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

Paper 75
Date: July 8, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.,
Petitioner,

v.

SHOCKWAVE MEDICAL, INC.,
Patent Owner.

IPR2019-00405
Patent 8,956,371 B2

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

WEATHERLY, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
Denying Petitioner'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 1–17 (the "challenged claims") of U.S. Patent No. 8,956,371 B2 (Ex. 1001, "the '371 patent").

35 U.S.C. § 311. Shockwave Medical, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp."). On July 9, 2019, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims on all grounds set forth by Petitioner. Paper 19 ("Institution Decision" or "Dec."). We instituted the review on the following challenges to the claims:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–6, 11, 14–16	103	Levy,[1] AAPA,[2] and Mantell,[3] Uchiyama,[4] or Willneff[5]
7, 12	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Hayes[6]
8, 12	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Duchamp[7]
9	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Naimark[8]

[1] European Patent Application EP 0571306 A1 (Ex. 1003, "Levy").

[2] Applicant Admitted Prior Art ("AAPA").

[3] U.S. Published Patent App. 2010/0036294 A1 (Ex. 1004, "Mantell").

[4] Japanese Laid Open Application No. JP 62-275446 A (Ex. 1005, "Uchiyama").

[5] German Patent Application No. DE 3038445 A1 (Ex. 1006, "Willneff").

[6] U.S. Patent No. 7,309,324 B2 (Ex. 1007, "Hayes").

[7] U.S. Published Patent App. 2002/0082553 A1 (Ex. 1008, "Duchamp").

[8] U.S. Patent No. 7,569,032 B2 (Ex. 1009, "Naimark").

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
10	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Beyer[9]
13	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Bhatta[10]
17	103	Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Schultheiss[11]
1–4, 6, 11, 15, 16	103	Willneff, AAPA, and Levy or Mantell
5, 14	103	Willneff, AAPA, and Levy or Mantell in further view of Uchiyama
7, 12	103	Willneff, AAPA, and Levy or Mantell in further view of Hayes
8, 12	103	Willneff, AAPA, and Levy or Mantell in further view of Duchamp
9	103	Willneff, AAPA, and Levy or Mantell in further view of Naimark
10	103	Willneff, AAPA, and Levy or Mantell in further view of Beyar
13	103	Willneff, AAPA, and Levy or Mantell in further view of Bhatta
17	103	Willneff, AAPA, and Levy or Mantell in further view of Schultheiss

[9] U.S. Published Patent App. 2006/0190022 A1 (Ex. 1010, "Beyar").

[10] U.S. Patent No. 5,152,768 (Ex. 1012, "Bhatta").

[11] U.S. Published Patent App. 2007/0239082 A1 (Ex. 1011, "Schultheiss").

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 39, "PO Resp."). Petitioner filed a Reply in support of the Petition (Paper 56, "Reply"). Patent Owner filed a Sur-reply responding to the Reply (Paper 64, "Sur-reply"). Patent Owner did not move to amend any claim of the '371 patent.

We heard oral argument on April 15, 2020. A transcript of the argument has been entered in the record (Paper 74, "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 1–4 and 6–17 are unpatentable, but it has failed to do so for claim 5.

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. 9,642,673, IPR2019-00408 (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. 13/646,570 filed on October 5, 2012, and issued as U.S. Patent No. 9,011,462;
- U.S. Patent Application No. 14/660,539 filed on March 17, 2015, and issued as U.S. Patent No. 10,039,561;
- U.S. Patent Application No. 16/028,225 filed on July 5, 2018;

- U.S. Patent Application No. 13/049,199 filed on March 16, 2011, and issued as U.S. Patent No. 8,956,374;
- U.S. Patent Application No. 13/465,264 filed on May 7, 2012, and issued as U.S. Patent No. 9,072,534; and
- U.S. Patent Application No. 13/646,583 filed on October 5, 2012.

Paper 3, 1–2.

C. THE '371 PATENT

The '371 patent 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. 1001, 1:13–16. The patent purports to improve upon the prior art angioplasty balloon catheter 10 illustrated in Figure 1 (reproduced below left) by adding electrodes 22, 24 as shown in Figure 2 (reproduced below right), which generate arcs that create shock waves within balloon 26 to break up calcified lesions in a blood vessel.

