ¶ 50).

It its Reply, Petitioner explained that both inductance and negative resistance are not relevant because "element 1[e] states that the 'power source terminates the voltage ***supplied to*** the electrodes for that pulse,' not the voltage ***'at'*** the electrodes (i.e., not the voltage pulse, the current, or the

resulting arc)." Pet. Reply 6–7. According to Petitioner, its understanding of the claim language is supported by the Specification. *Id.* at 7 (citing Ex. 1001, 7:50–51, 9:11–18, Figs. 2, 6). Petitioner asserts that the '091 patent Specification fails to discuss negative resistance or inductance or offer any solution for its effects. *Id.* at 8.

Patent Owner in its Sur-Reply contends that Petitioner "contrive[s] a new Reply claim construction under which the 'voltage pulse' need not be terminated" and is in conflict with positions taken in the Petition. Sur-Reply 2. According to Patent Owner, Petitioner originally took the position that the "claims are obvious because the prior art allegedly taught termination of voltage pulses," but now asserts that "the 'voltage pulse' need not be terminated" because "the claim requires terminating the 'voltage ***supplied to*** the electrodes.'" *Id.* at 2–3. Patent Owner contends that Petitioner's new argument "runs counter to the claim language, specification, file history, expert testimony, and the immutable scientific principles underlying the operation of the devices in question." *Id.* at 3. Patent Owner explains that according to the claims and the Specification, "[t]here is no difference between the 'voltage pulse supplied to the electrodes' and the 'voltage supplied to the electrodes for that pulse.' In other words, the 'voltage supplied to the electrodes for that pulse' ***is*** the voltage pulse." *Id.* at 4. Patent Owner further asserts that claim amendments during prosecution confirm this understanding. Claim 1 was amended as follows:

> a power source coupled to the electrodes for supplying [[a]] voltage pulses to the electrodes, ~~to generate~~ each voltage pulse generating an arc . . .

> wherein the power sources includes a current sensor for detecting the current flow between the electrodes during each voltage pulse, and wherein the current reaches a predetermined value during each voltage pulse, the sensor generates a signal that causes the power source to terminate the voltage ~~supply~~ supplied to the electrodes for that pulse.

Ex. 1010A, 32. Therefore, Patent Owner contends that it is the voltage pulse itself that is terminated. Sur-Reply 5.

Any claim construction analysis must begin with the words of the claim as the claim defines the scope of the invention. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The claim, however, is not read in isolation but rather in view of the specification. *Phillips*, 415 F.3d 1315; *Vitronics*, 90 F.3d at 1582 (characterizing the specification as "the single best guide to the meaning of a disputed claim"). In addition, the prosecution history should be examined because it "provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. Applying these principles, we agree with Petitioner that a current sensor that "generates a signal that causes the power source to terminate the voltage *supplied to* the electrodes for that pulse" means that the power source terminates the voltage supplied *to* the electrodes and not, as Patent Owner suggests, a signal that instantaneously terminates the voltage pulse across or at the electrode. Sur-Reply 5–6. The plain language of the claim is consistent with the Specification, which repeatedly describes application and termination of the voltage *supplied to* the electrodes. *See, e.g.*, Ex. 1001, 2:47–49; 2:67–3:4, 6:5–9, 9:18–23, 10:47–49. The prosecution history does not compel a different reading.

Patent Owner does not propose any express construction but nevertheless invites us to construe "terminate the voltage supplied to the electrodes for that pulse" as terminating the voltage pulse across (or at) the electrodes for that pulse. According to Patent Owner, such an understanding is the only way to achieve the intended purpose of the '091 patent, i.e., "termination of the voltage pulse during that pulse and that allows the benefits of electrode there and heat reduction to be controlled – to be achieved." Tr. 77:20–78:7; Sur-Reply 4 ("That benefit occurs only if the *voltage pulse across the electrodes* is actually shortened which is synonymous with terminating the voltage pulse." (emphasis added)). While claims are generally interpreted in light of the purpose of the invention, the purpose of the invention cannot be used to rewrite the claims or displace the plain, unambiguous meaning of the words. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (explaining that claims are interpreted in light of the specification but caution must be taken to avoid reading limitations into the claims); *Teleflex Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002) ("[T]he claims must be read in view of the specification, but limitations from the specification are not read into the claims." (citation omitted)). Despite the opportunity to amend, Patent Owner did not amend its claim to state that the voltage pulse *itself* was terminated.[7] *Innova/Pure Water*, 381 F.3d at 1119

[7] Patent Owner amended claim 1 to add "pulse" or "voltage pulse" five times (*see* Ex. 1010A, 32) yet did not amend the language to state that the "voltage *pulse*" was terminated.

("[W]hen an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms."). As written, the signal causes the power source to terminate the voltage supplied to the electrodes—without express limitations on the timing or effect on the voltage pulse across the electrodes; we will not discount the differences in Patent Owner's choice of words. *In re Hiniker Co.*, 150 F.3d 1362, 1368–69 (Fed. Cir. 1998) ("The invention disclosed in . . . [the] written description may be outstanding in its field, but the name of the game is the claim.").

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 pair within the balloon. *Id.* ¶ 3. The arc generator is connected to a power source and arcs across the electrodes to form 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

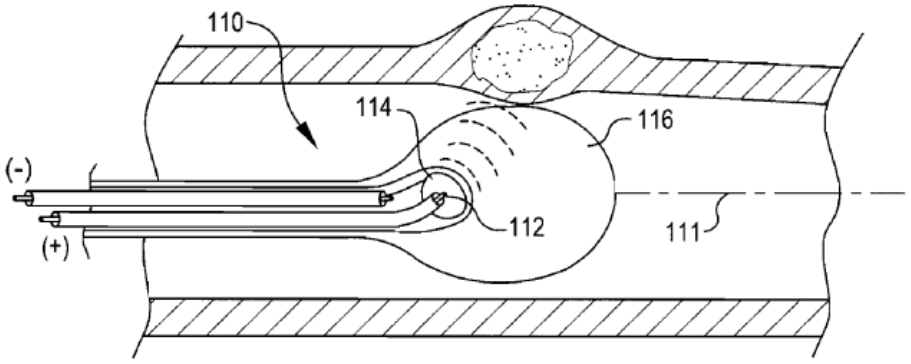

Figure 15 illustrates a dilation catheter 110 with a balloon 116. *Id.* ¶ 64. The catheter includes a parabolic reflector 114, which acts as an electrode, and electrode 112 between which an arc is formed that generates a shockwave focused on the calcified lesion. *Id.* The catheter may be equipped with a sensor, located on the distal end on one electrode, to sense reflected energy. *Id.* ¶¶ 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 of Claim 1

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 a 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. *Id*. at 12–14 (citing Ex. 1003 ¶¶ 2, 3, 10, 14, 19, 38, 42, 45, 46, 49–55, 56–62, 64 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.*; *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. Pet. 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 17–18 (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." Pet. 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 Li's current sensor would have been obvious to one of skill in the art. PO Resp. 18–32. We determine, Petitioner's argument and evidence establish by a preponderance of the evidence that all elements of claim 1 of the '091 patent, except for the claimed current sensor, are present in Hawkins. *See In re NuVasive*, 841 F.3d 966, 974 (Fed. Cir. 2016) (explaining that the Board need not make specific findings as to claim limitations that Patent Owner does not dispute are disclosed in the prior art). Below, we address whether the ordinarily skilled artisan would have reason to make the combination as claimed.

a. *whether Li is capable of controlling the current in Hawkins*

Patent Owner contends a person skilled in the art "would understand that the device of Li would not be able to be used in the lithotripter of Hawkins" because Hawkins[8], like known lithotripsy devices, operates at voltages of 5kV–30kV where "Li operates at voltages on the order of 70V and uses MOSFETs (metal-oxide semiconductor field-effect transistors) that, even in the best of circumstances could not tolerate voltages in excess

[8] Patent Owner argues that Hawkins' disclosure of between 100 and 3000 volts is a typographical error which should be read as requiring a voltage of between 1,000 and 30,000 volts. PO Resp. 19–20 & n.2.

of hundreds of volts." PO Resp. 19–20 (citing Ex. 2100 ¶¶ 77–78, 81–84; Ex. 2033, 1 (article on transient cavitation bubbles in lithotripsy); Ex. 1005 ¶ 84; Ex. 1006 ¶ 20; Ex. 2103, 14 (shockwave handbook)). Patent Owner, through the testimony of Dr. van der Weide, explains that "Li is assigned to Texas Instruments . . . [and that the] Texas Instruments data sheet ["the TI data sheet"] . . . represents the commercial embodiment of the device disclosed in Li." *Id.* at 20 (noting that both Li and the data sheet describe a "two-stage thermal protection") (citing Ex. 2100 ¶¶ 81, 83, 84; Ex. 1004, code (73)). Patent Owner asserts that the "data sheet discloses that the device operates at a maximum voltage of 70V" and even if "the Hawkins device operated at just 1kV, Li could not terminate its voltage [as] [t]hat voltage is far beyond Li's operational range." *Id.* at 20–21 (citing Ex. 2100 ¶¶ 82, 84). Patent Owner further relies on the testimony of Dr. Jensen, Petitioner's expert, who explains that the ordinarily skilled artisan would have known that operating circuitry at a higher level than its design point can cause damage. *Id.* at 21 (citing Ex. 1002 ¶ 94).

Petitioner responds that "Hawkins teaches a voltage between 100 and 3000 volts" and that Patent Owner's "'error' explanation seems unlikely, however, because numerous, related patents all recite the same 100 to 3000 volt range." Pet. Reply 10 (citing Ex. 1003 ¶ 52; Ex. 1200 ¶ 52). In addition, Petitioner notes that the '091 patent itself teaches that voltages as low as 500 volts can be used which contradicts Patent Owner's position that a minimum of 1000 volts is required. *Id.* (citing Ex. 1001, 7:64–66). Furthermore, Petitioner explains that Li discloses use of power field-effect transistors ("FETs") and the skilled artisan "would have understood that

power FETs can operate at voltages over 1000 volts." *Id.* at 11 (citing Ex. 1004 ¶ 15; Ex. 1200 ¶ 53–55; Exs. 1208–1210; Ex. 2100 ¶ 81).

