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Paper 70
Entered: July 20, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.,
Petitioner,

v.

SHOCKWAVE MEDICAL, INC.,
Patent Owner.

IPR2019-00408
Patent 9,642,673 B2

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

WEATHERLY, *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

A. BACKGROUND

Cardiovascular Systems, Inc. ("Petitioner") filed a petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–20 (the "challenged claims") of U.S. Patent No. 9,642,673 B2 (Ex. 1001, "the '673 patent"). 35 U.S.C. § 311. Shockwave Medical, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 10 ("Prelim. Resp."). On July 22, 2019, based on the record before us at the time, we instituted an *inter partes* review of claims 1–20. Paper 13 ("Institution Decision" or "Dec."). We instituted review on the following challenges to the claims:

Claims Challenged	**35 U.S.C. §**[1]	**Reference(s)/Basis**
1, 2, 5–8, 15, 16, 19, 20	103	Hawkins '020,[2] Hawkins '768,[3] Kunis[4]
3, 4, 9–14, 17, 18	103	Hawkins '020, Hawkins '768, Kunis, Lesh[5]

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 32, "PO Resp."). Petitioner

[1] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the '673 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version. *See* Ex. 1001, code (22).

[2] U.S. Published Patent App. 2010/0114020 A1 (Ex. 1004, "Hawkins '020").

[3] U.S. Published Patent App. 2009/0312768 A1 (Ex. 1003, "Hawkins '768").

[4] U.S. Patent No. 7,850,685 B2 (Ex. 1005, "Kunis").

[5] U.S. Published Patent App. 2005/0251131 A1 (Ex. 1006, "Lesh").

filed a Reply in support of the Petition (Paper 46, "Reply"). Patent Owner filed a Sur-reply responding to the Reply (Paper 52, "Sur-reply"). Patent Owner did not move to amend any claim of the '673 patent.

We heard oral argument on April 16, 2020. A transcript of the argument has been entered in the record (Paper 69, "Tr.").

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons expressed below, we conclude that Petitioner has demonstrated by a preponderance of evidence that claims 1–20 are unpatentable.

B. RELATED PROCEEDINGS

Petitioner identified no related matters. Pet. 2. Patent Owner has identified the following petitions for *inter partes* review and patents or patent applications as related matters:

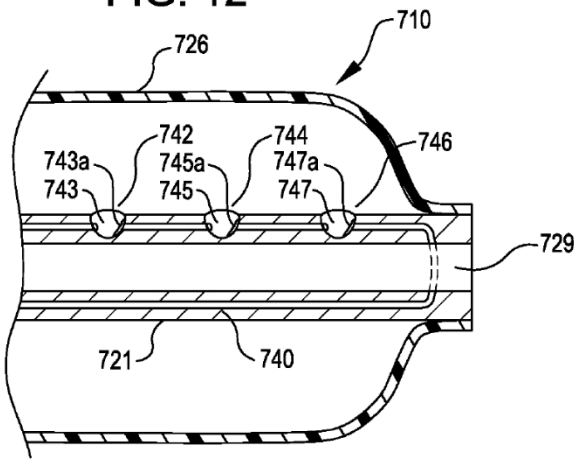
- Petition for *Inter Partes* Review of U.S. Patent No. 8,956,371, IPR2019-00405 (filed December 7, 2018);
- Petition for *Inter Partes* Review of U.S. Patent No. 8,728,091, IPR2019-00409 (filed December 7, 2018);
- U.S. Patent Application No. 14/271,342 filed on May 6, 2014, and issued as U.S. Patent No. 9,011,463 B2;
- U.S. Patent Application No. 15/474,885 filed on March 30, 2017, and issued as U.S. Patent No. 9,993,292 B2; and
- U.S. Patent Application No. 15/979,182 filed on May 11, 2018.

Paper 3, 1.

C. THE '673 PATENT

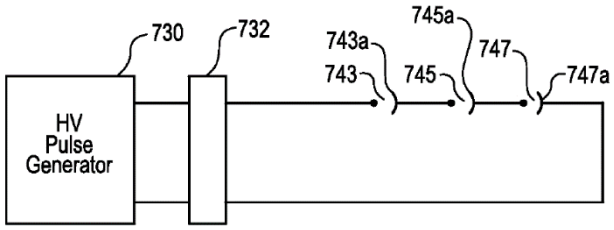
The '673 patent is directed to an angioplasty balloon catheter that uses electrohydraulic shockwaves to treat calcified lesions in blood vessels. Ex. 1001, code (57), 2:41–64. A wire-guided catheter is inserted into the patient's blood vessel and positioned near the calcified lesion, and a balloon fixed near the distal end of the catheter is inflated with saline so that the balloon contacts the lesion. *Id*. at 7:21–27. Electrodes within the balloon are connected to a voltage source, which sends electrical impulses of sufficient energy to generate arcs across the electrodes. *Id*. at 6:65–7:4. The arcs generate shockwaves inside the balloon that propagate through the saline and into the lesion, which causes the lesion to break up. *Id*. at 7:5–36.

FIG. 12



Although a number of embodiments of the balloon catheter are described in the Specification, the claims appear to recite features illustrated in Figure 12 (reproduced at right). Catheter 710 includes balloon 726 sealed to the distal end of carrier 721. *Id*. at 10:64–11:3. Carrier 721 includes a plurality of openings 742, 744, 746 spaced apart along its axis. One of electrode pairs 743, 745, and 747 is positioned within each of openings 742, 744, 746. *Id*. at 11:4–13. "One side of the openings 742, 744, and 746 are coated with a conductive material to render one electrode 743a, 745a, and 747a of each electrode pair larger in surface area [than] . . . its other corresponding electrode." *Id*. at 11:13–17.

FIG. 13



Electrode pairs 743, 745, 747, each of which is a shockwave source, are electrically connected in a series configuration to high voltage source 730 as shown in Figure 13 (reproduced at right). *Id*. at 11:19–23. The larger electrode surfaces 743a, 745a, 747a ensure "that all of the electrode pairs will reliably arc when the high voltage is applied across the string of shock wave sources." *Id*. at 11:23–26.

Claims 1, 9, and 15 are the independent claims among the challenged claims. *Id*. at 12:10–14:45. Claim 1, which is illustrative, recites:

> 1. A device comprising:
>
> [a] an axially extending elongate member;
>
> [b] a balloon surrounding a portion of the elongate member, said balloon being fillable with a conductive fluid;
>
> [c] a first electrode pair having first and second spaced apart electrodes and a second electrode pair having first and second spaced apart electrodes,
>
> [d] said electrode pairs being located within and spaced from the balloon, said electrode pairs being mounted on the elongate member and within the conductive fluid and wherein the electrode pairs are configured to produce shock waves that propagate through the liquid, and
>
> [e] wherein one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair; and
>
> [f] a high voltage source connectable to the first electrode of first electrode pair, and with the second electrode of first electrode pair being connected to the first electrode of the second electrode pair, and with the second electrode of the second

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

Id. at 12:10–38 (with line breaks and letter designations [a]–[g] added to aid discussion).

II. ANALYSIS

A. CLAIM INTERPRETATION

For petitions such as this one that are filed after November 13, 2018, we interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b), "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2019).[6] When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See In re*

[6] On October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)).

Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'" (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc))). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

1. Limitations Relating to Series Connections

Each independent claim recites a limitation relating to the manner in which individual electrodes within the two pairs of electrodes are connected. Limitation 1g refers to the following language in claim 1:

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

Pet. 23–24; *see also* Ex. 1001, 12:30–38. Earlier language in claim 1, limitation 1f, provides context for limitation 1g and recites: "high voltage source connectable to the first electrode of first electrode pair, and with the second electrode of first electrode pair being connected to the first electrode of the second electrode pair, and with the second electrode of the second electrode pair being connectable to the high voltage source." Pet. 23; *see also* Ex. 1001, 12:25–30. Claim 15 recites the same limitations 1f and 1g. Ex. 1001, 14:7–20. Claim 9 recites a materially similar limitations. *Id*. at 13:15–25; *see also* PO Resp. 30 (equating limitation 1g with limitations of claim 9).

In our Institution Decision, we invited Patent Owner to address two aspects of the meaning of limitation 1g as follows:

> Patent Owner appears to rely upon the language identified by Petitioner as element 1g as reciting the "floating architecture" of the electrodes. Prelim. Resp. 33. Patent Owner indicates that a "floating" electrode is one that is "not connected to either ground or a voltage source." *Id*. at 6 (citing Ex. 1001, 11:19–26). Patent Owner also appears to imply that element 1g requires a configuration in which individual arcs sequentially jump across each of the first and second electrode pairs. *Id*. at 33–35 (criticizing Jensen testimony). To the extent that Patent Owner contends that the claims recite the floating architecture or a device that sequentially generates arcs, it should precisely identify in its Patent Owner Response the language within the claim that recites such requirements and proffer any evidence that supports its interpretation of that language.

Dec. 14–15, n.9. Thus, we asked Patent Owner to address whether the claims require (1) a "floating" architecture for its electrodes and (2) that the device be configured to ensure that arcs are sequentially generated across the two gaps in the respective electrode pairs.

a. Whether the Claims Require a Floating Electrode Arrangement

In the parlance of limitation 1g, the floating electrodes refer to the second electrode of the first pair and the first electrode of the second pair. These two electrodes are connected to each other, but not physically connected to the voltage source.

Patent Owner now argues, based solely upon Dr. Van der Weide's testimony, that the claims do not require a floating electrode arrangement in which one of the electrodes from each pair are connected to each other but nothing else. PO Resp. 31 (citing Ex. 2100 ¶ 71). Dr. Van der Weide testifies that "[t]he electrical node defined by 'the second electrode of first electrode pair being connected to the first electrode of the second electrode

pair' (Ex. 1001 at claim 1[f]) could, in certain embodiments, be connected to ground in some fashion." Ex. 2100 ¶ 71. We are skeptical of the reliability of Dr. Van der Weide's testimony on this point for two reasons. First, and most importantly, his testimony is inconsistent with the Specification, which never describes an arrangement in which the middle two electrodes are connected to ground in some fashion. Tr. 43:20–44:7; *see also* Ex. 1001, 10:64–11:36, Figs. 12–14 (illustrating and discussing only floating electrode arrangement). Second, Dr. Van der Weide's testimony from ¶ 71 is inconsistent with his testimony in ¶ 75 in which he states that:

> The effect of such a series connection [i.e., limitation 1g] is that there is *only one path* to ground for the electrons flowing across the electrode gaps. In other words, in order to arrive at ground, the current must flow across each of the electrode pairs wired in series through the same fluid.