FIG. 1
(PRIOR ART)

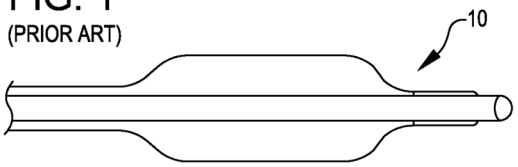


FIG. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter. *Id*. at 3:7–8.

FIG. 2

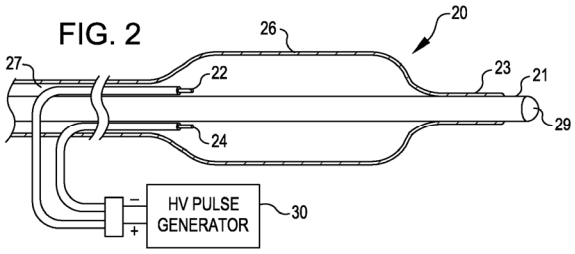
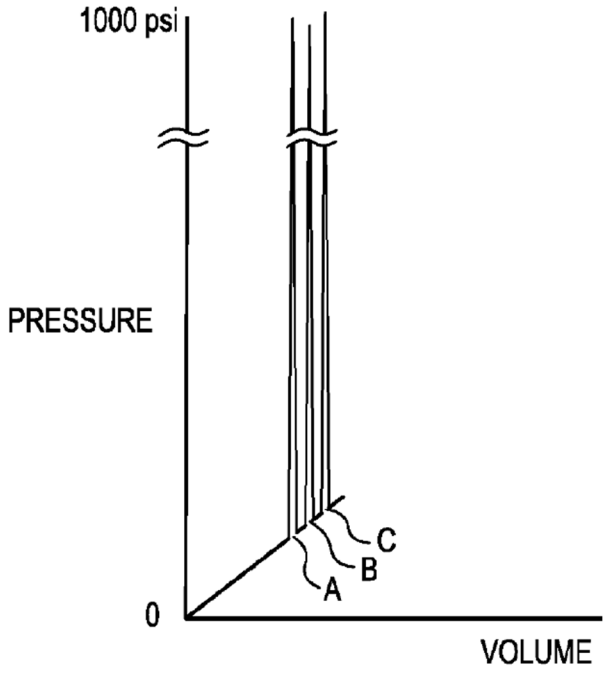


FIG. 2 is a side view of a dilating angioplasty balloon catheter with two electrodes within the balloon. *Id*. at 3:9–10.

Balloon 26 may be filled with water or saline to gently fix balloon 26 against the walls of an artery in direct proximity to a calcified lesion. *Id*. at 4:27–29. 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*. at 4:31–33. Electrical arcs between electrodes 22, 24 generate shock waves in the fluid. *Id*. at 4:16–17. Figure 11, reproduced in pertinent part at right, "is a pressure volume curve showing the various stages in the breaking of a calcified lesion with shock waves." *Id*. at 3:45–46.

FIG. 11



Figures 11A and 11B, reproduced below left and right respectively, are cross-sectional views illustrating a vessel before and after treatment.

FIG. 11A

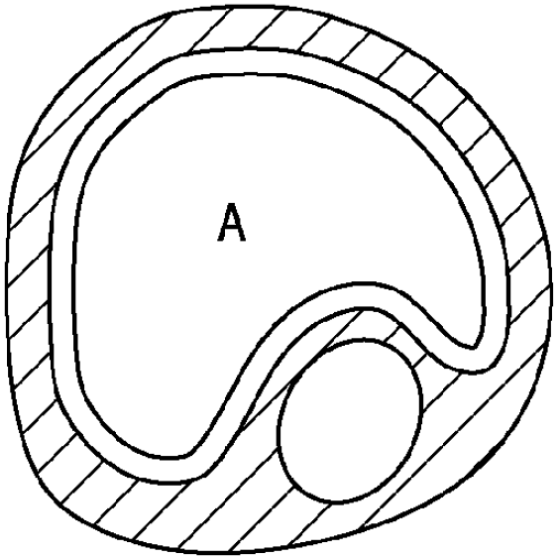


Figure 11A illustrates a compliant balloon expanded snugly against the vessel wall. *Id*. at 3:48, 5:31–32.