On this record, we disagree with Patent Owner because its argument is premised on Patent Owner's position that Hawkins involves high voltage applications and Li involves low voltage applications. To reach its conclusion, Patent Owner must establish two points—(1) that a typographical error exists in the Hawkins disclosure and (2) that Li is limited to voltages less than 1,000V. Neither argument is supported in the record. First, Patent Owner argues that Hawkins, which expressly discloses a voltage of 100 to 3,000 volts (Ex. 1003 ¶ 52), includes a typographical error and should be written as 1,000 to 30,000 volts. PO Resp. 19–20 & n.2. According to Patent Owner, such a reading is reasonable given that lithotripsy devices are known to operate in the range of 5kV to about 30kV. *Id*. at 19. However, the '091 patent itself describes voltages applicable for lithotripsy devices "as low as 500 volts" (Ex. 1001, 7:64–66) and the purported error in Hawkins was carried forward into numerous applications (some still pending) and at least four additional patents without correction or amendment. Ex. 1200 ¶ 52; Exs. 1205–1206; *see also* U.S. Patent Nos. 9,072,534, 10,039,561, 8,956,374; U.S. Patent Application Nos. 16/028,225, 16/544,516.

Second, Patent Owner argues that despite no express description of voltage levels, Li is limited to only low voltage applications and specifically, applications below about 1,000V. PO Resp. 20–21. However, the elicited testimony of Dr. van der Weide that the TI datasheet is the commercial embodiment of Li amounts to little more than speculation. *See, e.g.*, Ex.

2100 ¶¶ 82–83. The only identified commonality is the "two-stage thermal protection" system; without more, such testimony is unpersuasive. Furthermore, the evidence of record suggests that power FETs, like those described in Li, can operate at voltages between 600–4,500 volts. Ex. 1207 (describing power MOSFET operating ranges up to 4,500V); Ex. 1208 (identifying a power MOSFET operating up to 600V); Ex. 1209 (exemplifying a power MOSFET operating at 1,500V); Ex. 1210 (explanation of voltage ratings); Ex. 2100 ¶ 81; Ex. 2108 (MOSFET basics); Ex. 1200 ¶¶ 53–55. Thus, even if Hawkins was limited to an operating range of 1,000–30,000 volts, that range overlaps with the operating range of power FETs used in Li from 1,000–4,500V. Based on the foregoing, we are not persuaded by Patent Owner's argument that one of ordinary skill in the art would not have found it obvious to combine Li with Hawkins because Li discloses a low voltage and Hawkins discloses a high voltage device.

b. *whether the skilled artisan would have had reason to combine Hawkins and Li*

Patent Owner alleges that the skilled artisan would not have had reason to combine the teachings of Hawkins and Li to arrive at the subject matter of the invention because (1) "Hawkins already isolates the patient from the risk of electric shock" (PO Resp. 21–22), (2) only through improper hindsight would the skilled artisan overlook application of Level 2 protection in favor of Level 1 protection (*id.* at 24–27), and (3) the skilled artisan would not have understood Level 1 protection to be successful in early pulse termination because of negative resistance and inductance (*id.* at 27–30).

Patent Owner's first argument is that there is no reason to combine Hawkins and Li because Hawkins itself provides adequate protections. *Id.* at 21. According to Dr. van der Weide, Hawkins "provid[es] a balloon around the arc source and compl[ies] with FDA requirements that any medical device delivering electrical energy to a patient must be electrically isolated from the patient." Ex. 2100 ¶ 91; *see also* PO Resp. 22 (citing Ex. 2100 ¶¶ 91–95; Ex. 2111 § 8.1–8.2; Ex. 1003 ¶ 50). Further, Patent Owner argues that "[c]urrent control alone will not meaningfully reduce any purported risk . . . [because] [t]he risk of shock would stem from voltage and Li does little to control voltage in the context of Hawkins." PO Resp. 23 (citing Ex. 2100 ¶ 96).

We agree with Petitioner (*see* Pet. Reply 13) that even though Hawkins' balloon provides some protection against electric shock, the ordinarily skilled artisan would have investigated other options to provide added protection to a patient. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1353, 1368 (Fed. Cir. 2006) (explaining that the motivating benefit may be based in making a product "that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient"). Furthermore, we observe that protecting the patient against the risk of shock is not the only advantage advanced by Petitioner. For example, Petitioner explains that reducing excessive current leads to improved device life and enhanced reliability. *Id.* at 18 (citing Ex. 1002 ¶¶ 94–97). Thus, even if the patient is adequately protected against shock by the balloon, reducing current has

added benefits to the electrodes themselves. These advantages were not addressed by Patent Owner. *See generally* PO Resp. 21–23.

Next, Patent Owner contends that Petitioner relies on improper hindsight by focusing on Level 1 protection to terminate voltage. PO Resp. 24. According to Patent Owner, "Level 1 is intended for 'overload conditions,' and Level 2 is intended for 'short circuit' (*i.e.*, arcing) conditions." *Id.* (citing Ex. 1004 ¶ 20). Patent Owner asserts that Dr. Jensen's hindsight reconstruction is apparent as he considered only Level 1 protections in his analysis because "Level 2 does not terminate an existing pulse," and therefore, would not meet the claim. *Id.* (citing Ex. 1004 ¶¶ 20, 25–26; Ex. 2105, 65:11–68:22, 92:25–93:2).

Petitioner argues that Dr. Jensen did not employ improper hindsight reconstruction in forming his opinions relating to Li. Pet. Reply 13–14. Petitioner explains that Dr. Jensen did consider both levels of protection offered by Li and relied on Li's teachings that the two modes were "mutually exclusive" and "independent" of one another. *Id.* at 13 (citing Ex. 1002 ¶ 87; 1200 ¶¶ 15, 60–66; Ex. 1004 ¶¶ 20, 27, Fig. 1; Ex. 2105, 7:11–72:14).

We are not persuaded by Patent Owner's position that Petitioner, through the testimony of Dr. Jensen, engaged in improper hindsight by focusing on Level 1 shut-off circuit protection as opposed to Level 2. Dr. Jensen testifies that he considered the entirety of the references (Ex. 2105, 7:11–72:14) and that his focus on Level 1 circuit protection was due to the fact that Li describes Level 1 and Level 2 protections as being used independently of one another. Ex. 2105, 35:13–25, 67:9–13

(explaining that Dr. Jensen is "familiar with Level 2, but [he] just d[i]dn't find it relevant because Level 1 and Level 2 could be looked at completely separately."). For example, Li explains that

> [i]t is understood that the operation of the level 1 shut-off circuit 58 and the level 2 shut-off circuit 60 can be independent of each other. [Ex. 1004 ¶ 27].
>
> Furthermore, the overcurrent protection circuit 26 may not include both the level 1 shut-off circuit and the level 2 shut-off circuit 60, but instead could include only one or neither, as dictated by the application or the circuit design requirements. [*id.*].

Li broadly describes "that any of a variety of ways of monitoring the over-current condition and compensation can be implemented." *Id.* Furthermore, as we discussed above in Section II.C.2, the claims of the '091 patent are not limited to terminating an existing pulse at the electrodes but rather to terminating the voltage supplied to the electrodes.

Lastly, Patent Owner argues that the person of ordinary skill in the art would not apply the Level 1 shut-off control of Li for early pulse termination because other known methods of controlling heat in the device exist. PO Resp. 28–29. Patent Owner explains that "[a]ny skilled artisan . . . would readily recognize that early pulse termination would be unpredictable and potentially impossible in the context of the Hawkins device with pulses widths in the nanosecond to microsecond range." *Id.* (citing Ex. 2100 ¶¶ 115, 117, 157, 158). Specifically, Patent Owner asserts that, because of negative resistance and inductance, "a skilled artisan would not expect the Level 1 pulse termination of Li to be successful in terminating the arc-

generating high voltage pulse in Hawkins." *Id.*; *see also id.* at 20 (citing Ex. 2100 ¶ 37).

Petitioner argues that "[w]hile a [person of ordinary skill in the art] could have reduced heat in this way, a [person of ordinary skill in the art] would have understood that reducing heat could also have been accomplished by early termination of the pulse/arc." Pet. Reply 14 (citing Ex. 1002 ¶ 94; Ex. 1200 ¶¶ 69–70). We agree with Petitioner, because the existence of an alternative means of accomplishing the same result does not diminish the fact that terminating the voltage reduces heat in the circuit. *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) ("[J]ust because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes."). We credit Dr. Jensen's testimony that "[a] [person of ordinary skill in the art] would further have understood while he or she could have used Hawkins' mechanisms to control the magnitude of the shockwave to reduce heat ([PO] Resp., at 29–30), reducing heat could also have been accomplished by early termination of the pulse/arc." Ex. 1200 ¶ 70; Ex. 1002 ¶ 94.

c. *whether Li is analogous art*

Patent Owner argues that the skilled artisan would not have had reason to combine Hawkins and Li because Li is nonanalogous art. PO Resp. 30. According to Patent Owner, because Li is designed to work at low voltages and "[l]ithotripsy devices are high voltage medical devices," "one looking to terminate the high voltage pulses of Hawkins would not be inclined to look to art relating to low voltage devices." *Id.* at 30–31 (citing Ex. 2100 ¶¶ 85–90). Patent Owner further asserts that Dr. Jensen's "broad

view of analogousness is inconsistent with the law requiring the reference to be 'reasonably pertinent.'" *Id.* at 31.

Petitioner argues that "[t]he '091 patent addresses the problem of controlling the energy applied from its voltage pulses" and its field of endeavor, as described by Dr. van der Weide, is "concerned with voltage pulse production and control." Pet. Reply 11–12 (citing Ex. 1001, 2:30–53; Ex. 1203, 112:5–19 (van der Weide deposition)). Petitioner reasons that because "Li's 'over-current protection in a switching power supply' circuitry directly addresses this problem/endeavor by teaching a mechanism and method to detect, control, and protect against over-current through circuitry arrangements for providing controlled voltage pulses in high current conditions," Li is analogous art. *Id.* (citing Ex. 1004 ¶¶ 13, 19–21, 24–27; Ex. 1200 ¶¶ 56–57; Ex. 1002 ¶ 85).