Ex. 2100 ¶ 75 (emphasis added). If the claimed series connection defines only one path to ground passing through the two electrode gaps, then the two individual electrodes that are connected to each other could not also be "connected to ground in some fashion" as Dr. Van der Weide says in ¶ 71. Accordingly, we conclude that all claims are limited such that they require a floating electrode arrangement in which two of the four individual electrodes are connected to each other but are not connected to the voltage source or to ground.

b. Whether the Claims Require Sequentially Occurring Arcs across the Spaces between the Electrodes of Each Pair

Patent Owner, based solely upon testimony by Dr. Van der Weide, contends that an arc "must traverse the first electrode pair where it forms the recited 'first arc' and then move to the second electrode pair where it forms the recited 'second arc.' As a practical matter, the arcs will form in a

relatively simultaneous manner." PO Resp. 31–32 (citing Ex. 2100 ¶¶ 73–76). Thus, Patent Owner no longer argues that arcs form sequentially across the first electrode pair and the second electrode pair, but rather they form "in a relatively simultaneous manner."

However, after institution of review, Patent Owner raises a new argument that limitation 1g requires that arcs must form in the spaces between both electrode pairs in response to a single voltage pulse because the claim recites arcing when "a high voltage pulse is supplied." *Id*. at 31 (citing Ex. 2100 ¶¶ 73–76). Patent Owner identifies nothing in the Specification or prosecution history to support its position. *Id*. at 31–32. Petitioner disagrees, arguing that "[i]n claim construction, the indefinite article 'a' typically means 'one or more.'" Reply 12–13 (citing *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342–43 (Fed. Cir. 2008) ("That 'a' or 'an' can mean 'one or more' is best described as a rule, rather than merely as a presumption or even a convention.").

We need not resolve the dispute on this point because we find that Petitioner has demonstrated as discussed below that the combined teachings of Hawkins '020, Hawkins '768, and Kunis suggest two electrode pairs connected in series that are capable of supporting arcs across the gaps in those pairs when a single pulse of high voltage is applied.

2. "conductive fluid"

Patent Owner argues that the "conductive fluid" of limitations 1b and 1d must be limited to a liquid based on later claim language and the specification. PO Resp. 27–29. Limitation 1b refers to "a balloon surrounding a portion of the elongate member, said balloon being *fillable with a conductive fluid*." Pet. 30–31 (emphasis added); *see also* Ex. 1001,

12:12–13. Limitation 1d refers to "said electrode pairs being located within and spaced from the balloon, said electrode pairs being mounted on the elongate member and within the conductive fluid and wherein the electrode pairs are configured to produce shock waves that propagate through *the liquid*." Pet. 31–32 (emphasis added); *see also* Ex. 1001, 12:18–22.

Petitioner contends that an ordinarily skilled artisan would understand "fluid" to refer broadly to at least air, liquid, and plasma. Reply 12 (citing Ex. 1200 ¶¶ 59–60; Ex. 1001, 8:43–44, 11:57–58). Petitioner also correctly points out that all the prior art upon which its challenges rely operate in an environment in which the conductive fluid is a liquid. *Id*. Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec*, 868 F.3d at 1017. Therefore, we need not, and do not, resolve the dispute over whether "conductive fluid" is limited only to conductive "liquid."

3. "angioplasty" vs. "valvuloplasty" balloons

Dependent claims 7 and 8 respectively limit the device of claim 1 such that the balloon is either a "single chamber angioplasty balloon" or "two chambers configured for valvuloplasty." Ex. 1001, 12:64–67. Patent Owner argues that these two balloons are different with angioplasty referring to treating blood vessels and valvuloplasty referring to treating valves of the heart. PO Resp. 32. Patent Owner also argues that the two types of balloons are structurally different with angioplasty balloons being smaller and having lower burst pressures than those used for valvuloplasty.

Because we find below that Petitioner has persuasively demonstrated that Hawkins '020 describes both types of balloons, we need not resolve the

dispute about the precise differences between "angioplasty" and "valvuloplasty" balloons.

B. THE PARTIES' POST-INSTITUTION ARGUMENTS

In our Institution Decision, we concluded that the argument and evidence adduced by Petitioner demonstrated a reasonable likelihood that at least one claim was unpatentable, and we instituted review of all challenges to claims 1–20 as identified in the table in Part I.A above. Dec. 20. We must now determine whether Petitioner has established by a preponderance of the evidence that the specified claims are unpatentable over the cited prior art. 35 U.S.C. § 316(e) (2018). We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] may be deemed waived." Paper 14, 7; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner's failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Additionally, the Board's Trial Practice Guide states that the Patent Owner Response "should identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

C. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1–20 on the grounds that the claims are obvious. To prevail in its challenges to the patentability of the claims, Petitioner must establish unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (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 never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co*., 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18). In an *inter partes* review, 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).

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. *Magnum Oil*, 829 F.3d at 1380–81. Petitioner also must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *NuVasive*, 842 F.3d at 1382.

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.

D. LEVEL OF ORDINARY SKILL

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, Biomedical Engineering or equivalent, and at least three to five years of practical experience (or comparable and/or equivalent education or training), including familiarity with the various medical devices and techniques for treating plaque buildup in blood vessel or body passages, such as balloon angioplasty, ablation, rotational atherectomy, lithotripsy.

Pet. 16 (citing Ex. 1002 ¶ 18[7]).

[7] Petitioner mistakenly cites ¶ 19, which is apparent from our review of Exhibit 1002 and the context of the citation within the Petition.

Patent Owner disagrees and contends that the level of ordinary skill in the art would require

> at least (1) a masters or Ph.D. 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. 19 (citing Ex. 2100 ¶ 54).

Thus, Patent Owner argues that an ordinarily skilled artisan needs more education, a Ph.D., than Petitioner proposes, a bachelor's degree. Patent Owner argues that Dr. Jensen may not offer testimony from the perspective of an ordinarily skilled artisan because he does not have a Ph.D. and he allegedly fails to correctly understand certain aspects of arc-formation in conductive liquids. PO Resp. 19.

Petitioner argues that a Ph.D. in electrical engineering is not required for an ordinarily skilled artisan because none of the inventors of the '673 patent or any of the asserted prior art, or any of Patent Owner's witnesses other than Dr. Van der Weide has a Ph.D. in electrical engineering. Reply 7 (citing Exs. 1221, 1222, 1226, 1229, 1240, 1243–1246). Given that none of the people involved in the field of the invention at issue in this proceeding other than Dr. Van der Weide has the level of skill advocated by Patent Owner, we are persuaded that Petitioner's description of the level of skill is appropriate. We note also that if we were to have adopted Patent Owner's proposed higher level of skill, the invention would have been more likely to be obvious than Petitioner has demonstrated.

E. OVERVIEW OF THE ASSERTED PRIOR ART

1. Hawkins '020

Hawkins '020 relates to a "treatment system for stenotic or calcified aortic valves," using shockwaves generated within a balloon that propagate through liquid in the balloon to impinge upon the targeted valve. Ex. 1004 ¶¶ 7–8. One embodiment of the system is illustrated in Figure 3 (below).

FIG. 3

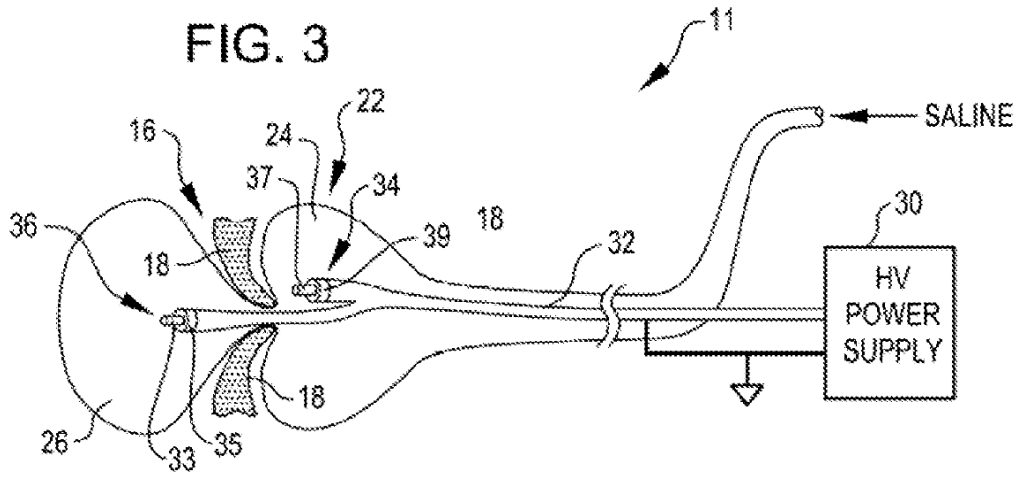


Figure 3 is a schematic view of a dual shockwave balloon attached to a high voltage power supply. *Id*. ¶ 24.

Dual shockwave balloon 22 of system 11 receives catheter 32 connected to high voltage power supply 30. *Id*. ¶ 28. Figure 3 illustrates balloon 22 positioned for treatment such that chambers 24 and 26 surround leaflets 18 of aortic valve 16. *Id*. Electrode pair 34 is located within chamber 24, and electrode pair 36 is located within chamber 26. *Id*. Electrode pair 34 includes central conductor 37 as one electrode and outer conductive shield 39 as the other electrode. *Id*. Electrode pair 36 is similarly arranged with central conductor 33 as one electrode and shield 35 as the other. *Id*. Figure 3 implies that shields 35, 39 are commonly connected to ground, but Hawkins '020 does not expressly describe how electrode pairs 34, 36 are wired to power supply 30. *Id*., Figure 3.

2. Hawkins '768

Hawkins '768 is directed 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. 1003 ¶ 2. Hawkins '768 illustrates its angioplasty balloon catheter 20 with electrodes 22, 24 within balloon 26 in Figure 2 (reproduced below), which generate arcs that create shock waves within balloon 26 to break up calcified lesions in a blood vessel.

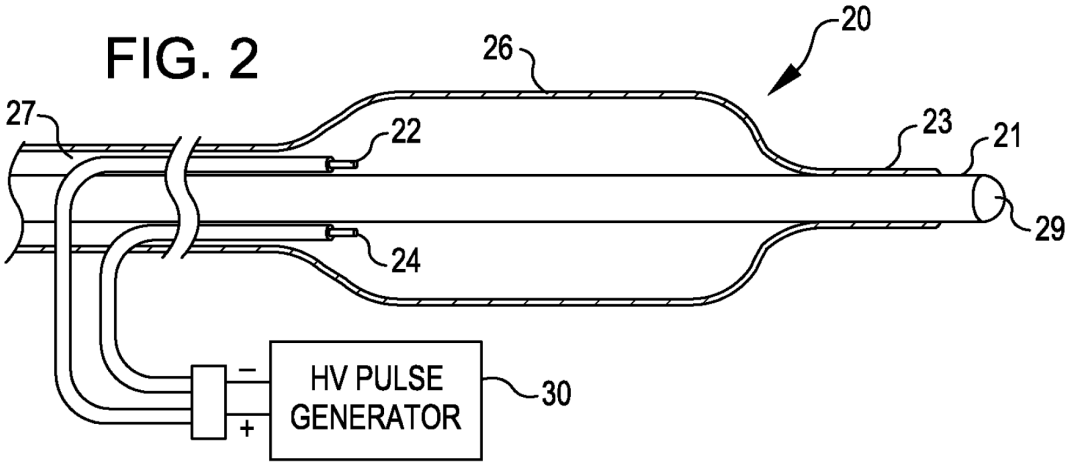
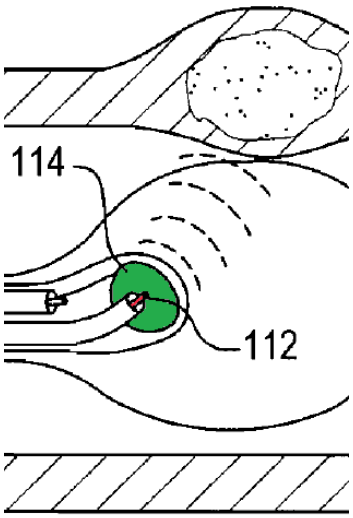


FIG. 2 is a side view of a dilating angioplasty balloon catheter with two electrodes within the balloon. *Id*. ¶ 28.