FIG. 11B

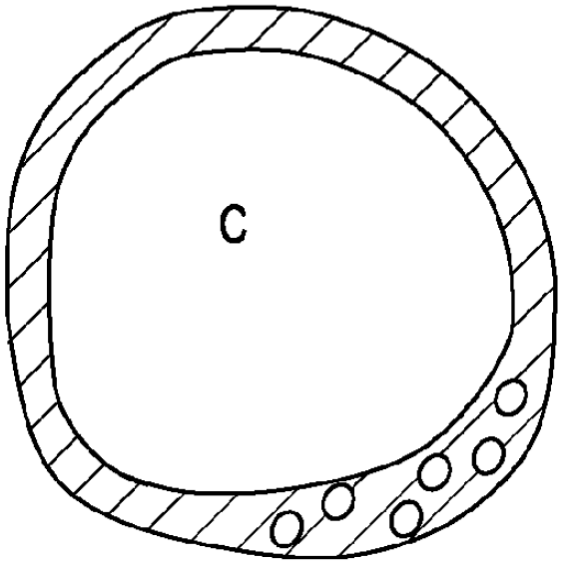


Figure 11B illustrates pulverized, calcified plaque "on a vessel wall." *Id*. at 3:50–51.

The Specification explains that: "As the High Voltage pulses generate shock waves (Region B and C) extremely high pressures, extremely short in duration will chip away the calcified lesion slowly and controllably expanding the opening in the vessel to allow blood to flow un-obstructed (FIG. 11B)." *Id*. at 5:33–38.

Claims 1 and 15 are the independent claims among the challenged claims. *Id*. at 6:21–8:16. Illustrative claim 1 recites:

> 1. An angioplasty catheter comprising:
>
> [a] an elongated carrier sized to fit within a blood vessel, said carrier having a guide wire lumen extending therethrough;
>
> [b] an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the

> balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon; and
>
> [c] an arc generator including a pair of electrodes,
>
> [d] said electrodes being positioned within and in non-touching relation to the balloon,
>
> [e] said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shock wave.

Id. at 6:21–39 (with third and fourth line breaks and letter designations [a]–[e] 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).[12] 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,

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

1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See In re 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. "angioplasty balloon"

Petitioner and Patent Owner disagree about the meaning of "angioplasty balloon" as used in the challenged claims. Petitioner contends that "angioplasty balloon" means "an inflatable sac that is configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels." Pet. 12. Patent Owner argues that "angioplasty balloon" refers to "a balloon that displaces the plaque into the vessel wall to expand the lumen of the vessel." PO Resp. 5.

a. Intrinsic Evidence

The plain language of the claim does not refer to any limitation on the type of "angioplasty" for which the "balloon" is designed. Rather, the claim merely recites an "angioplasty balloon." Dependent claims 7 and 8 limit the balloon to being formed of "compliant" or "non-compliant" material respectively. Ex. 1001, 6:51–54. Thus, the plain language of the claims does not reflect a requirement that the claimed "angioplasty balloon" must displace plaque "into the vessel wall."

The Specification states that the "present invention relates to a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is used to cross a lesion in order to dilate the lesion and restore normal blood flow in the artery." *Id*. at 1:13–18. This passage implies that an "angioplasty balloon" is used "to dilate the lesion and restore normal blood flow in the artery" without specifying or limiting how the dilation is achieved.

The Specification later illustrates the use of two types of "angioplasty balloons," a prior art balloon that does not employ shockwaves, Ex. 1001, Figs. 10A–C, and the claimed balloon that does employ shockwaves, *id*. Figs. 11A, 11B, 12, 13. When describing an embodiment of the claimed balloon in Figure 11A, the Specification indicates that the balloon is "expanded to fit snugly to the vessel wall . . . but this is not a requirement." *Id.* at 5:32–33. When describing Figure 11B, the Specification states that shockwaves will cause "extremely high pressures, extremely short in duration [that] will chip away the calcified lesion slowly and controllably expanding the opening in the vessel." *Id*. at 5:33–37. Figures 12 and 13 of the '371 patent illustrate calcified plaque that is "pulverized by the shock waves" and "reshaped" by "the expanded balloon." *Id*. at 5:39–48, Figs. 12, 13. In all instances, the Specification illustrates and describes breaking and redistributing plaque within a vessel wall without ever explicitly referring to displacing plaque "into the vessel wall" from outside the wall. Accordingly, we find that the Specification alone does not resolve whether "angioplasty balloon" refers to a balloon that must dilate a blood vessel, at least in part, by displacing "the plaque into the vessel wall."