We are unpersuaded by Patent Owner's argument that Li is nonanalogous. Analogous art is either (1) art from the same field of endeavor, regardless of the problem addressed or (2) art that is reasonably pertinent to the particular problem with which the inventor is involved. *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374, 1379 (Fed. Cir. 2019). As explained above, we reject Patent Owner's contentions that Hawkins is limited to high voltage pulses and that Li is limited to low voltage devices. *See supra* Section II.D.1. Further, that Li is analogous to the '091 patent—describing the field of endeavor as addressing the "need in the art to be able to control the energy applied to the electrodes of an electrical arc shock wave generator"—is supported by the evidentiary record. Ex. 1001, 2:30–53; *see also* Ex. 1203, 112:5–19 (testimony of Dr. van der Weide explaining

that "the '091 [is] concerned with voltage pulse production and control"). Li, by way of example, describes circuitry to address this very problem. In particular, Li explains that "[t]he present invention relates to electronic circuits, and more specifically to . . . systems and methods for providing over-current protection in a switching power supply." Ex. 1004 ¶ 13; *see also id.* ¶¶ 2, 5–6, 19–21, 24–27; Ex. 1002 ¶ 85. Thus, we find that Li is analogous art to the '091 patent.

Based on the foregoing, Petitioner has established, by a preponderance of the evidence, that the combination of Hawkins and Li discloses all of the limitations of claim 1 and that one of ordinary skill in the art would have been motivated to combine Hawkins with Li. As a result, when weighed with the evidence of secondary indicia of nonobviousness (*see infra* Sections II.H. and II.I.), Petitioner has established by a preponderance of the evidence claim 1 would have been obvious based on Hawkins and Li.

4. Analysis of the Remaining Claims (2–14)

Patent Owner does not challenge Petitioner's allegations as to independent claims 6, 10, and 14 or dependent claims 2–5, 7–9, and 11–13 separate from the arguments considered above for claim 1. Based on our independent review of the Petition and cited evidence, we determine that Petitioner has established by a preponderance of the evidence that the subject matter of claims 2–14 was suggested by the combined teachings of Hawkins and Li. For example, claims 2, 7, and 11 additionally require that the "predetermined value" for the current is 50 amps. Ex. 1001, 11:47–48, 12:13–14, 12:33–34. Petitioner explains that the selection of the

predetermined current threshold involves optimization of a result effective variable and is merely a design choice. Pet. 24. According to Petitioner, the ordinarily skilled "artisan would have understood current as an important variable in shockwave generation of lithotripsy devices" and that the treatment of calculi with at least fifty amps was known in the art. *Id.* (citing Ex. 1002 ¶ 109; Ex. 1003 ¶ 50 (explaining that "[t]he magnitude of the shock waves can be controlled by controlling the magnitude of the pulsed voltage, the current, the duration and repetition rate"); Ex. 1005, claim 2; Ex. 1010A, 50). Hawkins further discloses a guidewire lumen as claimed by claims 3 and 8. *Id*. at 25 (citing Ex. 1003 ¶¶ 9, 18, 23, 51, claims 8, 13, 18; Ex. 1002 ¶ 110). Furthermore, Li describes use of a delay timer (claims 4, 12, and 14) and, according to Petitioner, delaying termination of the voltage supply for 100 nanoseconds or more (claims 5, 6, 9, and 13) involves optimization of a result effective variable, was a design choice based on component selection, and was well known in the art. *Id.* at 26–29 (citing Ex. 1002 ¶¶ 112, 114–115, 117; Ex. 1004 ¶¶ 13, 21, 25), 29–31 (citing Ex. 1001, 10:60–11:9 (explaining that delay time is dependent on the natural response delay of the circuitry); Ex. 1002 ¶¶ 120–121; Ex. 1005 ¶ 59). Lastly, claim 10 recites a method which incorporates each of the limitations of claim 1. *Compare* Ex. 1001, 11:28–46, *with id.* at 12:18–32. As a result, Petitioner has established by a preponderance of the evidence that the subject matter of claim 10 was suggested by the combined teachings of Hawkins and Li for the same reasons discussed above for claim 1.

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.

2. Analysis of Claim 1

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 38–39 (citing Ex. 1005 ¶ 72; Ex. 1002, 148). Petitioner contends that the skilled artisan would have had 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 focuses its argument on whether Petitioner has shown that the modification of Hawkins to include Chernenko's current sensor would have been obvious. *See generally* PO Resp. 32–43. After reviewing the parties' briefing and evidence of record, we are persuaded by Petitioner's arguments and supporting evidence that Hawkins describes each of the limitations of claim 1 identified by Petitioner, which is not challenged Patent Owner. We address Patent Owner's arguments relating to the deficiencies of Chernenko and whether the ordinarily skilled artisan would have reason to combine the teachings of Hawkins and Chernenko.

a. *whether Chernenko teaches early termination of voltage pulses*

Patent Owner argues that Chernenko does not teach early termination of a voltage pulse but rather, "Chernenko teaches only termination of

subsequent pulses." PO Resp. 32. Patent Owner explains that the object of Chernenko is to "detect the onset of the fragmentation process and to terminate ***further generation of high voltage impulses***." *Id.* at 33 (citing Ex. 1005 ¶ 38; Ex. 2100 ¶ 120). According to Patent Owner, the two portions of Chernenko—paragraph 69 and claim 8—relied on by Dr. Jensen during his deposition do not "provide[] that a pulse can be terminated early in Chernenko." *Id.* at 33. Patent Owner contends that paragraph 69, for example, does not include an embodiment that senses current and even Dr. Jensen stated that he cannot rely on paragraph 69 entirely. *Id.* (citing Ex. 2105, 121:5–16; 122:9–18; Ex. 2100 ¶ 121). And, according to Patent Owner, "[c]laim 8, if anything, actually demonstrates that Chernenko does *not* have the ability to terminate pulses early." *Id.* In particular, claim 8 relates to terminating the "generation" of the impulses and does not recite "that a single arc-generating voltage pulse is terminated early." *Id.* at 33–34 (Ex. 2100 ¶ 122; Ex. 1005 ¶ 38). Patent Owner further asserts that "there is no evidence to suggest that a skilled artisan would understand that such early termination of an arc-generating voltage pulse would not impact the efficacy of the shockwave." *Id.* at 34 (citing Ex. 2100 ¶ 143). Patent Owner, in its Sur-Reply, further contends that "[t]he charging means 210 does not supply any voltage directly to the electrodes" and that "terminating the charging means would not terminate the voltage pulse even if the charging means somehow was found to supply voltage to the electrodes," because charging means 210 charges the capacitors. Sur-Reply 14 (citing Ex. 2100 ¶¶ 70, 123–142).

Petitioner first argues that the claims do not require "terminating the pulse, the current/arc, or the time required to do so," as Patent Owner alleges. Pet. Reply 17. Petitioner also contends that Chernenko's teaching that "the generation of impulses is terminated" is not limited to terminating the subsequent pulse, but rather, a person ordinarily skilled in the art would have understood the disclosure to mean terminating the voltage during any particular pulse. *Id.* (citing Ex. 1005 ¶¶ 72, 83; Ex. 1002 ¶¶ 144–155; Ex. 1200 ¶¶ 89–92).

We find Petitioner's arguments and evidence persuasive. In particular, we construe the claimed current sensor according to its plain meaning, i.e., that the sensor generates a signal that causes the power source to terminate the voltage supplied to the electrodes. *See* Section II.C.2. Accordingly, the claim does not require early termination of the voltage *pulse* itself as Patent Owner suggests. With respect to Patent Owner's argument that the charging means of Chernenko does not *directly* supply voltage to the electrodes and therefore, terminating the voltage would not terminate the voltage supplied to the electrodes, we observe that the claims do not require that voltage be directly supplied to the electrodes.

b. *whether Figures 4a and 4b of Chernenko disclose a system capable of early termination of an arc-generating voltage pulse*

Patent Owner also asserts that Figure 4a does not illustrate "a circuit capable of terminating an arc-generating high voltage pulse early," a fact Dr. Jensen admitted during his deposition. PO Resp. 35 (citing Ex. 1002 ¶ 147; Ex. 2105, 129:22–130:18; Ex. 2100 ¶ 123). Patent Owner explains that Figure 4a should be read in conjunction with Figure 4b, as it provides

more detailed schematics for Figure 4a. *Id.* (citing Ex. 1005 ¶¶ 50–51). But, "Dr. Jensen admitted that he did not understand the operation of the circuit disclosed in 4b" or other aspects of Chernenko. *Id.* at 35–38 (citing Ex. 1002 ¶ 149; Ex. 2105, 110, 123, 129:22–130:18; Ex. 2043, 69 (showing Jensen's edits to ¶ 149 of Ex. 1002); Ex. 1005 ¶¶ 77–78, Figs. 4a, 4b; 2100 ¶ 141). Patent Owner relies on the testimony of Dr. van der Weide who explains that "the circuit depicted in Figs. 4a and 4b cannot terminate a pulse that is already underway." *Id.* at 38 (citing Ex. 2100 ¶¶ 126, 132–138). Rather, sensors 490 and 491 control operation of the charging means and terminates the charging means when either a present number of pulses has been generated or when a breakdown occurs, but "cannot terminate a pulse that is already underway." *Id.* at 38–39 (citing Ex. 1005 ¶ 72; quoting Ex. 2100 ¶ 126). Dr. van der Weide explains that because Figure 4a includes a capacitor bank, charge will flow and continue until the capacitor bank is discharged. *Id.* at 39–40 (citing Ex. 2100 ¶¶ 134–137).

Petitioner argues that Patent Owner's arguments impermissibly limit Chernenko to the embodiment described in Figure 4b and the use of gas discharge tubes. Pet. Reply 18 (citing Ex. 2105, 100:13–101:10, 110:4–13, 122:19–125:2, 130:19–132:18, 160:17–161:22; Ex. 1200 ¶¶ 93–100). According to Petitioner, Chernenko is not limited to particular components. *Id.* (citing Ex. 1005 ¶ 113).