Balloon 26 may be inflated with water or saline to gently fix balloon 26 against the walls of an artery in direct proximity to a calcified lesion. *Id*. ¶ 51. Carrier 21 includes lumen 29 through which a physician inserts a guide wire (not shown) to guide catheter 20 to the desired location in a patient's body. *Id*. Electrical arcs between electrodes 22, 24 generate shockwaves in the fluid. *Id*. The magnitude of the shockwaves is controlled by altering the voltage, current, duration, and frequency of the signal sent from pulse generator 30 to electrodes 22, 24. *Id*. ¶ 52.

Hawkins '768 illustrates one embodiment of its electrodes in the colorized version of Figure 15 (reproduced in pertinent part at right). Petitioner contends that the surface area of electrode 114 (green) is larger than the surface area of electrode 112 (red). Pet. 25. Electrode 114 is configured as a parabolic reflector, and electrode 112 is positioned at the coaxial center of reflector 114. Ex. 1003 ¶ 64. The parabolic shape of electrode 114 focuses shockwave energy in a desired direction. *Id*.



3. Kunis

Kunis is directed to "catheters and methods for performing targeted tissue ablation." Ex. 1005, 1:12–13. Kunis's device treats heart arrhythmia by ablating specific portions of heart tissue to correct the manner in which electrical signals propagate through that tissue. *Id*. at 1:20–31. An array of multiple electrodes simultaneously or serially deliver electrical ablation energy to targeted tissue over a relatively large area. *Id*. at 5:18–27, 7:53–58. Kunis also describes delivering ablation energy as acoustic, electromagnetic, thermal, or mechanical energy, and combinations of those types of energy. *Id*. at 25:29–36. Kunis indicates that its electrodes may be "electrically connected in parallel, in series, individually, or combinations" of these types of connections. *Id*. at 25:41–42. Kunis also indicates that, for devices "with large numbers of electrodes, individual pairs of wires for each electrode may be bulky and compromise the cross-sectional profile of the ablation catheter." *Id*. at 25:59–62. Kunis suggests serially connecting the

electrodes to reduce the number of wires to avoid undesirable bulk and shrink the cross-sectional profile of the device. *Id*. at 25:62–65.

F. CLAIMS 1, 2, 5–8, 15, 16, 19, AND 20: OBVIOUSNESS IN VIEW OF HAWKINS '020, HAWKINS '768, AND KUNIS

For the reasons expressed below, Petitioner persuades us by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claims 1, 2, 5–8, 15, 16, 19, and 20 unpatentable as obvious.

1. Independent Claim 1

a. Summary of Petitioner's Argument and Evidence

Petitioner relies upon Hawkins '020 as expressly describing every limitation of claim 1 except for aspects of elements 1e and 1g. Pet. 23–24, 30–39. Petitioner contends that the individual electrodes of Hawkins '020 "necessarily have different surface areas" as required in element 1e. *Id*. at 32–34 (citing Ex. 1004 ¶ 28, Figure 3; Ex. 1002 ¶ 70[8]). Petitioner alternatively relies upon Hawkins '768 as demonstrating that electrode pairs in which each electrode has a different surface area (element 1e) was a well-known configuration. *Id*. at 24–26. Petitioner recognizes that Hawkins '020 may not expressly describe whether its electrodes are connected in a serial or parallel arrangement, but contends that it would have been obvious to "try either a series or a parallel connection" between the two pairs of electrodes largely because an ordinarily skilled artisan would have understood that series and parallel connections were the two options for connecting "adjacent and commonly driven electrode pairs." *Id*. at 26–27

[8] Based on our review of Dr. Jensen's testimony, it is readily apparent that Petitioner intended to cite paragraph 70 rather than paragraph 71.

(citing Ex. 1002 ¶¶ 53–64, 76–79). Petitioner further relies upon Kunis as expressly suggesting serially connecting commonly driven electrode pairs to reduce the bulk, stiffness, and cross-sectional profile of intravascular medical devices using such electrode pairs. *Id*. at 28–29, 37–39 (citing Ex. 1005, 5:18–37, 25:38–42, 25:59–67, Figure 17b; Ex. 1002 ¶¶ 53–64, 76–79).

b. Obvious to Try Series Connections

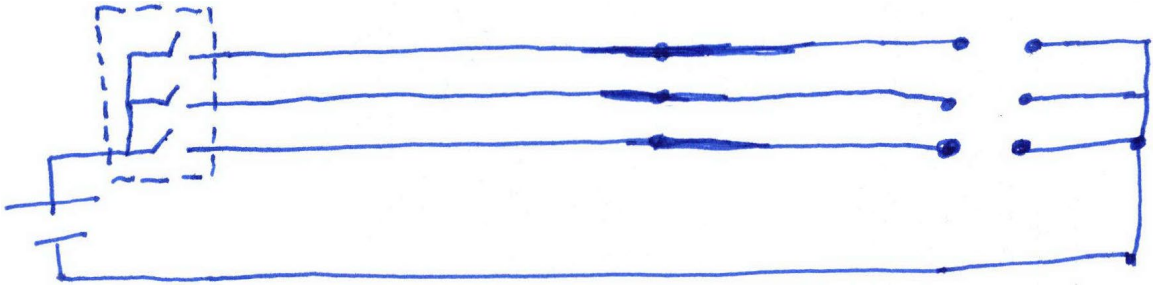
Patent Owner argues that it would not have been obvious to try "either a series or a parallel connection between the two pairs of electrodes" as Petitioner argues for two reasons. PO Resp. 34–46. First, Patent Owner argues that Petitioner fatally failed to address a third option for wiring the electrodes about which an ordinarily skilled artisan would have known, a switched or multiplexed configuration. *Id*. at 35–37. Second, Patent Owner argues that the finite options that would have been obvious to try must be "predictable solutions," and the physics of arc-formation across a series connection is so unpredictable that an ordinarily skilled artisan would not have found it obvious to try a series configuration. *Id*. at 37–46. Petitioner's arguments are more persuasive on both issues.

i. Third Solution—Switched or Multiplexed Configuration

While addressing limitation 1g, Petitioner argues, based upon Dr. Jensen's testimony, that "because there are only two fundamental ways for analog connections, series and parallel, selecting between a series and parallel connection would be a functionally equivalent design choice and

obvious to try" for an ordinarily skilled artisan. Pet. 52 (citing Ex. 1002 ¶ 88[9]).

Patent Owner argues that, because Hawkins '020 uses a third configuration for wiring its electrodes, and Petitioner fails to address the switched configuration, it would not have been obvious for an ordinarily skilled artisan to have tried a series connection for the electrodes recited in limitation 1g. PO Resp. 35–36. Patent Owner correctly points out that Dr. Jensen described a switched configuration of three electrode pairs as shown in the Figure reproduced below, which he drew during his deposition.



Dr. Jensen drew the circuit diagram above as illustrating a "parallel circuit with switches." *See* Ex. 2156, 22:16–23:7 (drawing the figure above on Exhibit 2040).

Dr. Jensen testifies that the configuration above provides the option to individually select any one of the electrode pairs or a parallel configuration. *Id*. at 23:25–24:7. Patent Owner also contends, based on testimony by Dr. Van der Weide, that Hawkins '020 describes a switched configuration because it is the "only way to 'synchronize' the shockwaves so that they

[9] The Petition includes an erroneous citation to Ex. 1002 ¶ 89. Pet. 52. The error is apparent from our review of Dr. Jensen's testimony. *See* Ex. 1002 ¶ 88 (addressing whether it would have been obvious to try a series or parallel connection among the electrodes).

impact the calcium" on the target heart valve. PO Resp. 36–37 (citing Ex. 2100 ¶¶ 97–98; Ex. 1004 ¶ 27, Fig. 3).

Petitioner responds with two types of arguments. First, Petitioner contends that the configuration of the two electrode pairs in Hawkins '020 is not "limited to a 'switched' configuration" because Hawkins '020 merely states that "shockwaves can be synchronized." Reply 15. Petitioner also argues that difficulties in controlling the timing of shockwave formation that Patent Owner alleged in IPR2019-00409 demonstrate that precise synchronization of shockwaves is difficult and Hawkins '020 fails to address those difficulties. *Id*. 15–16 (citing Ex. 1203, 69:18–102:10). Based on the evidence of record, Patent Owner persuades us that an ordinarily skilled artisan would have inferred that Hawkins '020 describes two electrode pairs that are likely wired individually, i.e., in a switched configuration.

Second, Petitioner argues that even if a third configuration for two pairs of electrodes were also possible (i.e., a switched configuration), an ordinarily skilled artisan would still have found it obvious to try a series configuration because it is one of the fundamental configurations for electrically connecting circuit components that is "taught in basic undergraduate engineering courses." *Id*. at 16 (citing Ex. 1203, 9:14–10:11). Petitioner, relying on Dr. Jensen's testimony, argues that an ordinarily skilled artisan still would have found it obvious to try a series connection because at most three well-known configurations for the electrodes existed, all of which provided predictable solutions. *Id*. at 17 (citing Ex. 1200 ¶¶ 64–69).

Patent Owner counter-argues, based on testimony by Dr. Van der Weide, that arranging two electrode pairs in series and placing

them in the same conductive liquid would have been considered to be a circuit with such unpredictable behavior that an ordinarily skilled artisan would not have found obvious to try. Sur-reply 6–8 (citing Ex. 2100 ¶¶ 31–49). Based on our review of Dr. Van der Weide's testimony, we disagree with Patent Owner.

Dr. Van der Weide testifies that "Dr. Jensen incorrectly assumes that all current will flow in the path of least resistance" from the first to the last electrode pair shown in the illustration that we reproduce below. Ex. 2100 ¶ 47.

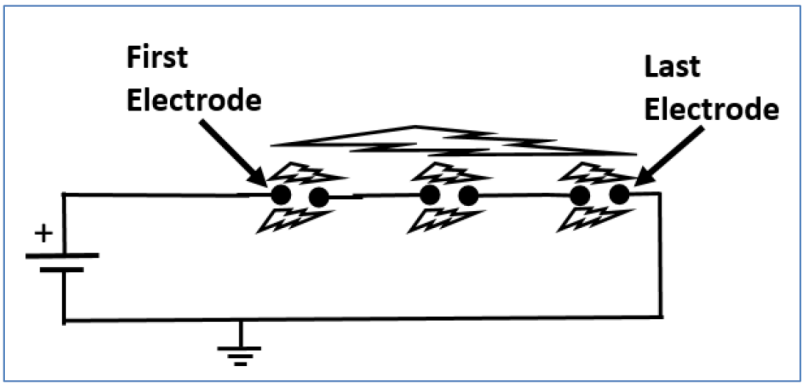


Figure illustrating sparks guaranteed to fire across all three electrode pairs when voltage applied is "large enough." Ex. 1002 ¶ 61.

Dr. Van der Weide explains that "[w]hile it is true that the lowest resistance path will have the highest current, it is equally true that the higher resistance paths (perhaps through the surrounding environment) will of course have current flows as well. That principle, standing alone, is basic electronics . . . ." Ex. 2100 ¶ 48. Thus, Dr. Van der Weide and Dr. Jensen agree that "basic electronics" principles indicate that at least the highest current will flow across the path of least resistance. Ex. 1002 ¶ 47; Ex. 2100 ¶ 48. Later, when discussing a version of the claimed circuit with two pairs of

electrodes, which is materially similar to the one illustrated above, Dr. Van der Weide testifies that:

> The effect of such a series connection is that there is only one path to ground for the electrons flowing across the electrode gaps. In other words, in order to arrive at ground, the current must flow across each of the electrode pairs wired in series through the same fluid.

Ex. 2100 ¶ 75. Dr. Van der Weide draws this conclusion even after recognizing that "the detailed physics of arc formation remain unpredictable." *Id*. ¶ 73. We find that although an ordinarily skilled artisan would have recognized that some amount of current might flow unpredictably in circuits having electrode pairs arranged in series, the "highest current" would flow across the gaps between the electrodes. Accordingly, Petitioner persuades us that an ordinarily skilled artisan would have considered it obvious to try arranging electrode pairs in series as recited in limitation 1g.

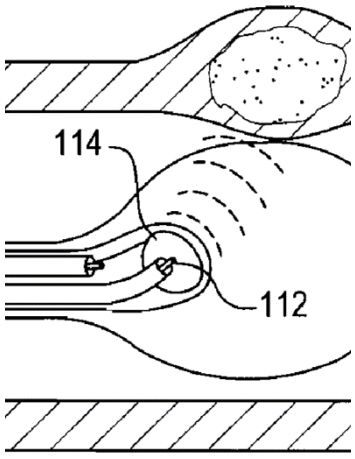
ii. Predictability of Arc Formation across Electrodes in Series

Patent Owner also argues that an ordinarily skilled artisan would not have expected that a series arrangement of electrode pairs would successfully generate arcs in a predictable way. PO Resp. 37–46. Patent Owner argues, based on testimony by Dr. Van der Weide, that "one of skill in the art would find that a series connection of coaxial electrodes in Hawkins '020 would not produce reliable arcing across the intended electrode pairs." *Id*. at 39 (citing Ex. 2100 ¶ 117). Dr. Van der Weide reaches his conclusion after analyzing the drawings of Hawkins '020 and opining that its center conductors 33, 37 have a "slightly larger surface area, by a factor of 5%" than the conductive shields 35, 39. Ex. 2100 ¶ 107. He then concludes that "the center conductor and outer conductor have

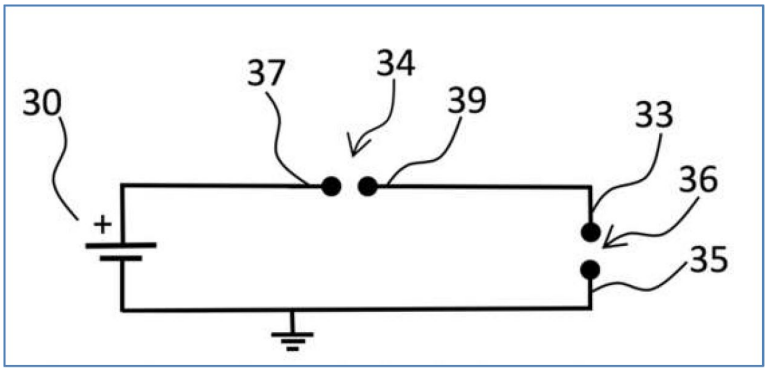
essentially the same surface area." *Id.* ¶ 108. Petitioner responds, based on testimony from Dr. Jensen, that the surface areas of Hawkins '020's conductive shields (35, 39) are 21–27% larger than the surface areas of the central conductors (33, 37). Reply 17 (citing Ex. 1200 ¶¶ 72, 84–104). Both experts try to use great care in trying to divine precise measurements from the low resolution illustrations of Hawkins '020.

On balance, we consider the competing analyses to establish merely that Hawkins '020's electrode pairs are of slightly different surface areas. However, we need not resolve precisely how different Hawkins '020's surface areas are because Petitioner also correctly points out and relies upon the clear description in Hawkins '768 of an electrode pair in which one of the electrodes is significantly larger than the other. Reply 17–18 (citing Ex. 1003, Fig. 15, reproduced at right in pertinent part).

FIG. 15



Patent Owner argues, based on Dr. Van der Weide's testimony, that, if Hawkins '020 were arranged as illustrated below in Dr. Jensen's schematic illustration of Hawkins '020's electrodes connected in series, some arcing would occur from electrode 37 to 35, bypassing the intendend path from 37 to 39 and 33 to 35. PO Resp. 42 (citing Ex. 2100 ¶ 112).



The Figure above is a schematic diagram of a potential series connection of the electrode pairs of the device shown in Figure 3 of Hawkins '020. Ex. 1002 ¶ 76.

First, we note that Dr. Jensen's depiction is schematic, and not a scale drawing of the physical arrangement of Hawkins '020's electrode pairs 34, 36. Ex. 1002 ¶ 76. Dr. Van der Weide's "analysis" of this figure appears to be based on the premise that the figure illustrates physical distances among the components shown. To the extent that Dr. Van der Weide's testimony is based on this premise, we consider it to be faulty and untrustworthy.

Second, Petitioner persuasively argues that an ordinarily skilled artisan would have understood that arc formation is controlled by adjusting the shape of the electrodes, Reply 18 (citing Ex. 1203, 138:13–139:5), and adjusting the distance between the electrodes, *id*. (citing Ex. 1200 ¶¶ 72–78). Moreover, Dr. Van der Weide agrees that the distance between electrodes influences whether an arc forms across a gap between them when the dielectric surrounding the electrodes is homogenous. Ex. 1203, 162:16–163:11. Dr. Van der Weide also testified that once an arc is formed between the electrodes, the current will flow predictably along that arc rather than in other directions. *Id*. at 164:9–165:3. Accordingly, Petitioner has persuaded us that an ordinarily skilled artisan would have understood that

one could shape and position the electrodes to reasonably ensure success in generating arcs between the electrodes arranged in series.

c. Motive to Wire Hawkins '020 in Series

Petitioner argues that an ordinarily skilled artisan would have been motivated to electrically connect electrodes in series because such an arrangement is expressly suggested by Kunis. Pet. 28–29 (citing Ex. 1005, 25:38–42, 25:59–67). Kunis states: "The ablation elements can deliver energy individually, in combination with or in serial fashion with other ablation elements. The ablation elements can be *electrically connected* in parallel, in series, individually, or combinations thereof." Ex. 1005, 25:38–42 (emphasis added). This passage unequivocally suggests electrically wiring electrodes in series. Patent Owner argues that "Kunis is **not** discussing a series electrical connection." PO Resp. 47. We disagree based on the express language from Kunis quoted immediately above.

Petitioner also cites the following passage from Kunis as expressly stating the reason why an ordinarily skilled artisan would employ a series connection for its electrodes:

> In configurations with large numbers of electrodes, *individual pairs of wires for each electrode may be bulky and compromise the cross-sectional profile of the ablation catheter*. In an alternative embodiment, one or more electrodes, *connected in serial fashion* such that a reduced number of wires, such as two wires, can be attached to two or more electrodes, include switching means such that while a first electrode is powered, the remaining electrodes do not transmit ablative energy.

Ex. 1005, 25:59–67 (emphases added). This passage expressly explains that individual pairs of wires for each electrode may have disadvantages and addresses the disadvantage using electrodes "connected in serial fashion."

Patent Owner attempts to blunt Kunis' express suggestion of connecting electrodes in series by arguing that the quoted language merely refers to electrodes that are physically arranged in series, not electrodes that are electrically connected in series and that series and parallel electrical connections in Kunis' device would result in the same number of wires, two. PO Resp. 47–49 (citing Ex. 1005, 25:38–40 (electrodes deliver energy "in serial fashion"); Ex. 2100 ¶¶ 121–122). Patent Owner's argument fails to rebut Petitioner's showing.

First, we disagree that the second passage from Kunis quoted above, when stating "connected in serial fashion," refers to the physical connection of Kunis's electrodes rather than the electrical connection. When Kunis refers to delivering energy "in serial fashion" it refers to the order in which energy is delivered by its electrodes. Ex. 1005, 25:38–40. Later, Kunis expressly states that its electrodes may be "connected in serial fashion," which is an express indication of the manner in which the electrodes are connected. Second, even if the same number wires would be used in Kunis's device for a parallel or series electrical configuration, Petitioner has still demonstrated that a series configuration would be less bulky than individually wiring the electrodes, which is one of the three fundamental options for wiring electrodes.

In its Reply, Petitioner also argues that an ordinarily skilled artisan would have been motivated to use a series connection rather than a parallel connection to increase safety. Reply 21. More specifically, in a series configuration, when "one electrode wire fails, then the connection is broken and an open circuit would exist, but if the wires were in parallel, then some electrodes would likely continue to fire, concealing a possible safety issue."

Id. (quoting Ex. 1200 ¶ 81). Patent Owner argues that Dr. Jensen originally testified that an ordinarily skilled artisan "would not wire multiple electrode gaps in parallel because if one fires, the others will not," Sur-reply 15 (citing Ex. 1002 ¶¶ 59–63), which Patent Owner contends to be "an inoperable embodiment," *id*.