Having rejected Patent Owner's arguments (above Section II.C.2) that the claims require early termination of an existing voltage pulse and therefore Chernenko is not applicable, we similarly reject Patent Owner's arguments here for the same reasons.

c. *whether negative resistance or inductance would prevent early pulse termination in Chernenko*

Patent Owner further contends "negative resistance and inductance each pose a significant challenge with respect to early termination of a pulse." PO Resp. 43 (citing Ex. 2100 ¶¶ 146–159). As a result, "[a person of ordinary skill in the art] would have understood that the combined effect of negative resistance and inductance would make it nearly impossible to reliably terminate Hawkins' or Chernenko's lithotripsy pulse in the middle of an existing pulse." *Id*.

Petitioner argues that the plain language of the claim requires only that the voltage supplied to the electrodes is terminated and not that the existing pulse itself is terminated. As a result, concepts of negative resistance or inductance are irrelevant. Pet. Reply 6–10, 17.

As we discuss above, as properly construed, the claims do not require termination of the pulse mid-stream. Rather, the claims require only "terminat[ing] the voltage *supplied to* the electrodes for that pulse," so the delay associated with negative resistance and inductance is not relevant to the claims at issue.

Based on the foregoing, Petitioner has established, by a preponderance of the evidence, that the combination of Hawkins and Chernenko discloses all of the limitations of claim 1 and that one of ordinary skill in the art would have been motivated to combine Hawkins with Chernenko. As a result, when weighed with the evidence of secondary indicia of nonobviousness (*see infra* Sections II.H. and II.I.), Petitioner has established by a preponderance of the evidence claim 1 would have been obvious based on Hawkins and Chernenko.

3. Analysis of the Remaining Claims (2, 3, 10)

Patent Owner does not present additional argument for claims 2, 3, and 10 separate from that argued for independent claim 1. *See generally* PO Resp. 32–43. Based on our independent review of the Petition, the cited evidence, and for the reasons discussed above in Section II.D., we determine that Petitioner has shown by a preponderance of the evidence that the additional limitations of claims 2, 3, and 10 were suggested by Hawkins. Therefore, we determine that Petitioner has shown by a preponderance of the evidence that subject matter of claims 2, 3, and 10 would have been obvious based on the combined teachings of Hawkins and Chernenko.

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 id.* at 12–44, *with id.* at 44–52.

Patent Owner argues only that "Petitioner fails to carry its burden to show that Ground 3 renders the claims of the '091 patent obvious for the reasons set forth above with respect to Grounds 1 and 2. Patent Owner incorporates herein its explanation as to Grounds 1 and 2." PO Resp. 43.

For the same reasons discussed above in addressing the combinations of Hawkins with Li and Hawkins with Chernenko, we determine that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 1–14 would have been obvious based on the combined teachings of Hawkins, Chernenko, and Li.

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 of Claim 1

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. 1002 ¶¶ 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.* (citing Ex. 1006 ¶¶ 4, 14, 24, 33, 26). Petitioner reasons a person skilled in the art would have realized Heeren's dynamic pulse control would reduce excessive current flows from shockwave devices like Hawkins. *Id.* at 54–55 (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* PO Resp. 43–50. As discussed above, we determine Petitioner's argument and evidence establish by a preponderance of the evidence that Hawkins describes each limitation of claim 1 that Petitioner identifies. *See In re NuVasive*, 841 F.3d at 974 (Fed. Cir. 2016). Below, we address whether Heeren teaches the requisite current sensor, which Patent Owner disputes, as well as whether the ordinarily skilled artisan would have had reason to combine Heeren with Hawkins as argued.

a. *whether Heeren describes early termination of a pulse based on a current threshold value*

Patent Owner contends that "Heeren teaches sensing a *rate of change* in the current, not a value of the current[, and] [a]s such, Heeren does not disclose the 'current sensing' limitation of claim 1." PO Resp. 47 (citing Ex. 2100 ¶ 169). Patent Owner explains that Heeren measures the "*sudden increase* of electric current" and that "Heeren is monitoring the *rate of change* of the current because a rapid increase in current would indicate a dielectric breakdown." *Id.* (citing Ex. 1006 ¶ 27; Ex. 2100 ¶¶ 168–171). Dr. van der Weide testifies that "it would make little sense for Heeren to monitor whether the current has crossed a certain threshold because Heeren is interested in detecting the onset of dielectric breakdown, *i.e.*, the moment

just before or as dielectric breakdown occurs" and a determination of the rate of change of current is a better indication of dielectric breakdown. *Id.* at 47–48 (citing Ex. 2100 ¶¶ 168, 170, 172).

Petitioner argues that the current sensor of Heeren "***measures*** the strength of the current" and that the "sensor is connected to a transducer monitor configured to ***compare*** a signal collected from the sensor to a ***predetermined threshold***." Pet. Reply 15 (citing Ex. 1006 ¶¶ 15, 18–19, 27, 30). Petitioner explains that simply the threshold, which relates to an increase in current, is "[b]ased on a result of the comparison between the sensor data and the 'predetermined threshold." *Id.* at 15–16 (citing Ex. 1006 ¶¶ 30–33). Petitioner, through the testimony of Dr. Jensen, explains that a person skilled in the art would have understood that the threshold could have been set to a known current value indicative of a breakdown. *Id.* at 16 (citing Ex. 1200 ¶¶ 73–81). Further, Petitioner asserts that "Heeren does not sense rate of change; Heeren's current sensor measures electric current." *Id.* (citing Ex. 1006 ¶ 27). And, Petitioner alleges that even if Heeren measures the rate of change in current, "that specific delta of the rate of change is still a predetermined threshold and thus would meet element 1[e]." *Id.* (citing Ex. 1200 ¶¶ 82–83).

After reviewing the parties' briefing and evidence of record, we are persuaded by Petitioner's arguments and supporting evidence. In particular, we are persuaded by Petitioner that Heeren, in fact, measures current and generates a signal when a predetermined value is reached. Pet. 52–53; Pet. Reply 15–16. For example, Heeren explains that its surgical device includes at least one sensor to detect characteristics of dielectric breakdown.

Ex. 1006 ¶ 6. These sensors may include various sensor types including "a photon sensor, a pressure sensor, and/or a thermal sensor, or various meters for measuring voltage or current, etc." *Id.* ¶ 15; *see also id.* ¶¶ 18 (describing "a flow rate sensor, a photon sensor, a pressure sensor, a thermal sensor, a current sensor, a volt meter, a bubble formation detector, and so on"), 25 (explaining that "[a] dielectric breakdown is generally accompanied by a flash, a burst of pressure wave, and/or changes in current or voltage."). Heeren's current sensors "measure the strength of the electric current passing through probe 114 to detect a sudden increase of electric current." *Id.* ¶ 27. Therefore, Heeren detects "current flow" as claimed. Furthermore, embodiments of Heeren are broadly described as being "configured to compare a reading collected by sensors 126 to a predetermined threshold and obtain a comparison result. Based on the comparison result from transducer monitor 155, control circuit 150 in FIG. 3 controls pulse generator 170." *Id.* ¶ 19; *see also id.* ¶¶ 30–31. Accordingly, the detected current is compared to a predetermined value to determine whether the sensor generates a signal like that of claim 1. Though certain of Heeren's claims state that "the threshold corresponds to an increase of current predetermined to the cause dielectric breakdown" (*id.* at claim 6) these claims cannot limit the scope of Heeren's broad disclosure that data collected by current sensors is compared to threshold values, that is, a predetermined current value. Furthermore, even accepting Patent Owner's contention that the term "predetermined value" necessarily "refer[s] to a specific number" (Sur-Reply 18), the rate of change of a value is a specific number—in this case, current over time. Ex. 1200 ¶¶ 81–82.

b. *whether Heeren teaches early termination of a pulse*

Patent Owner also argues that Heeren does not teach early termination of a pulse, but rather, "teaches that certain parameters of a pulse (*e.g.* voltage) can be adjusted after pulse termination." PO Resp. 48–49 (citing Ex. 1006 ¶ 33, Fig. 7, Diagram 702; Ex. 2100 ¶ 174). Furthermore, Patent Owner contends that "[i]n order for the current . . . to stop, the dielectric must reestablish, which as discussed herein will not happen instantaneously." *Id.* at 49 (citing Ex. 2100 ¶ 175). Dr. van der Weide testifies that because "Heeren's pulses are about a million times faster than the dielectric relaxation time [of the protein complexes being treated] (1 ms v. 1 ns), a skilled artisan would understand that Heeren simply could not immediately cut off the current in the middle of a pulse." *Id.* at 49–50 (citing Ex. 2045 ¶ 70 (Kovalcheck patent application for removing proteinaceous tissue); Ex. 1006 ¶ 22; Ex. 2100 ¶ 176). And, as asserted above, Patent Owner argues that "the combined effects of negative resistance and inductance would make it nearly impossible to terminate the voltage pulse in Heeren." *Id.* at 50 (citing Ex. 2100 ¶¶ 178–191).

Petitioner argues that Patent Owner's "arguments ignore element 1[e]'s language [which] says nothing about terminating the pulse, current/arc, or the time required to do so." Pet. Reply 15. Rather, the claims require only that the voltage supplied to the electrodes be terminated. *Id.* at 6–10, 15. Furthermore, Petitioner argues that Heeren does teach terminating the pulse where Heeren describes that its system can "(i) 'reduc[e] the strength, duration, and/or shape of the pulses,' (ii) adjust 'operational parameters' (*e.g.*, such as 'voltage') 'in the middle of the pulse,'

(iii) turn the pulses off completely, and (iv) make the adjustments 'dynamically.'" *Id.* at 16 (citing Ex. 1006 ¶¶ 32–33).

As we explain above, we do not construe claim 1 to require early termination of the voltage pulse itself, rather, the plain language of the claim requires only that "the power source terminate the voltage *supplied to* the electrodes for that pulse." Accordingly, we are not persuaded by Patent Owner's arguments based on the purported failure of Heeren to describe early pulse termination.