However, the cited portion of Dr. Jensen's testimony fails to support Patent Owner's argument. Overall, the cited testimony is merely Dr. Jensen's explanation of how parallel and series configurations of electrodes would work. Ex. 1002 ¶¶ 59–63. He initially states that "[t]here are advantages and disadvantages for both the parallel and serial design in connecting multiple electrode pairs for spark creation." *Id*. ¶ 59. After explaining how each configuration would work, he concludes:

> If sparks are required to arc across all electrode pairs, the serial connection is best if setup correctly and if the voltage is sufficient to provide all sparks simultaneously. In contrast, although the parallel connection may be easier to get to fire, only one electrode would spark at a time and thus it may be more difficult to synchronize the impingement.

Id. ¶ 63. Thus, each configuration has "advantages and disadvantages." One of the "advantages" of the series configuration is increased safety against a failure in the wiring. Ex. 1200 ¶ 81.

For the reasons expressed above, Petitioner persuades us that an ordinarily skilled artisan would have been motivated to use a series configuration for the electrodes in a shockwave generator.

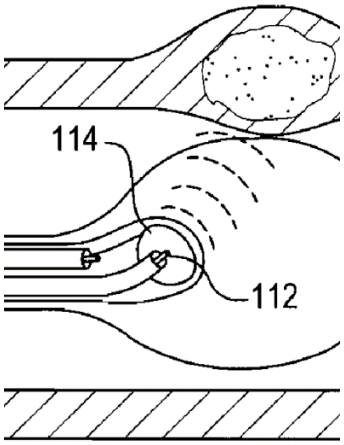
d. Motive to Use Different Surface Areas on Each Electrode of the Two Pairs

Limitation 1e recites that "one electrode in each pair has a surface area larger than the surface area of the other electrode in the pair."

Ex. 1001, 12:22–24. The claim thus merely requires that the two electrodes in each pair have a different surface area without any express or implied limitations on how different the surface areas must be or which electrode in each pair must have a larger surface area. Petitioner contends that an ordinarily skilled artisan would have understood that Hawkins '020 describes electrodes meeting limitation 1e. Pet. 22; *see also id*. at 33–34 (citing Ex. 1002 ¶ 70[10]).

Petitioner also argues that Hawkins '768, which is effectively incorporated by reference into Hawkins '020,[11] clearly depicts in Figure 15 (reproduced in pertinent part at right) an electrode pair in which one electrode 114 has a larger surface area than the other electrode 112. *Id*. at 25 (citing Ex. 1003, Fig. 15). Because Hawkins '020 and Hawkins '768 both describe "coaxial electrode pairs," Petitioner argues that an ordinarily skilled artisan would have considered the different configurations to be "interchangeable design choice" and that "skill and background knowledge" of an ordinarily skilled artisan would have been sufficient to modify Hawkins '020 to use the

FIG. 15



[10] Petitioner mistakenly cites Ex. 1002 ¶ 71 rather than ¶ 70, which is apparent from our review of Exhibit 1002 and the Petition.

[11] Hawkins '768 claims priority to U.S. Provisional App. 60/061,170 (the "'170 Provisional"). Ex. 1003 ¶ 1. Hawkins '020 incorporates the '170 Provisional by reference and explains that its electrodes generate shockwaves as described in the '170 Provisional. Ex. 1004 ¶¶ 27–28. The '170 Provisional also includes a hand drawn version of Figure 15 that is materially the same as Figure 15 of Hawkins '768.

arrangement suggested by Hawkins '768. *Id*. at 25–26; *see also id*. 33–35 (citing Ex. 1002 ¶¶ 71–73).

Patent Owner argues Petitioner contends that the electrodes of Hawkins '020 "necessarily have different surface areas" but that "the electrodes of Hawkins '020 do not have to have different surface areas relative to each other." PO Resp. 50 (citing Ex. 2156, 64:6–65:7, 66:25–67:6). Patent Owner's argument is an unpersuasive strawman. First, Petitioner argues that Hawkins '020 expressly, not inherently, describes electrodes of different surface areas in its Figure 3, Pet. 22, 33–34. Second, both experts agree that Hawkins '020 describes electrodes that have different surface areas. Ex. 1002 ¶ 70; Ex. 2100 ¶¶ 107; Ex. 1200 ¶¶ 82–98. The claim requires nothing more than different surface areas for each of the respective electrodes in a pair.

Patent Owner also argues that Petitioner fails to explain how an ordinarily skilled artisan would have incorporated the electrode pair 112, 114 from Hawkins '768 into Hawkins '020. PO Resp. 52. Petitioner persuasively argues that "the test for obviousness is not whether the features of a one reference may be bodily incorporated into the structure of another, but what the combined teachings suggested to those of ordinary skill in the art." Reply 22 (citing *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). Hawkins '020 also expressly refers to the '170 Provisional (i.e., the priority document for Hawkins '768) as a source of guidance for how to generate shockwaves using electrodes. Ex. 1004 ¶¶ 27–28. To the extent that Patent Owner relies upon testimony from Dr. Van der Weide about alleged difficulties resulting from bodily incorporating electrodes 112, 114 from Hawkins '768 into Hawkins '020 (PO Resp. 52–53 (citing Ex. 2100

¶¶ 142–144), the testimony fails to address the salient issue, namely what the combined teachings of the references suggest to an ordinarily skilled artisan.

For the reasons above, Petitioner persuades us that an ordinarily skilled artisan would have considered Hawkins ’020 to describe paired electrodes having different surface areas and would have considered it an obvious design choice to incorporate such electrodes of different sizes as suggested by Hawkins ’768.

e. Objective Indicia of Nonobviousness

Patent Owner argues that industry praise and commercial success stemming from the ease of use of its IVL devices represents significant and objective evidence of non-obviousness. PO Resp. 61–65.

i. Nexus

Patent Owner bears the burden of establishing that a nexus exists “between the evidence and the patented invention.” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019)). Patent Owner is entitled to a rebuttable presumption of nexus “when 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.’” *Id*. (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)); *see also Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 32 (PTAB Jan. 24, 2020) (Final Written Decision) (precedential). “A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature that is claimed by a different patent and that materially impacts the product’s functionality . . . .” *Fox Factory*, 944 F.3d at 1375. Nevertheless, even if a patentee fails to demonstrate a

presumption of nexus, it may directly establish a nexus between the claimed invention and the objective evidence of non-obviousness. *Id*. at 1378. The patentee bears the burden of directly proving such a nexus. *Id*.

Patent Owner argues that a "substantial amount of the praise, success and other objective evidence arose from the safety enhancement provided by the technology recited in claim 7 of the '673 patent and embodied in the Shockwave IVL device." PO Resp. 65 (citing Ex. 2100 ¶ 204). Patent Owner contends that claim 7 is directed to the commercial versions of its IVL devices. *Id*. at 61 (citing Ex. 2100 ¶ 173); Exs. 2178–2180 (claim charts). 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. 45–46. However, Patent Owner does not argue that it is entitled to a presumption in its Patent Owner Response. *See* PO Resp. 60–65. We instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] may be deemed waived." Paper 14, 7; *see also Nuvasive,* 842 F.3d at 1381 (holding that patent owner's failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Therefore, we do not apply a presumption of nexus. Rather, we consider the parties' arguments and evidence regarding alleged industry praise and commercial success and whether Patent Owner has affirmatively demonstrated nexus between the claimed features and such evidence.

ii. Industry Praise

Patent Owner contends that the industry praises its IVL device as being easy to use and links the ease of use to the presence of "multiple electrodes" on the catheter. PO Resp. 61–64. Petitioner responds, and we

agree, that Patent Owner's evidence fails to demonstrate that the claimed invention is the basis of such praise. Reply 26–27. Patent Owner's cited evidence simply does not bear scrutiny.

Patent Owner relies upon testimony from Dr. Van der Weide and three clinicians, Drs. Soukas, Armstrong, and Kereiakes. PO Resp. 61–64 (citing Ex. 2170 ¶¶ 10–11; Ex. 2173 ¶¶ 23–24; Ex. 2174 ¶ 19; Ex. 2100 ¶¶ 188–197). At the outset, we note that Dr. Van der Weide merely cites and reiterates testimony by the three clinicians and reports from a financial analyst from the Motley Fool. *See* Ex. 2100 ¶¶ 188–197 (citing Ex. 2170 ¶¶ 10–11; Ex. 2173 ¶¶ 23–24; Ex. 2174 ¶ 19; Ex. 2139, 11). The testimony from Drs. Soukas, Armstrong, and Kereiakes does not carry more probative weight simply because Dr. Van der Weide relies upon it. Nor does Dr. Van der Weide's reliance upon unsubstantiated views of one employee of the Motley Fool increase its probative weight.

Collectively, the testimony by Drs. Soukas, Armstrong, and Kereiakes simply fails to establish that a claimed feature that was not previously well known was the basis for praise that the IVL is easy to use. Patent Owner cannot establish nexus by linking objective evidence of non-obviousness to "prior art features in isolation or unclaimed features." *Fox Factory*, 944 F.3 at 1378. All three doctors testify that the IVL devices are easy to use because the devices are used just like a familiar traditional angioplasty balloon. Ex. 2170 ¶ 11; Ex. 2173 ¶ 23; Ex. 2174 ¶ 17. Although Drs. Armstrong and Soukas testify that multiple electrodes on the IVL devices contributes to its ease of use, neither doctor provides any credible testimony that they are aware whether the electrodes in the devices are electrically wired as required in the claims. Ex. 2170 ¶¶ 10–11; Ex. 2173

¶¶ 23–24. We find that Patent Owner has failed to carry its burden of establishing that its evidence of industry praise is sufficiently tied to novel claimed features. Accordingly, Patent Owner has not established that industry praise favors a conclusion of nonobviousness.

iii. Commercial Success

Patent Owner contends, based on Dr. Van der Weide's testimony, that its IVL devices have "enjoyed substantial success." PO Resp. 64 (citing Ex. 2100 ¶¶ 198–199). Dr. Van der Weide testifies that Patent Owner: (1) "projects revenue for the full year 2019 to range from $38 million to $40 million, which represents 210% to 226% growth over the company's prior year revenue"; (2) realized a 339% increase (of $7.7 million) in revenue for the second quarter of 2019 over the second quarter of 2018; and (3) has a current market capitalization of "about $1 billion." Ex. 2100 ¶¶ 198–199 (citing Ex. 2175 ¶ 8;[12] Ex. 2164). Patent Owner also relies upon testimony from Dr. Kereiakes that "seasoned interventional cardiologists often ask how they can invest in the technology" as evidence of commercial success. PO Resp. 64 (citing Ex. 2174 ¶ 19).