Furthermore, Heeren's disclosure expressly contradicts Patent Owner's assertions in this regard. For example, 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 (italics emphasis added); *see also id*. ¶¶ 4 (same), 21 (explaining that control circuit 150 controls pulse amplitude, pulse duration, repetition rate, pulse pattern, and pulse train length based on sensor data). Figure 7, reproduced below, exemplifies adjusting the operational parameters according to Heeren.

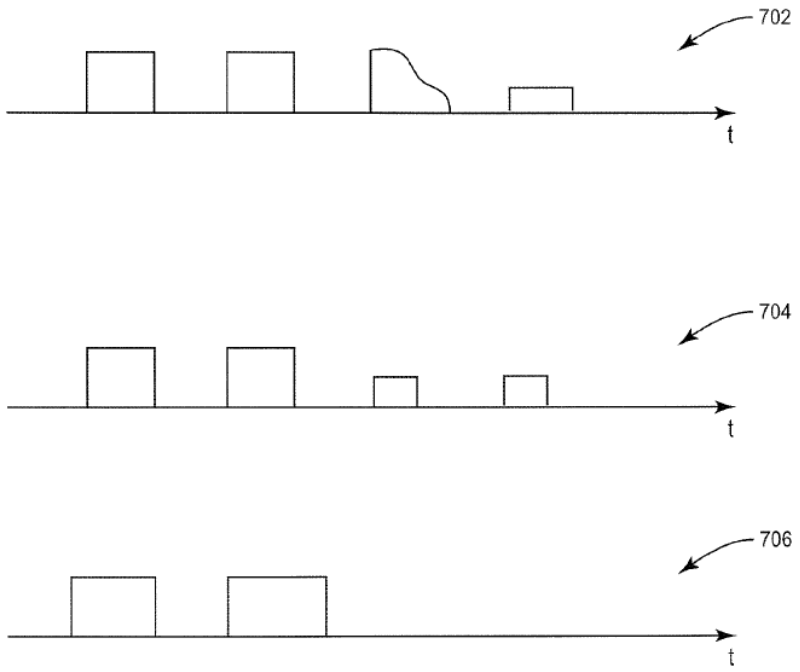

FIG. 7

Figure 7 "illustrates series of electric pulses with parameters adjusted during a dielectric breakdown." Ex. 1006 ¶ 13. Heeren further explains that "[b]y dynamically adjusting the operational parameters of pulse generator 170 in response to an imminent dielectric breakdown or a dielectric breakdown, PEF device 200 can prevent or reduce damage[] caused by a dielectric breakdown." *Id.* ¶ 33. And, as Dr. Jensen testifies, adjusting or reducing the pulse duration "necessarily sets the pulse termination as the end of the given pulse." Ex. 1002 ¶ 189.

Based on the foregoing, Petitioner has established, by a preponderance of the evidence, that the combination of Hawkins and Heeren discloses all of the limitations of claim 1 and that one of ordinary skill in the art would have been motivated to combine Hawkins with Heeren. As a

result, when weighed with the evidence of secondary indicia of nonobviousness (*see infra* Sections II.H. and II.I.), Petitioner has established by a preponderance of the evidence claim 1 would have been obvious based on Hawkins and Heeren.

3. Analysis of the Remaining Claims (2–14)

Patent Owner does not challenge Petitioner's allegations as to independent claims 6, 10, and 14 or dependent claims 2–5, 7–9, and 11–13 separate from the arguments considered above for claim 1. Based on our independent review of the Petition and cited evidence, we determine that Petitioner has established by a preponderance of the evidence that the subject matter of claims 2–14 would have been obvious based on the combined teachings of Hawkins and Heeren. For the reasons discussed above, the additional limitations claims 2, 3, 7, 8, 10, and 11 would have been suggested by Hawkins and understanding of the skilled artisan in the art. *See* Section II.D.4. And, the additional limitation of claims 4, 12, and 14, i.e., a delay timer, are suggested by Heeren's dynamic control which sets the pulse duration. Pet. 58–59 (citing Ex. 1006 ¶¶ 32–33; Ex. 1002 ¶¶ 203–204). Furthermore, the duration of the delay, relevant for claims 5, 6, 9, and 13, involves optimization of a result effective variable, is a matter of design choice based on component selection, and was well known in the art. *Id.* at 60–62 (citing Ex. 1001, 10:60–11:9 (explaining that delay time is dependent on the natural response delay of the circuitry); Ex. 1002 ¶¶ 207–211; Ex. 1010, Fig. 4; Ex. 1005 ¶ 59).

H. Objective Indicia of Nonobviousness

The fourth *Graham* factor instructs that we must consider—apart from what the prior art itself would have suggested— whether objective evidence of nonobviousness (i.e., secondary considerations) may lead to a conclusion that the challenged claims would not have been obvious. *See, e.g.*, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (instructing that evidence of secondary considerations, when present, must always be considered in determining obviousness). Objective evidence of nonobviousness may include evidence of commercial success, licensing, copying, praise by others, longfelt but unresolved need, and failure or skepticism of others. *Graham*, 383 U.S. at 17–18. But, secondary considerations are only a part of the "totality of the evidence"; its mere existence does not control the conclusion of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co*., 122 F.3d 1476, 1483 (Fed. Cir. 1997) (citations omitted). Objective evidence of nonobviousness "may often be the most probative and cogent evidence in the record" and "may often establish that an invention appearing to have been obvious in light of the prior art was not." *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

Objective evidence of nonobviousness "is only relevant to the obviousness inquiry 'if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].'" *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (2006)). A "nexus" is a legally and factually sufficient connection between the objective evidence and the claimed

invention such that the objective evidence should be considered in the determination of obviousness. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019); *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). A presumption of nexus arises where "the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))); *see also Teva Pharms. USA, Inc. v. Sandoz, Inc*., 723 F.3d 1363, 1372 (Fed. Cir. 2013) (explaining that a "presumption of a nexus" exists where a product is "coextensive" with a patent claim). If, however, the patented invention is only a component of the commercial embodiment, the patentee is not entitled to a presumption of nexus. *Fox Factory*, 994 F.3d at 1374. "A patent is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the products' functionality." *Id.* at 1375. But, "[a] finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations"; rather, "the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is 'the direct result of the unique characteristics of the claimed invention.'" *Id.* at 1374 (quoting *In re Huang*, 100 F.3d 125, 140 (Fed. Cir. 1996). Patent Owner bears the burden of establishing that a nexus exists between the evidence of secondary considerations and the patented invention. *Id.* at 1373.

Patent Owner argues that there exists substantial evidence of nonobviousness in the form of industry acclaim, skepticism of others, and commercial success. *See* PO. Resp. 50–59. In particular, Patent Owner contends that "[t]he claims of the '091 patent are directed to an important aspect of the Shockwave device that contributes substantially to patient safety." *Id.* at 51 (citing Ex. 2100 ¶ 196). Patent Owner attributes patient safety to the ability of its "improved shockwave catheter [to] deliver[] 'a maximum intensity shockwave . . . formed without wasting energy, without unduly eroding the electrodes, and without generating unnecessary heat.'" *Id.* (citing Ex. 1001, 11:14–16). Patent Owner further explains that its current monitoring sensor and pulse termination ensures that the Shockwave device "generates less heat in the balloon" as too much heat may damage tissue. *Id.* According to Patent Owner, the safety of the Shockwave IVL is evidenced by industry praise, skepticism in the art, and commercial success. *See generally* PO Resp. 50–59. Through the testimony of Dr. van der Weide, Patent Owner contends "that the Shockwave IVL device includes each feature recited in the claims of the '091 patent." *Id.* (citing Ex. 2100 ¶ 195; Exs. 2178–2180 (claim charts)). Patent Owner, however, does not argue that the Shockwave IVL device is coextensive with any of the challenged claims or address whether a presumption of nexus is appropriate in this case.[9] *Id.* Therefore, we assume for purposes of our analysis that all

[9] Patent Owner initially asserted that it was entitled to a presumption of nexus because the Shockwave product was coextensive with the claimed features. Prelim. Resp. 56–57. Patent Owner, however, did not reassert this

of the challenged claims cover the Shockwave IVL device, but do not apply a presumption of nexus because Patent Owner waived that argument. Below we consider the parties' arguments and evidence regarding any purported industry praise, skepticism in the art, and commercial success in light of any alleged nexus.

1. Industry Praise

Patent Owner contends that "[t]he Shockwave IVL device has achieved significant praise from those in the industry for its superior safety, which derives in substantial part from the claimed invention." PO Resp. 53. As evidence of this praise, Patent Owner points to the "Breakthrough Device" designation awarded to the Shockwave IVL device by the U.S. Food and Drug Administration ("FDA"). *Id.* According to Patent Owner, the "designation is awarded to a device that 'provides for more effective treatment' with 'no approved or cleared alternatives' while 'offer[ing] significant advantages over existing approved or cleared alternatives . . . .'" *Id.* (citing Ex. 2135, 7 (FDA Guidance on Breakthrough Devices Program)). Dr. van der Weide testifies that "while he 'understand[s] the Breakthrough Designation was not awarded solely based on the pulse terminating

---

position in its Response and as a result, Patent Owner has waived this argument. *Unified Patents Inc. v. Nonend Inventions N.V.*, IPR2016-00174, Paper 28, 3–4 (PTAB July 25, 2017) (arguments raised in a patent owner preliminary response but not reasserted in a patent owner response are waived); *see also* Paper 15, 7–8 ("Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.").

innovation disclosed and claimed in the '091 patent, that innovation does contribute to the safety profile of the Shockwave IVL device.'" *Id.* (quoting Ex. 2100 ¶ 202).

Patent Owner also relies on the testimony of clinicians who "regularly use the Shockwave IVL device and have praised its safety." *Id*. at 53 (citing Ex. 2100 ¶ 203). For example, Dr. Kereiakes testifies that the "Shockwave IVL has generated excitement in the community due to its ease of use and safety profile" and that he tells his colleagues that "they should expect 'zero' complications of the procedure with Shockwave IVL." *Id.* at 53–54 (quoting Ex. 2174 ¶¶ 17–18). Dr. Soukas testifies that the Shockwave IVL is "extremely safe" and that he has "never encountered an issue with . . . the energy creating an unacceptable amount of heat in the hundreds of times [he] ha[s] used Shockwave IVL." *Id.* at 54 (first alteration in the original). Dr. Soukas explains that "Shockwave IVL includes controls that limit the duration of energy, which creates shockwaves to prevent too much heat from being generated." *Id.* (quoting Ex. 2170 ¶ 20). Dr. Armstrong attests that the "Shockwave device has an amazing safety profile" and that it is "much safer than traditional angioplasty balloons and atherectomy devices." *Id.* (quoting Ex. 2173 ¶ 22). And, Dr. Lyden affirms that "[t]he device is also extremely safe with no adverse events from shockwaves" and identifies "[o]ne of the safety feature[s] is the result of a sensor that allows the electric charge to be terminated before it generates too much heat." *Id.* at 55 (quoting Ex. 2171 ¶ 20) (alterations in original).

Lastly, Patent Owner contends that financial analyst reporting and industry articles reflect industry praise. *Id.* at 55–56. In particular, these

articles characterize the Shockwave IVL device and accompanying technology as "innovative, potentially paradigm-changing" and "disruptive" (*id.* (quoting Ex. 2132, 3, 52, 59; quoting Ex. 2133, 14)), "elegant" and "easy to use" (*id.* at 56 (quoting Ex. 2016, 1)), "revolutionary" (*id.* (quoting Ex. 2003, 1)), "amazing" and "actually space-age technology" (*id.* (quoting Ex. 2002, 2)), and "'safer' than other devices" (*id.* (quoting Ex. 2114, 11)).

Much of Patent Owner's evidence—the Breakthrough Device designation, analyst reports, and articles—is "generalized praise" unattributed to any claimed feature (or combination of features) of the '091 patent. Similarly, much of the clinician testimony is largely unrelated to claimed features of the '091 patent, much less the current monitoring sensor purportedly responsible for improved safety due to the generation of less heat within the balloon. *See* Ex. 2174 ¶ 18 (testimony of Dr. Kereiakes that "[t]here have not been any reported arterial ruptures or perforations caused by the angioplasty balloon" or "reported incidents of atheroembolization"); Ex. 2170 ¶ 20; Ex. 1212, 148:20–149:19 (testimony of Dr. Soukas crediting the button delivering energy as responsible for preventing too much heat from being generated); Ex. 2173 ¶ 22 (failing to tie reduction in excessive heat to any feature of the Shockwave device). Only the testimony of Dr. Lyden provides any nexus to the safety feature claimed by the '091 patent. Ex. 2171 ¶ 20 ("One of the safety feature[s] is the result of a sensor that allows the electric charge to be terminated before it generates too much heat."). Dr. Lyden has received between $5,000–$10,000 in consulting fees from Shockwave separate from the consulting work performed in connection

with this matter which, as of January 2020, has not been billed. Ex. 1214, 2 (questions regarding Lyden and Armstrong).

Therefore, having considered the record evidence, we find that some evidence of industry praise with a nexus to the '091 patent, namely the testimony of Dr. Lyden, exists in the record. We also do not view such "financial interest" to be noteworthy or find other evidence of bias on the part of Dr. Lyden. On balance, we accord moderate weight to Patent Owner's evidence of industry praise as significant industry praise tied to the claimed features has not been shown.

2. Skepticism in the Art

Patent Owner asserts that "clinicians that regularly use the device expressed skepticism as to whether the Shockwave IVL would generate an unsafe amount of heat that could result in tissue damage." PO Resp. 56 (citing Ex. 2100 ¶ 216). For example, Dr. Soukas explained that he had concerns about the device creating an unacceptable amount of heat that could cause damage to the arterial wall, but "that his concern 'proved to be unwarranted as the device is extremely safe.'" *Id.* at 56–57 (quoting Ex. 2170 ¶¶ 19–20). Further, Dr. Armstrong testifies that "when [he] first learned of the technology [his concern] was whether it would generate too much heat" because "[i]t is well known in this field that heating the blood vessel by more than about two degrees Celsius could damage the vessel wall, which would almost certainly lead to restenosis." *Id.* at 57 (quoting Ex. 2173 ¶ 21) (second quote alteration in original). But, Dr. Armstrong "testifies that his safety concerns were 'allayed by the Shockwave clinical

studies and the clinical experience of physicians.'" *Id.* (quoting Ex. 2173 ¶ 21).

The testimony of Drs. Soukas and Armstrong provide some evidence of skepticism. Specifically, Dr. Armstrong was skeptical about: (1) the ability of the Shockwave IVL device to pass through heavily calcified lesions, especially in light of the additional components included in the device (Ex. 2173 ¶¶ 15–17), (2) the risk of embolism (*id.* ¶¶ 18–19), (3) whether the "balloon could survive the pressure generated by the shockwave" and rupture (*id.* ¶ 20), and (4) whether the Shockwave IVL would generate too much heat and cause restenosis (*id.* ¶ 21). Similarly, Dr. Soukas expressed skepticism that a balloon could be used to treat heavily calcified lesions (Ex. 2170 ¶¶ 10, 19), concern that the angioplasty balloon would rupture (*id.* ¶ 19), worry that "the generation of energy in the form of a shockwave would create an unacceptable amount of heat" (*id.*), and concern over the potential for embolism (*id.* ¶ 21). Only Dr. Soukas tied his concern of overheating to a feature of the Shockwave IVL—specifically that the "Shockwave IVL includes controls that limit the duration of energy, which creates the shockwaves to prevent too much heat from being generated." *Id.* ¶ 20. When questioned about this statement, however, Dr. Soukas testified that he was referring the ability to deliver voltage using a button control.

> Q. What artery is -- never mind. You answered that. So, you make a statement, Shockwave IVL includes controls that limit the duration of energy. What were you referring to with respect to those controls?
>
> A. The fact that you have to keep your finger on the button in order to deliver the spark.

Q. Okay. So, you can't -- as soon as your finger comes off, the sparks stop; is that fair?

A. That's correct.

Q. Yeah, can you -- so, let me ask this. So, to deliver the 30 pulses maximum in -- in one button press if you will, how long does that take?

A. 30 seconds.

Q. One per second?

A. (Witness nodding.)

Q. So, you can -- can you precise -- so, can you just deliver 10 by looking at your watch and counting 10 seconds?

A. Sure.

Q. Okay. When you're using the Shockwave device is that typical, or do you either use one pulse or the full 30?

A. Most of the time I use the full 30.

Ex. 1212, 148:20–149:19. Thus, the skepticism expressed by Dr. Soukas—and tied to features of the Shockwave IVL—are not attributed to the advantages of the claimed invention because none of the claims recites use of a control button to control the delivery of energy. Rather, the evidence of nonobviousness expressed here is due to "additional unclaimed features." *Polaris*, 882 F.3d at 1072. As such, we assign little weight to Patent Owner's evidence of skepticism as Patent Owner failed to adequately link the record evidence to the claimed features of the '091 patent.

3. Commercial Success

Patent Owner states that "Shockwave IVL sales have skyrocketed due, in part, to the safety profile of the device discussed above. Because the invention claimed in the '091 patent makes a substantial contribution to the safety of the device, it follows that the innovation has made a substantial

contribution to the success of the Shockwave IVL device." PO Resp. 57. Patent Owner explains that Shockwave "sells only one product with different model numbers used for different indications." *Id.* at 58 (citing Ex. 2100 ¶ 219; Ex. 2141, 10 (SEC Form 10-Q, consolidated financial statements)). As evidence of commercial success, Patent Owner explains that "Shockwave's current market capitalization is about $1 billion" (Ex. 2122 (Yahoo Finance data)), projected revenue for 2019 "range from $38 million to $40 million, which represents 210% to 226% growth over the company's prior year revenue" (Ex. 2176, 1 (Shockwave 2d Quarter Financial Results); Ex. 2175 ¶ 8 (Stephens declaration)), and "second quarter revenue of 2019 was $10.0 million, an increase of $7.7 million, or 339%, compared to the second quarter of 2018" (PO Resp. 58). Dr. Kereiakes also testifies that the Shockwave IVL effectiveness, ease of use, and safety profile are responsible for its success. *Id*. at 58 (citing Ex. 2174 ¶ 19). Further, Dr. Kereiakes "recounts that '[u]pon seeing or using Shockwave IVL, seasoned interventional cardiologists often ask how they can invest in the technology, which in 'estimation [] is a ringing endorsement of the technology that is traced directly to the effectiveness, ease of use, and safety profile of Shockwave IVL.'" *Id.* (quoting Ex. 2174 ¶ 19) (alterations in original).

While we agree, in view of the evidence and supporting testimony, that the Shockwave IVL device is commercially successful and has resulted in significant sales, Patent Owner does little, if anything, to tie that commercial success to any patented features of the '091 patent, much less safety in general. The record lacks evidence as to whether the Shockwave

device sales are the result of the unique characteristics of the claimed invention as opposed to other economic or commercial factors unrelated to the safety of the invention, such as successful marketing and promotion. *See* Ex. 1216, 30:20–37:7 (testimony by Mr. Stephens that the sales force has "gone up meaningfully" since 2018); Ex. 2141, 4, 20–23 (Patent Owner's 10-Q detailing a 59% increase in its sales and marketing expenses from 2018-2019). And though Dr. Kereiakes credits the Shockwave safety profile as a partial contributor to its commercial success, his testimony is based on the fact that "[t]here have not been any reported arterial ruptures or perforations caused by the angioplasty balloon" or "reported incidents of atheroembolization (plaque particles being dislodged and going 'downstream' to cause distal vessel occlusion)." Ex. 2174 ¶ 18; *see also id.* ¶ 14 (explaining that known angioplasty balloons rupture 1–2% of the time). Accordingly, we accord only moderate weight to Patent Owner's evidence of commercial success in the absence of a more substantial nexus to the claims.