Petitioner responds that Patent Owner has failed to provide evidence that its increased sales were "a direct result of the unique characteristics of the claimed invention." Reply 27 (quoting *Huang*, 100 F.3d at 140). Petitioner also points out that the increase is just as likely to have been caused by a 59% increases in sales and marketing expenditures from 2018 to 2019. *Id*. (citing Ex. 1216, 30:20–37:7; Ex. 2141, 4, 20–23). Petitioner also correctly notes that Dr. Kereiakes's assertion that unnamed "cardiologists"

[12] Dr. Van der Weide mistakenly cites ¶ 6 of Mr. Stephens's Declaration, which is apparent from our review of Mr. Stephens's testimony.

desire to invest in Patent Owner is not tied to any aspect of the claims. *Id*. at 28. According to Petitioner, even Dr. Van der Weide could not quantify the effect on commercial success that was driven by a novel claimed feature. *Id*. (citing Ex. 219:22–221:5).

More importantly, however, "the more probative evidence of commercial success relates to whether the sales represent a substantial quantity in the market." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1300 (Fed. Cir. 2012) (internal quotations omitted) (quoting *In re Huang*, 100 F.3d 135 140 (Fed. Cir. 1996)). Patent Owner's evidence of revenue increases wholly fails to establish the amount of market share attained by Patent Owner's devices. Just as important, however, is that Patent Owner's "evidence" of revenue increases does not pass muster. Patent Owner relies upon testimony from Dr. Van der Weide and Mr. Stephens. PO Resp. 64 (citing Ex. 2100 ¶ 198–199; Ex. 2175 ¶ 8). The cited testimony from both witnesses relies upon the same document, a press release by Patent Owner reporting financial results and *projected* revenue increases for 2019 over 2018. Ex. 2100 ¶ 199 (citing Ex. 2175 ¶ 8); Ex. 2175 ¶ 8 (citing Ex. 2176). The press release rightly points out that "forward looking statements" such as revenue projections "are uncertain" and thus "actual results may differ materially from those projected." Ex. 2176, 1. The press release also reports a net loss of $10.6 million for Q2, 2019, which was $0.5 million higher than the loss reported for Q2, 2018. *Id*. Patent Owner's evidence of its market capitalization is an undated printout of Yahoo's stock quote page. Ex. 2164. Patent Owner fails to explain how its market capitalization meaningfully reflects commercial success, and we discern no reason to find it probative of commercial success. Based on the foregoing, we find that

Patent Owner has not established a nexus between any of the claims and alleged commercial success.

Even if we were to conclude that Patent Owner's increases in revenue are sufficiently tied to the claimed features to establish nexus, which we do not, we would find Patent Owner's showing of commercial success to be weak.

f. Weighing of Evidence of Obviousness and Conclusion

We conclude that Petitioner has proven that the alleged improvement over Patent Owner's devices as described in Hawkins '020 and Hawkins '768, namely wiring at least two pairs of electrodes in an angioplasty balloon in series, was well known and obvious to try for an ordinarily skilled artisan. We consider Petitioner's showing of obviousness to be rather straightforward and well supported.

Patent Owner's objective evidence of non-obviousness is weak for all the reasons that we express above even if we were to credit Patent Owner as having established some nexus. When we consider all the evidence and arguments adduced by the parties, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claim 1 unpatentable as obvious.

2. Independent Claim 15

Petitioner contends that claim 15 is identical to claim 1 in all material respects and reasserts its arguments that claim 1 is unpatentable against claim 15. Pet. 61–62. Patent Owner implicitly agrees by not identifying any material differences between claims 1 and 15 and arguing for patentability of claim 1 and claim 15 for the same reasons. *See* PO Resp. 33–53 (addressing claims 1 and 15 concurrently without identifying any feature of claim 15 that

materially differs from claim 1). Our review of the two claims reveals no material differences. *Compare* Ex. 1001, 12:10–38 (claim 1), *with id.* at 13:39–14:20 (claim 15). Accordingly, for the reasons expressed in Part II.F.1 above, we determine that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claim 15 unpatentable as obvious.

3. Dependent Claims 2 and 16

Claim 2 depends from claim 1 and further recites:

> further including a third electrode pair having first and second spaced apart electrodes, with the second electrode of the second electrode pair being connectable to the first electrode of the third electrode pair and with the second electrode of the third electrode pair being connectable to the high voltage source.

Ex. 1001, 12:39–44. Claim 16 depends from claim 15 and recites the same limitation recited in claim 2. *Id.* at 14:21–26. Because claims 1 and 15 are materially identical, we consider claims 2 and 16 also to be materially identical to each other, and we address them together.

Petitioner argues that adding a third pair of electrodes to the device of claim 1 "is nothing more than the mere duplication of parts and thus would have been obvious." Pet. 39 (citing *In re Harza*, 274 F.2d 669, 671 (CCPA 1960)). Petitioner also argues that the Specification fails to explain how the addition of a third electrode would produce an unexpected result and that an ordinarily skilled artisan would have known how to connect the claimed third electrode. *Id.* at 39–40 (citing Ex. 1002 ¶¶ 53–64, 81). Petitioner also contends that Kunis describes using multiple electrodes beyond two mounted along the length of a catheter to increase the effective coverage area of its ablation device. *Id.* at 40 (citing Ex. 1005, 5:18–37, Fig. 17b). Kunis also suggests that its ablation electrodes may be configured to deliver

other forms of energy including "acoustic, ultrasound, electrical, magnetic, microwave, thermal, chemical, light, mechanical radiation and combinations thereof." *Id*. (citing Ex. 1005, 25:25–36). Based on the teachings of Kunis, Petitioner contends that an ordinarily skilled artisan would have used a third electrode pair connected in series to reduce bulk and the cross-sectional profile of the device. *Id*. at 40–41 (citing Ex. 1005, 25:38–42, 25:59–67; Ex. 1002 ¶ 82).

Patent Owner argues, based on testimony from Dr. Van der Weide, that Petitioner's argument fails because it does not explain how a third electrode would be incorporated into the device of Hawkins '020. PO Resp. 54–57 (citing Ex. 2100 ¶¶ 152–154). "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Keller*, 642 F.2d at 425. Dr. Van der Weide's testimony fails to address the salient issue, namely what the combined teachings of the references suggest to an ordinarily skilled artisan.

Accordingly, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claims 2 and 16 unpatentable as obvious.

4. Dependent Claims 5 and 19

Claim 5 depends from claim 1 and further recites: "wherein at least two of the electrode pairs are spaced longitudinally along the elongated member." Ex. 1001, 12:59–61. Claim 19 depends from claim 15 and recites the same limitation as claim 5. *Id*. at 14:41–43. Petitioner argues that Hawkins '020 and Kunis each describe two electrodes spaced longitudinally

apart. Pet. 53–54 (citing Ex. 1004, Fig. 3; Ex. 1005, Fig. 17b). Petitioner also contends, based on testimony by Dr. Jensen, that an ordinarily skilled artisan would have considered arranging electrodes longitudinally to provide recognized treatment advantages. *Id*. (citing Ex. 1002 ¶¶ 92–93). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20).

Based on our review of Petitioner's argument and evidence, which we adopt as our own findings, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claims 5 and 19 unpatentable as obvious.

5. Dependent Claims 6 and 20

Claim 6 depends from claim 1 and further recites: "wherein the elongated member comprises a guide wire lumen." Ex. 1001, 12:62–63. Claim 20 depends from claim 15 and recites the same limitation as claim 6. *Id*. at 14:44–45. Petitioner argues that Hawkins '020, Hawkins '768, and Kunis each describe a catheter having a guidewire lumen. Pet. 55 (citing Ex. 1004 ¶ 11, ¶¶ 27–28 (incorporating '170 Provisional by reference); Ex. 1003 ¶ 9; Ex. 1005, 6:51–63); *see also* Ex. 1009 ¶ 26 (over-the-wire balloon), Fig. 1). Patent Owner argues, based on Dr. Van der Weide's testimony, that Petitioner fails to explain how a guidewire lumen would be incorporated into Hawkins '020's device without puncturing Hawkins '020's balloon. *See* PO Resp. 59–60 (citing Ex. 2100 ¶¶ 167–169).

Petitioner responds by citing additional portions of Hawkins '020 (via its incorporation of the '170 Provisional) and Hawkins '768 describe the use of guidewire lumens in their respective catheter systems. Reply 24 (citing Ex. 1004 ¶¶ 27–28; Ex. 1009 ¶¶ 4, 26; Ex. 1003 ¶¶ 27, 49, Fig. 1; Ex. 1200

¶¶ 109–110). We agree with Petitioner that each of Hawkins '020, Hawkins '768, and Kunis describe or suggest including a guidewire lumen in their respective catheter assemblies.

"The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Keller*, 642 F.2d at 425. Dr. Van der Weide's testimony fails to address the salient issue, namely what the combined teachings of the references suggest to an ordinarily skilled artisan.

Based on our review of Petitioner's argument and evidence, which we adopt as our own findings, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claims 6 and 20 unpatentable as obvious.

6. Dependent Claim 7

Claim 7 depends from claim 1 and further recites: "wherein said balloon is a single chamber angioplasty balloon." Ex. 1001, 12:64–65. Petitioner contends that Hawkins '020 and Hawkins '768 each describe a single-chamber balloon adapted for angioplasty within which electrodes for generating shockwaves are placed. Pet. 56–57 (citing Ex. 1003 ¶ 50, Figs. 2, 4–8; Ex. 1004 ¶¶ 27–28 (via incorporating '170 Provisional by reference), Fig. 4 (illustrating single-chamber balloon suitable for angioplasty)).

Patent Owner argues that Hawkins '020 never addresses angioplasty at all but is limited to devices configured for valvuloplasty. PO Resp. 57. Patent Owner also argues that Petitioner never identifies any reason to modify Hawkins '020 so that its balloon is configured for angioplasty. *Id*.

at 58. Patent Owner argues, based on Dr. Van der Weide's testimony, that an ordinarily skilled artisan would not consider modifying the balloon of Hawkins '020 because valvuloplasty balloon require catheters of 4–4.6 mm diameter, which is larger than a "standard angioplasty catheter," which is 1.7–2 mm in diameter. *Id*. (citing Ex. 2100 ¶ 161). Patent Owner's argument is unpersuasive because the evidence upon which it relies directly conflicts evidence relating to the diameter of its own commercial angioplasty catheters, which are of 2.5–7 mm and thus larger than the alleged diameter of a valvuloplasty catheter. Ex. 2028, 1 (available diameters of S4 angioplasty catheters); Ex. 2030, 1 (available diameters of M5 angioplasty catheters). We also agree with Petitioner that Figure 4 of Hawkins '020 illustrates a single-chamber balloon and that the incorporated '170 Provisional describes a single-chamber angioplasty balloon.

For the reasons expressed above and based on our review of Petitioner's argument and evidence, which we adopt as our own findings, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claim 7 unpatentable as obvious.

7. Dependent Claim 8

Claim 8 depends from claim 1 and further recites: "wherein said balloon includes two chambers configured for valvuloplasty." Ex. 1001, 12:66–67. Petitioner argues that Hawkins '020 expressly describes a balloon that includes two chambers adapted for vavluloplasty treatment. Pet. 57 (citing Ex. 1004 ¶¶ 8, 27, Fig. 3). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20).

Based on our review of Petitioner's argument and evidence, which we adopt as our own findings, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claim 8 unpatentable as obvious.

8. Conclusion

For the reasons expressed above, Petitioner persuades us by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, and Kunis render claims 1, 2, 5–8, 15, 16, 19, and 20 unpatentable as obvious.

G. CLAIMS 3, 4, 9–14, 17, AND 18: OBVIOUSNESS IN VIEW OF HAWKINS '020, HAWKINS '768, KUNIS, AND LESH

Claims 3, 4, 9–14, 17, and 18 all recite limitations that have already been addressed in Part II.F above and Petitioner relies upon Hawkins '020, Hawkins '768, and Kunis in its challenges to claims 3, 4, 9–14, 17, and 18 in the same manner addressed in that Part. However, claims 3, 4, 9–14, 17, and 18 further require that the device include more than two pairs of electrodes with the electrodes being selectively connected to the voltage source via a multiplexer. *See*, *e.g.*, Ex. 1001, 12:45–53 (claim 3); 13:13–25 (claim 9).

Petitioner relies upon Lesh as describing the well-known use of a multiplexer for switching between various electrodes in intravascular devices and testimony from Dr. Jensen to establish that an ordinarily skilled artisan would have considered it obvious to incorporate such a multiplexer into the devices described by Hawkins '020, Hawkins '768, and Kunis. *See, e.g.*, Pet. 47 (in connection with claim 3, citing Ex. 1006 ¶ 114; Ex. 1002 ¶¶ 85–86; Ex. 1007, 6:8–23). Patent Owner does not argue that Lesh fails to describe a multiplexer or that it would not have been obvious to incorporate a multiplexer into an angioplasty catheter with multiple pairs of electrodes to

control which electrodes are connected to a voltage source. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20).

For the reasons expressed below, Petitioner persuades us by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claims 3, 4, 9–14, 17, and 18 unpatentable as obvious.

1. Independent Claim 9

Independent claim 9 is materially similar to independent claim 1 but requires two sets of two pairs of electrodes with each set of two pairs of electrode being selectively connected to a high voltage generator by a multiplexer. Petitioner relies upon Lesh as describing the use of a multiplexer with multiple electrodes in an intravascular device. Pet. 59 (incorporating *id*. at 47 (analyzing Lesh in connection with claim 3 and citing Ex. 1006 ¶ 114; Ex. 1002 ¶¶ 85–86; Ex. 1007, 6:8–23)). Patent Owner does not contest Petitioner's showing that the prior art described and suggested incorporating the claimed multiplexer. *See* PO Resp. 33–65 (not addressing multiplexer limitation).

Based on our review of Petitioner's argument and evidence in connection with the multiplexer of claim 9, which we adopt as our own findings, and the reasons stated in Part II.F above, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claim 9 unpatentable as obvious.

2. Dependent Claims 3 and 17

Claim 3 depends from claim 1 and recites:

> further including a third electrode pair having first and second spaced apart electrodes and a fourth electrode pair having first and second spaced apart electrodes, with the second electrode of the third electrode pair being connected to the first electrode of the fourth electrode pair, said device further including a multiplexer for selectively connecting the high Voltage source to either the first and second electrode pairs or the third and fourth electrode pairs.

Ex. 1001, 12:45–53. Claim 17 depends from claim 15 and recites the same limitation. *Id*. at 14:27–35. Petitioner relies upon Lesh as describing the well-known use of a multiplexer for switching between various electrodes in intravascular devices and testimony from Dr. Jensen to establish that an ordinarily skilled artisan would have considered it obvious to incorporate such a multiplexer into the devices described by Hawkins '020, Hawkins '768, and Kunis. *See, e.g.*, Pet. 47 (in connection with claim 3, citing Ex. 1006 ¶ 114; Ex. 1002 ¶¶ 85–86; Ex. 1007, 6:8–23). Patent Owner does not argue that Lesh fails to describe a multiplexer or that it would not have been obvious to incorporate a multiplexer into an angioplasty catheter with multiple pairs of electrodes to control which electrodes are connected to a voltage source. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20).

Based on our review of Petitioner's argument and evidence in connection with the multiplexer of claim 3, which we adopt as our own findings, and the reasons stated in Parts II.F above in connection with claims 1 and 15, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claims 3 and 17 unpatentable as obvious.

3. Dependent Claims 4, 10, and 18

Claim 4 depends from claim 3 and further recites: "wherein the second electrode of the second electrode pair and the second electrode of the fourth electrode pair are connectable to a common conductor providing a return path to the high voltage source." Ex. 1001, 12:54–58. Claim 10 depends from claim 9 and recites materially similar limitations to those introduced in claim 4. *Id*. at 13:26–29. Claim 18 depends from claim 17 and recites an identical limitation to those introduced in claim 4. *Id*. at 14:36–40.

Petitioner relies upon Lesh as describing the required multiplexer for each of claims 4, 10, and 18. Pet. 49 (claim 4), 59 (claim 10), 64 (claim 18). Petitioner also argues that Kunis suggests adding third and fourth electrode pairs and that adding such electrodes is "mere duplication of parts" that would have been obvious. *Id*. at 49 (citing *Harza*, 274 F.2d at 671; Ex. 1005, 5:18–37, 25:38–42, Fig. 17b; Ex. 1002 ¶ 87). Patent Owner does not argue separately that limitations introduced in claims 4, 10, and 18 are a basis for overcoming Petitioner's challenge to the claims. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20).

For the reasons expressed above in connection with intervening claims 1, 3, 9, 15, and 17, and based on our review of Petitioner's argument and evidence relating to the limitations introduced in claims 4, 10, and 18, which we adopt as our own, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claims 4, 10, and 18 unpatentable as obvious.

4. Dependent Claim 11

Claim 11 depends from claim 9 and further recites: "wherein at least two of the electrode pairs are spaced longitudinally along the elongated member." Ex. 1001, 13:30–32. This limitation is materially identical to the limitation introduced in claim 5. *Id*. at 12:59–61. Patent Owner does not argue separately that limitations introduced in claims 5 and 11 is a basis for overcoming Petitioner's challenge to the claims. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20). For the reasons expressed above in connection with claims 1, 5, and 9, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claim 11 unpatentable as obvious.

5. Dependent Claim 12

Claim 12 depends from claim 9 and further recites: "wherein the elongated member comprises a guide wire lumen." Ex. 1001, 13:33–34. This limitation is materially identical to the limitation introduced in claim 6. *Id*. at 12:62–63. We address Patent Owner's argument regarding the limitations introduced in claim 6 in Part II.F.5 above. For the reasons expressed above in connection with claims 1, 6, and 9, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claim 12 unpatentable as obvious.

6. Dependent Claim 13

Claim 13 depends from claim 9 and further recites: "wherein said balloon is a single chamber angioplasty balloon." Ex. 1001, 13:35–36. This limitation is materially identical to the limitation introduced in claim 7. *Id*.

at 12:64–65. We address Patent Owner's argument regarding the limitations introduced in claim 7 in Part II.F.6 above. For the reasons expressed above in connection with claims 1, 7, and 9, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claim 13 unpatentable as obvious.

7. Dependent Claim 14

Claim 14 depends from claim 9 and further recites: "wherein said balloon includes two chambers configured for valvuloplasty." Ex. 1001, 13:37–38. This limitation is identical to the limitation introduced in claim 8. *Id*. at 12:66–67. Patent Owner does not argue separately that limitations introduced in claims 8 and 14 is a basis for overcoming Petitioner's challenge to the claims. *See* PO Resp. 33–65 (presenting arguments only for claims 1, 2, 6, 7, 9, 12, 13, 15, and 20). For the reasons expressed above in connection with claims 1, 8, and 9, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claim 14 unpatentable as obvious.

8. Conclusion

For the reasons expressed above, Petitioner persuades us by a preponderance of evidence that the combined teachings of Hawkins '020, Hawkins '768, Kunis, and Lesh render claims 3, 4, 9–14, 17, and 18 unpatentable as obvious.

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 2002–2004, 2006, 2008, 2015–2017, 2025, 2026, 2112, 2116, 2125, 2139, 2141, 2153, 2154,

2161–2164, 2166, 2169–2176, 2178–2180, 2189, 2197, and 2209–2211 and certain paragraphs from Dr. Van der Weide's Declaration for various reasons. Paper 58 ("Pet. Motion" or "Pet. Mot."). Patent Owner opposes the Motion. Paper 61 ("PO Opposition" or "PO Opp."). Petitioner filed a reply brief in support of the Motion. Paper 65 ("Pet. Motion Reply" or "Pet. Mot. Reply"). For the reasons explained below, we deny the Petitioner's Motion as unpersuasive, moot, or both.

A. HEARSAY

Petitioner moves to exclude Exhibits 2002–2004, 2006, 2008, 2015–2017, 2025, 2026, 2125, 2139, 2141, 2164, and 2175 ¶ 6 as containing inadmissible hearsay under Federal Rules of Evidence 801, 802, and 805. Pet. Mot. 1–5. These Exhibits include news articles (Exs. 2002–2004), materials from financial analysts or investment bankers (Exs. 2006, 2008, 2016, 2017, 2132, 2133, 2139), materials received from or authored by the FDA (Exs. 2124, 2125), Yahoo Finance data (Ex. 2164), one of Patent Owner's 10-Q submissions (Ex. 2141), and one paragraph from the Stephens Declaration (Ex. 2175 ¶ 6). *Id*.

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 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.

Petitioner fails to persuade us that we should exclude any of these exhibits. These exhibits are, for the most part, offered in support of Patent

Owner's argument that objective evidence of nonobviousness exists, *i.e.*, long felt need, failure of others, skepticism, industry praise, and commercial success. *See generally* PO. Resp. 60–65. Patent Owner often does not rely on statements made in these exhibits for the truth of the matter asserted. 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 that 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 upon evidence that is not of a type upon which "experts in the field would reasonably rely," we have assigned very little weight to such evidence. The Stephens Declaration, including ¶ 6, is not hearsay because it is not an "out of court statement" under Rule 42.53(a), which requires parties to submit direct testimony in the form of an affidavit or declaration.[13] Mr. Stephens testifies that he has personal knowledge of the facts stated in his Declaration, which include those expressed in ¶ 6. Ex. 2175 ¶ 9. Therefore, we deny Petitioner's motion to exclude these Exhibits 2002–2004, 2006, 2008, 2015–2017, 2025, 2026, 2125, 2139, 2141, 2164, and 2175 ¶ 6 as being unpersuasive, moot, or both.

[13] Under 37 C.F.R. § 42.2, "affidavit" is defined to include declarations under 37 C.F.R. § 1.68 or 28 U.S.C. § 1746.