I. Conclusion as to Obviousness

Petitioner persuasively explains where Hawkins in combination with either of Li, Chernenko, Chernenko and Li, or Heeren discloses the limitations of the challenged claims. *See generally* Pet. Petitioner also persuasively explains why one of ordinary skill in the art would have had reason to modify Hawkins in view of the secondary references to achieve the invention as claimed. *Id.* When this evidence of obviousness is considered in combination with Patent Owner's evidence of objective indicia of nonobviousness, we determine that Petitioner has demonstrated by a

preponderance of the evidence that claims 1–14 of the '091 patent would have been obvious over the combined disclosures (1) Hawkins and Li (claims 1–14), Hawkins and Chernenko (claims 1–3 and 10), Hawkins, Chernenko and Li (claims 1–14), and Hawkins and Heeren (claims 1–14).

III. MOTIONS TO EXCLUDE

A. Petitioner's Motion to Exclude

Petitioner filed a Motion to Exclude Exhibits 2002–2004, 2006, 2008, 2048, 2015–2018, 2025, 2026, 2100, 2106, 2107, 2111, 2114, 2116–2122, 2132–2138, 2141, 2143, 2153, 2154, 2159-–2163, 2170, 2172, 2173, and 2175–2180. Pet. MTE 1.

1. Hearsay Objections

Petitioner moves to exclude Exhibits 2002, 2003, 2006, 2016, 2017, 2114, 2117, 2119, 2122, 2132, 2133, 2134, 2135, 2141, and 2175–2177 as inadmissible hearsay under Federal Rules of Evidence 801, 802, and 805. Pet. MTE, 1–2.[10] The objected to exhibits include news articles (Exs. 2002, 2003, 2114), analyst materials (Exs. 2006, 2007, 2016, 2017, 2132, 2133), partial transcripts of a Shockwave roundtable discussion (Exs. 2117, 2119), Yahoo Finance data (Ex. 2122), FDA Breakthrough letter and Guidance paper (Exs. 2134, 2135), Shockwave 10-Q (Ex. 2141), and the Stephens' Declaration and supporting documents (Exs. 2175–2177). *Id.*

[10] Though Petitioner objected to Exhibits 2004, 2008, 2015, 2025, and 2026 as inadmissible hearsay (*see* Paper 17), Petitioner does not move to exclude these exhibits as improper hearsay, but rather, as uncited exhibits. Pet. MTE 7.

Patent Owner argues that "laudatory statements" are not offered for the truth of the matter but rather to show that the statements were made. PO MTE Opp. 1–2. Patent Owner further contends that the exhibits Petitioner seeks to exclude "are relied upon by an expert, who is entitled to rely on hearsay materials to support his or her opinions." *Id.* at 2. Lastly, Patent Owner argues that the exhibits are sufficiently trustworthy in light of the totality of the circumstances. *Id.* at 3.

We are not persuaded that Exhibits 2002, 2003, 2006, 2016, 2017, 2114, 2117, 2119, 2122, 2132, 2133, 2134, 2135, 2141, and 2175–2177 should be excluded. These exhibits are, for the most part, offered in support of Patent Owner's argument that objective evidence of nonobviousness exists, *i.e.*, industry praise, skepticism, and commercial success. *See generally* PO Resp. 50–59. Patent Owner does not rely on statements made in these exhibits for the truth of the matter asserted, for example, that the Shockwave device "has an amazing safety profile [Ex. 2173 ¶ 22]" or that it is "space-age technology [Ex. 2002, 1]." Rather, Patent Owner relies upon these statements to show that industry actors took notice of and commented on the Shockwave device. *Quanergy Sys., Inc. v. Velodyne Lidar, Inc.*, IPR2018-00256, Paper 66 at 5–6 (PTAB May 21, 2020) ("[S]tatements offered solely for the purpose of showing they were made are admissible."); *Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 59 at 59 (PTAB Apr. 2, 2018). To the extent the evidence may have served a hearsay purpose, we assign it little, if any, weight. Further, experts like Dr. van der Weide are permitted to rely on hearsay if experts in the same field would reasonably rely on such materials in forming opinions and inferences based

on the subject. *See* Fed. R. Evid. 703. To the extent that Dr. van der Weide relies on evidence that is not of the type which "experts in the field would reasonably rely," we have assigned very little weight to such evidence.[11] Therefore, we deny Petitioner's motion to exclude these Exhibits 2002, 2003, 2006, 2016, 2017, 2114, 2122, 2132, 2133, 2134, 2135, 2141, and 2175–2177.

Exhibits 2117 and 2119, though considered by Dr. van der Weide in forming his opinions, are not relied upon by Patent Owner in advancing its positions. Accordingly, we deny Petitioner's motion to exclude Exhibits 2117 and 2119 as moot.

2. Uncited Exhibits

Petitioner moves to exclude exhibits 2004, 2008, 2015, 2025, 2026, 2048, 2106, 2107, 2116, 2118, 2120, 2121, 2136–2138, 2143, 2153, 2154, 2159–2163, and 2173 as irrelevant under Federal Rules of Evidence 401 and 402. Pet. MTE 7. Petitioner argues that because Patent Owner did not cite to these exhibits in any of its pleadings and declarations, "the exhibits 'ha[ve] no bearing on any fact that is of consequence in determining the outcome of the proceeding' and should be excluded under FRE 401 and 402." *Id.* at 8 (quoting *One World Technologies, Inc. v. The Chamberlain*

[11] Even if we accorded the identified exhibits and testimony substantial weight, it would not alter our ultimate decision finding the claims obvious as Patent Owner's showing of nexus between the objective indicia of nonobviousness and the claims is inadequate.

Group, Inc., IPR2017-00126, paper 56 at 16 (PTAB October 24, 2018)) (alteration in original).

Patent Owner contends that the uncited exhibits should not be excluded because "the better course is to preserve them in the record." PO MTE Opp. 6–7.

We are not persuaded by Petitioner's arguments that the evidence on which Patent Owner relies must be excluded from the record. Patent Owner does not rely on Exhibits 2004, 2008, 2015, 2025, 2026, 2048, 2106, 2107, 2116, 2118, 2120, 2121, 2136–2138, 2143, 2153, 2154, 2159–2163, and 2173 to support its arguments. *See generally* PO Resp., Sur-Reply. Because Petitioner does not rely on Exhibits 2004, 2008, 2015, 2025, 2026, 2048, 2106, 2107, 2116, 2118, 2120, 2121, 2136–2138, 2143, 2153, 2154, 2159–2163, and 2173, we do not consider these exhibits in rendering our Decision. Accordingly, we deny Petitioner's motion to exclude these Exhibits as moot.

3. Deposition Exhibits

Petitioner moves to exclude Exhibits 2178–2180, that is, claim charts mapping certain claims to the Shockwave devices. Pet. MTE 8–9. According to Petitioner, "Mr. Stephens and Dr. van der Weide lack[] personal knowledge of the information recited in the exhibits." *Id.* at 9.

Patent Owner argues that Petitioner failed to make a timely objection to Exhibits 2178–2180 and therefore such objection is waived. PO MTE Opp. 7. Patent Owner further explains that Exhibits 2178–2180 are relied upon by Dr. van der Weide, not Mr. Stephens, and further that there is no

requirement that an expert have personal knowledge about the facts and data upon which he relies. *Id.* at 8.

Our rules require that "[a] party wishing to challenge the admissibility of deposition evidence must make an objection during the deposition [and, a] party wishing to challenge evidence other than deposition evidence, must file any objections within five business days of service of evidence." 37 C.F.R. §§ 42.64(a); Patent Trial and Appeal Board Consolidated Trial Practice Guide 78–79 (Nov. 2019) ("Consolidated TPG").[12] Any such "[o]bjections may be preserved by filing a motion to exclude the evidence." 37 C.F.R. §§ 42.64(c); Consolidated TPG 78–79. The failure to raise an objection at the appropriate time, results in a waiver of the objection. As a result, we advise parties that "[a] motion to exclude evidence should . . . [i]dentify where in the record the objection was originally made." Consolidated TPG 79. Here, Petitioner does not identify the portion of the record where its objection to Exhibits 2178–2180 were originally made (*see* Pet. MTE 8–9) and our review of the Petitioner's Objections (Papers 17, 37), as well as the deposition testimony of Mr. Stephens and Dr. van der Weide, show that Petitioner failed to object to Exhibits 2178–2180. Therefore, we deny Petitioner's Motion to Exclude Exhibits 2178–2180.

[12] The Consolidated TPG is available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf).

4. Objections under Federal Rule of Evidence 401, 402, and 403

Petitioner moves to exclude exhibits 2002, 2003, 2006, 2016, 2018, 2111, 2122, 2132–2135, 2141, 2171, and 2173 as irrelevant under Federal Rules of Evidence 401, 402, and 403. Pet. MTE 9. The exhibits identified as objectionable include news articles (Exs. 2002, 2003), analyst materials (Exs. 2006, 2016, 2132, 2133), the Motisan reference (Ex. 2018), international standard documentation (Ex. 2111), Yahoo Finance data (Ex. 2122), FDA Breakthrough letter and Guidance paper (Exs. 2134, 2135), Shockwave 10-Q (Ex. 2141), and the declaration testimony of Drs. Lyden and Armstrong (Exs. 2171, 2173). *Id.* Petitioner contends the identified exhibits provide scant, cumulative, and unhelpful information that should be excluded. *See generally id.* at 9–13.

Patent Owner argues that, instead of excluding evidence deemed to be irrelevant, little weight should be accorded such evidence. PO MTE Opp. 8–9. Patent Owner explains that each of Petitioner's arguments go to the weight of the evidence as opposed to admissibility. *See generally id.* at 8–15. Patent Owner also contends that the declarations of Drs. Lyden and Armstrong (Exs. 2171, 2173) each "bring[] a different perspective and emphasize[] different aspects of the Shockwave device," and therefore are not cumulative. *Id.* at 11. Further, according to Patent Owner, "[t]he declarations also corroborate one another in various respects, which is another important aspect of the declarations." *Id.* at 11–12.