B. UNCITED EXHIBITS

Petitioner moves to exclude exhibits 2002–2004, 2112, 2116, 2153, 2154, 2161, 2162, 2163, 2164, 2166, 2169, 2172, 2176, 2189, 2197, and 2209–2211 as being irrelevant under Fed. R. Evid. 401 and 402 because Patent Owner does not cite them in its briefing. Patent Owner responds that Dr. Van der Weide directly or indirectly cites and relies upon Exhibits 2161–2164 and 2209–2211. PO Opp. 6 (citing Ex. 2100 ¶¶ 173, 185, 198; Exs. 2161–2163 (citing Exs. 2178–2180)). We deny Petitioner's Motion because the exhibits are relied upon by Dr. Van der Weide in offering his testimony.

Patent Owner also contends that we should not exclude Exhibits 2002–2004, 2112, 2116, 2153, 2154, 2161, 2162, 2163, 2164, 2166, 2169, 2172, 2176, 2189, 2197, and 2209-2211 because the Federal Circuit encourages the Board to "consider all evidence of record that is probative of the background knowledge of ordinary skill." PO Opp. 6–7. However, Patent Owner does not identify where it or any of its declarants cite or rely upon these Exhibits. *Id*. at 6–7. Nevertheless, we have explained the basis of our Decision and the manner in which we have considered and relied upon evidence of record. To the extent that we did not consider any of these exhibits, we consider Petitioner's Motion to be moot, and we dismiss it in part on that basis.

C. PERSONAL KNOWLEDGE

Petitioner moves to exclude Exhibit 2178–2180, which are claim charts mapping certain claims to the Shockwave devices, because Mr. Stephens has no personal knowledge of who prepared the exhibit. Pet. Mot. 6–7. Patent Owner correctly contends that Dr. Van der Weide, not

Mr. Stephens, relies upon Exhibits 2178–2180. PO Opp. 7. Accordingly, Petitioner's argument that the exhibits should be excluded due to Mr. Stephens's lack of personal knowledge is unpersuasive. Patent Owner also argues that Petitioner failed to timely object to Dr. Van der Weide's reliance upon Exhibits 2178–2180 and therefore waived any objection now raised. *Id*. Patent Owner further argues that an expert need not have personal knowledge about the facts and data upon which he relies. *Id*. at 8. Petitioner does not respond to Patent Owner's arguments. *See generally*, Pet. Mot. Reply.

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, November 2019, 78–79 ("Consolidated TPG").[14] "A motion to exclude evidence must be filed to preserve any objection." 37 C.F.R. § 42.64(c). 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." *Id.* at 79. Here, Petitioner does not identify the portion of the record where its objection to Exhibits 2178–2180 were originally made. *See* Pet. Mot. 6–7. Our review of the Petitioner's Objections (Papers 17, 34), the testimony of Mr. Stephens (Ex. 1216), and the testimony of Dr. Van der Weide (Ex. 1203) show that Petitioner failed to

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

object to Exhibits 2178–2180. Therefore, we deny Petitioner's Motion to Exclude Exhibits 2178–2180.

D. RELEVANCE OR PREJUDICE

Petitioner moves to exclude Exhibits 2006, 2125, 2139, 2141, and 2170–2176 as irrelevant or prejudicial under Federal Rules of Evidence 401, 402, and 403. Pet. Mot. 7–10. Petitioner contends the identified exhibits provide scant, cumulative, and unhelpful information that should be excluded. *See generally id*.

Patent Owner argues that instead of excluding evidence deemed to be irrelevant, little weight should be accorded such evidence. PO Opp. 8. Patent Owner explains that each of Petitioner's arguments go to the weight but not the admissibility of the evidence. *See generally id*. at 8–14. Patent Owner also contends that the declarations of Drs. Lyden, Kereiakes, Hill, Soukas, and Armstrong (Exs. 2170–2174) 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*.

We are not persuaded by Petitioner's arguments that Exhibits 2006, 2125, 2139, 2141, and 2170–2176 must be excluded from the record. The evidence Petitioner seeks to exclude supports Patent Owner's argument that the challenged claims of the '673 patent are nonobviousness; specifically, the exhibits relate to objective indicia of nonobviousness. Therefore, the objected to 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, unhelpful needlessly cumulative and/or misleading information," Pet. Mot. 7, will confuse or mislead the panel such that the probative value is outweighed by the danger of unfair prejudice. Fed. R. Evid. 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."). As appropriate, we have explained above the weight that we accord various aspects of these exhibits. For the reasons above, we are not persuaded that the testimony or documents at issue should be excluded and, thus, we deny Patent Owner's Petitioner's Motion to exclude Exhibits 2006, 2125, 2139, 2141, and 2170–2176 under Fed. R. Evid. 401, 402, or 403.

E. PORTIONS OF DR. VAN DER WEIDE'S TESTIMONY

Petitioner moves to exclude portions of the declaration testimony of Dr. Van der Weide under Federal Rules of Evidence 702 and 703. Pet. Mot. 10. More specifically, Petitioner argues:

> paragraphs 31 (unfounded speculation for the statement "a skilled artisan at the time of filing would have expected that [creating series arcs] to be very difficult to predictably achieve"), 45 (Jensen testimony mischaracterized), 106-110 (measurements flawed), 184, 195 (experts in the particular field would not reasonably rely on those kinds of facts or data in forming an opinion on the subject, i.e., subjective financial analyst reports), 198 (subjective market capitalization unrelated to the claimed invention), 199 (subjective revenue projections), 201 (speculative reimbursement), and 202 (sales analysis provide by Dr. Soukas who is not qualified to opine on the sales/reimbursement relationship) are inadmissible under FRE 702(b) and/or 703.

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 statements are speculative, how the measurements are 'flawed,' how financial figures are 'subjective' or why an expert should not rely upon such evidence, why Dr. Soukas was not qualified to provide the testimony, or what alternative facts or data could or should instead have been considered." PO Opp. 14–15.

Whether Dr. Van der Weide's opinions are conclusory, mischaracterize evidence, or are not adequately based on objective evidence goes to the weight we should accord to his testimony. As appropriate, we have explained above the weight that we accord the allegedly objectionable testimony by Dr. Van der Weide. Thus, we deny Petitioner's motion to exclude the identified paragraphs of Dr. Van der Weide's declaration (Ex. 2100).

IV. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude Exhibits 1002 and 1200 (Paper 57, "PO Motion" or "PO Mot."), i.e., the expert opinion testimony offered by Dr. Morten Jensen. PO Mot. 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 that 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 fundamental science

of arc-formation in conductive liquid (*id.* at 3); (2) did not understand the concept of "stray currents" (*id.* at 5); (3) opined that "no scenario exists in which a spark would occur at one electrode gap and not others" (*id.*); (4) did not understand how Kunis operates (*id.* at 6); (5) opined that an ordinarily skilled artisan "would not need to know these details of the physics of a spark or arc creating circuit to be able to work with it and have a reasonable expectation of success" (*id.* at 7); and (6) did not understand how to create a series connection between multiple spark gaps (*id*.). Therefore, Patent Owner contends that, because Dr. Jensen's testimony is based on a fundamental misunderstanding of the technology, it is unreliable, unhelpful, and prejudicial to Patent Owner. *Id.* at 8.

Regarding Exhibit 1002, Petitioner argues that Patent Owner objected only to specific paragraphs of Dr. Jensen's testimony, which objections were cured by serving supplemental evidence to which Patent Owner lodged no objections. Paper 59, 1 ("Pet. Opp."). Therefore, Petitioner reasons that Patent Owner did not preserve its objections. *Id.* at 2. Regarding Exhibit 1200, Petitioner similarly contends that Patent Owner objected to specific paragraphs of the declaration, which objections Petitioner cured by serving supplemental evidence to which Patent Owner lodged no objection. *Id*.

Patent Owner responds that it is unaware of any requirement that Patent Owner address the sufficiency of supplemental evidence in order to preserve its objections. We agree. Rather, Petitioner is obliged to file its supplemental evidence in response to any motion to exclude and explain how, if at all, the supplemental evidence cured Patent Owner's objections. "Supplemental evidence is not filed at the time of the objection, but simply served, and is filed only in support of an opposition to a motion to exclude."

ConsolidatedTPG, 79 (citing 37 C.F.R. §§ 42.64(a), (b)(2)). Petitioner failed to file any supplemental evidence or explain the curative nature of that evidence. Accordingly, Patent Owner's objections to Dr. Jensen's testimony are preserved.

Nevertheless, 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, 4. Thus, we observe Patent Owner failed to preserve any objection to 1002 on the ground that Dr. Jensen is unqualified, as alleged in Patent Owner's Motion to Exclude. Accordingly, we deny Patent Owner's motion to exclude Exhibit 1002 on this basis.

Regarding Exhibit 1200, we are not persuaded we should exclude Dr. Jensen's supplemental declaration testimony as an unqualified expert under Rule 702. Dr. Jensen holds an undergraduate degree in electrical and computer engineering with 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 ¶ 9. 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.* ¶ 10. 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.* ¶ 11. 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 '673 patent, Dr. Jensen had the requisite academic training and sufficient experience necessary to provide expert testimony regarding the technology embodied in the '673 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 S. A. v. Montgomery Ward & Co. Inc.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010) (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. Opp. 1. Petitioner also asserts that the portions of Dr. Jensen's testimony to which Patent Owner objects have been taken in isolation and not considered as a whole. *Id*. 4–9.

We agree with Petitioner that Patent Owner originally objected only to paragraphs 23, 35, 39, 42, 43, 47, 49, 55, 57–63, and 88 of Exhibit 1002 under Rule 703. *See* Paper 16, 4. And, regarding Exhibit 1200, Patent Owner specifically objected to paragraphs 37–44, 49–58, 60, 62-63, 65–104,

106–110, and 112–123. Paper 49, 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. Paper 49, 2. 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. Pet. Opp. 2–4. 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 testimony embodied in Exhibits 1002 and 1200. *See, e.g.*, Exs. 2156, 2237. "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.

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

V. CONCLUSION[15]

In summary,

Claim(s)	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 5–8, 15, 16, 19, 20	103	Hawkins '020, Hawkins '768, Kunis	1, 2, 5–8, 15, 16, 19, 20	
3, 4, 9–14, 17, 18	103	Hawkins '020, Hawkins '768, Kunis, Lesh	3, 4, 9–14, 17, 18	
Overall Outcome			1–20	

VI. ORDER

For the reasons given, it is:

ORDERED, based on a preponderance of evidence, that claims 1–20 of U.S. Patent 9,642,673 B2 are *unpatentable* as obvious under 35 U.S.C. § 103;

[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).

FURTHER ORDERED that Petitioner's Motion to Exclude Exhibits 2002–2004, 2006, 2008, 2015–2017, 2025, 2026, 2112, 2116, 2125, 2139, 2141, 2153, 2154, 2161–2164, 2166, 2169–2176, 2178–2180, 2189, 2197, 2209–2211, and 2100 (¶¶ 31, 45, 106–110, 184, 195, 198, 199, 201, and 202) is *denied*;

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

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

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