We are not persuaded by Petitioner's arguments that Exhibits 2002, 2003, 2006, 2016, 2018, 2111, 2122, 2132–2135, 2141, 2171, and 2173 must be excluded from the record. The evidence Petitioner seeks to exclude

supports Patent Owner's argument that the claims of the '091 patent are nonobviousness; specifically, the exhibits relate to objective indicia of nonobviousness. Therefore, the exhibits are relevant as having a "tendency to make a fact more or less probable." Fed. R. Evid. 401. Further, because the decision here is rendered by the panel, as opposed to a jury, there is little risk that the purported "scant, cumulative, and unhelpful information" will confuse or mislead the panel such that the probative value is outweighed by the danger of unfair prejudice. *Id.* at 403; *see Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) ("Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well-positioned to determine and assign appropriate weight to the evidence presented."). For the above reasons, we are not persuaded that the testimony at issue should be excluded and, thus, we deny Patent Owner's Motion to Exclude Exhibits 2002, 2003, 2006, 2016, 2018, 2111, 2122, 2132–2135, 2141, 2171, and 2173.

5. Testimony of Dr. van der Weide

Petitioner moves to exclude portions of the declaration testimony of Dr. van der Weide under Federal Rules of Evidence 702 and 703. Pet. MTE 14. In particular, Petitioner seeks to exclude certain paragraphs of Dr. van der Weide's declaration (Ex. 2100), including:

> paragraphs 68, 70, 78 (testimony not based on sufficient facts or data), 83 (unfounded conclusion; testimony not based on sufficient facts or data that the TI data sheet represents the commercial embodiment of the Li reference, Ex. 1004); 91, 92, 94, 95 (prior art never address FDA requirements; testimony not based on sufficient facts or data), 127–131 (testimony not based

> on sufficient facts or data), and 172 (mischaracterizes Heeren; testimony not based on sufficient facts or data).

Id.

Patent Owner argues that Petitioner's basis for excluding certain paragraphs of Dr. van der Weide's declaration are conclusory and that Petitioner "does not explain how the testimony is not based on sufficient facts or data, what alternative facts or data could or should instead have been considered, or how the prior art is mischaracterized." PO MTE Opp. 15.

Whether Dr. van der Weide's opinions are conclusory, mischaracterizes evidence, or not adequately based on record evidence, in this case, goes to the weight we should give to his testimony. Thus, we deny Petitioner's motion to exclude the identified paragraphs of Dr. van der Weide's second declaration (Ex. 2100).

B. Patent Owner's Motion to Exclude

Patent Owner filed a Motion to Exclude Exhibits 1002 and 1200, i.e., the expert opinion testimony offered by Dr. Morten Jensen. PO MTE 1. According to Patent Owner, "Dr. Jensen is not qualified to testify either as a person of ordinary skill in the art or as an expert in this proceeding." *Id.* Patent Owner objected to Exhibit 1002 under Federal Rule of Evidence 703, i.e., including statements that are unsupported by facts, data or other evidence, and Exhibit 1200 under Rule 702, that is, Dr. Jensen's opinions are unreliable because he is not qualified as an expert. *Id.* Patent Owner argues Exhibits 1002 and 1200 should be excluded for the same reasons—Dr. Jensen is not qualified, as established by the facts that Dr. Jensen: (1) did not understand the concept of negative resistance (*id.* at 3); (2) "did

not consider the impact inductance would have had on any attempt to terminate an arc-generating voltage pulse early" (*id.* at 4); (3) "does not understand the prior art references on which he relied" (*id.* at 5); and (4) admitted "he had only a 'general understanding' of the preferred embodiment of the '091 patent (Fig. 6) and 'didn't dive into great detail'" (*id.* at 7). Therefore, Patent Owner contends that, because Dr. Jensen's testimony is based on a misunderstanding of the technology, it is unreliable, unhelpful, and prejudicial to Patent Owner. *Id.* at 8.

Regarding Exhibit 1200, Petitioner argues that Patent Owner did not timely object or respond to Petitioner's supplemental evidence. Pet. MTE Opp. 1. Therefore, Petitioner reasons that Patent Owner did not preserve its objections. *Id.* at 2.[13]

We are not persuaded we should exclude Dr. Jensen's declaration testimony (Ex. 1200) as an unqualified expert under Rule 702.[14] Dr. Jensen holds an undergraduate degree in electrical and computer engineering with

---

[13] Petitioner's argument that Patent Owner did not timely object is without merit. Petitioner complains that Patent Owner filed its objections six days and not the requisite five days after Petitioner served Exhibit 1200. Pet. MTE Opp. 1. But, February 17, 2020 fell on the third Monday in February, i.e., Presidents' Day, a federal holiday. Therefore, Patent Owner's objections are not tardy.

[14] Patent Owner did not originally object to Exhibit 1002 on the grounds that Dr. Jensen was unqualified to testify as an expert under Rule 702. Rather, Patent Owner only objected to certain paragraphs under Rules 703 and 403. *See* Paper 16, 2. Thus, we observe Patent Owner also failed to preserve any objection to 1002 on the ground that Dr. Jensen is unqualified, as alleged in Patent Owner's Motion to Exclude.

an emphasis on biomedical engineering, a master's degree in biomedical engineering, and a doctorate in both medicine (Ph.D.) and medical science (Dr.Med.). Ex. 1002 ¶ 8. Dr. Jensen indicates that he is currently employed as a professor of biomedical engineering and the University of Arkansas and is an adjunct professor in the Department of Cardiothoracic Surgery at the University Hospital of Aarhus where he teaches biomedical engineering. *Id.* ¶ 9. Dr. Jensen has "published numerous articles relating to aspects of device interactions with cardiovascular tissues, including device design, performance and specific features that allow these devices to function optimally." *Id.* ¶ 10. Dr. Jensen has observed and participated in hundreds of heart surgeries on large animals, in particular porcine models—"well-known model[s] for the human heart and cardiovascular system"—as part of his research efforts. *Id.* ¶¶ 11–12. Therefore, at the time of invention for the '091 patent, Dr. Jensen had the requisite academic training and sufficient experience necessary to provide expert testimony regarding the technology embodied in the '091 patent. Though his experience may not specifically relate to arcs, arc formation, or the generation and management of shockwaves, complete overlap between an expert's technical qualifications and the field of invention is not required. *SEB*, 594 F.3d at 1373 (stating that there is no requirement that of a perfect match between the expert's experience and the field of invention so long as there is "sufficient relevant technical expertise."). At a minimum, there exists "an adequate relationship between [Dr. Jensen's] experience and the claimed invention" sufficient to provide testimony as to what a person of ordinary skill in the art would have understood at the time of invention. *Id.* at 1372–1373.

With respect to Patent Owner's objections to Exhibit 1002 under Rule 703, Petitioner argues that Patent Owner did not preserve its objection to the entirety of Exhibit 1002, but rather, objected only to twelve paragraphs. Pet. MTE Opp. 2. Petitioner also asserts that the portions of Dr. Jensen's testimony Patent Owner objects to have been taken in isolation and not considered as a whole. *Id*. 5–8.

We agree with Petitioner that Patent Owner originally objected only to paragraphs 55, 56, 60–63, 74, 75, 97, 102, 192, and 203 of Exhibit 1002 under Rule 703. *See* Paper 16, 2. And, regarding Exhibit 1200, Patent Owner specifically objected to paragraphs 32–33, 36, 37, 40–70, 73–88, 90–101, 103, and 106. Paper 52, 2. Our rules instruct that a motion to exclude evidence should:

(a) Identify where in the record the objection originally was made;

(b) Identify where in the record the evidence sought to be excluded was relied upon by an opponent;

(c) Address objections to exhibits in numerical order; and

(d) Explain the basis and grounds for each objection.

37 C.F.R. §§ 42.64(c); Consolidated TPG 79. Here, Patent Owner fails to identify where Petitioner relies on the evidence to be excluded and does not explain the substance of its objections for each paragraph. *Id.* Accordingly, Patent Owner's Motion to Exclude is procedurally deficient.

Furthermore, Patent Owner's objections go to the weight and sufficiency of the testimony, rather than its admissibility. PO MTE 5–8. Whether Dr. Jensen may not understand certain concepts or may have failed to consider certain evidence in the manner Patent Owner prefers does not

warrant exclusion of his testimony in this case. Patent Owner had the opportunity to, and in fact did, thoroughly cross examine Dr. Jensen about the purported deficiencies in his declaration testimony. *See*, *e.g.*, Ex. 2105, 122:19–123:17; Ex. 2205, 7:20–46:19, 174:7–180:16. "Vigorous cross-examination [and] presentation of contrary evidence . . . are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993). And, because the panel, not a jury, will assess the evidence, the risk of prejudice is mitigated. *Corning*, IPR2013-00053, Paper 66 at 19.

Thus, we deny Patent Owner's motion seeking to exclude the testimony of Dr. Jensen in this proceeding.

IV. CONCLUSION[15]

For the reasons set forth above, we determine that Petitioner has established by a preponderance of the evidence that claims 1–14 of the '091 patent are unpatentable.

---

[15] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–14	103	Hawkins, Li	1–14	
1–3, 10	103	Hawkins, Chernenko	1–3, 10	
1–14	103	Hawkins, Chernenko, Li	1–14	
1–14	103	Hawkins, Heeren	1–14	
Overall Outcome			1–14	

V. ORDER

Accordingly, it is

ORDERED that claims 1–14 of U.S. Patent No. 8,728,091 B2 have been shown to be *unpatentable*;

FURTHER ORDERED that Petitioner's Motion to Exclude Exhibits 2002–2004, 2006, 2008, 2048, 2015–2018, 2025, 2026, 2100, 2106, 2107, 2111, 2114, 2116–2122, 2132–2138, 2141, 2143, 2153, 2154, 2159–2163, 2170, 2172, 2173, and 2175–2180 is *denied*;

FURTHER ORDERED that Patent Owner's Motion to Exclude Exhibits 1002 and 1200 is *denied*; and

FURTHER ORDERED that, because this is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Mark C. Nelson
Jeffrey Stone
BARNES & THORNBURG LLP
mnelson@btlaw.com
jstone@btlaw.com

PATENT OWNER:

Greg H. Gardella
Michael Stallman
W. Cook Alciati
Natalie J. Grace
Ruth G. Davilla
GARDELLA GRACE P.A.
ggardella@gardellagrace.com
calciati@gardellagrace.com
ngrace@gardellagrace.com
rdavila@gardellagrace.com

Michael Stallman
MORRISON & FOERSTER LLP
mstallman@mofo.com