Patent Owner argues, based on testimony from Dr. Berger, that intrinsic evidence in the form of two prior art patents submitted during prosecution of the '371 patent use "'angioplasty balloon' in a manner consistent with the plain meaning of that term as used in the '371 patent." PO Resp. 10–11 (citing Ex. 2109 ("O'Boyle"), 1:33–37 (angioplasty balloon used to "stretch and compact the stenosis material against the wall of the artery"); Ex. 2110 ("O'Connor"), 3:8–12 (angioplasty balloon that "opens the occluded part of the artery by pressing the thrombus against the internal wall of the artery")). Neither quoted passage from O'Boyle and O'Connor supports Patent Owner's argument that an "angioplasty balloon" must displace plaque "into the vessel." Petitioner correctly points out that the passages more strongly support its argument for a broader definition because both passages merely describe compacting or pressing material "against" rather than "into" the wall of the vessel. Reply 11.

Even more importantly, O'Boyle and O'Connor each describe angioplasty as a procedure that can result in the removal of material from the vessel wall via ultrasonic ablation, without displacing material "into the vessel wall." For example, O'Boyle's device, which is described as an "angioplasty catheter," Ex. 2109, 3:20–21, performs angioplasty through ultrasonic ablation of stenosis material without significant "crushing of the material of the stenosis against the vessel wall," *id*. at 3:53–62. O'Connor describes angioplasty as being performed by ablating a thrombus and softening calcified plaque within a vessel. Ex. 2110, 3:23–57. O'Connor's angioplasty balloon includes an ultrasound transducer and is inflated with saline to only 1–3 atmospheres. *Id*. at 3:36–41. The low-pressure saline ensures that the balloon presses against the thrombus to transmit and focus

ultrasonic energy to break the thrombus into "microparticulate matter" (i.e, ablation) while also creating "microfractures within the calcified plaque 12 which is embedded in the wall" of the artery. *Id*. at 3:41–57. O'Boyle and O'Connor thus support Petitioner's broader definition of "angioplasty balloon" as not requiring that the balloon displace plaque "into the vessel wall" but merely requiring that the balloon widens a narrowed or obstructed vessel.

b. Extrinsic Evidence

We do not consider it necessary to rely upon extrinsic evidence to support our conclusion that an "angioplasty balloon" is not limited to those balloons that displace material "into the vessel wall." Nevertheless, the balance of such evidence of record supports our conclusion that Patent Owner's definition of "angioplasty balloon" is unduly narrow.

Patent Owner contends that medical and lay dictionaries and testimony from Dr. Berger and Dr. Jensen that establish that an "angioplasty balloon" must displace plaque "into the vessel wall." PO Resp. 11–12 (citing Ex. 2100 ¶¶ 86–88; Ex. 2111, 126:8–16; Ex. 2018; Ex. 2020). Five of the six definitions of "angioplasty" proffered by Patent Owner as establishing that angioplasty refers to displacing plaque "into the vessel wall" fail to go so far. Rather, Petitioner persuasively points out that five of the six definitions refer to angioplasty more generally as merely referring to surgical repair of a blood vessel, sometimes by compressing deposits of fatty substances or plaque blocking the vessel, and other times by using a laser beam or replacing part of the vessel. Ex. 2019, 1–3; Ex. 2020, 1. One of Patent Owner's dictionaries states that an angioplasty is a procedure in which a "balloon is inflated to compress the fatty matter into the artery

wall," which supports Patent Owner's argument. Ex. 2018, 1. However, we find that the group of definitions proffered by Patent Owner as a whole demonstrate that angioplasty refers more broadly to procedures that repair blood vessels and do not necessarily involve displacing material "into the vessel wall."

Patent Owner also relies upon Dr. Berger, who opines that, based on definitions in a lay dictionary for "angio-," "plasty," "plastic," and "elastic deformation," an ordinarily skilled artisan understands "angioplasty" to refer to a procedure that "involves the plastic or permanent deformation or molding of blood vessels." Ex. 2100 ¶ 86 (citing Exs. 2166–2169, 2190). Based on his etymological analysis of "angioplasty," and without further evidentiary support, he extends his opinion by concluding that "the plastic molding of the vessel takes place by the displacement of plaque into the vessel wall to expand the lumen."

We heavily discount Dr. Berger's conclusion about angioplasty requiring "displacement . . . into the vessel wall" as a non sequitur. At most, the evidence upon which he bases his opinion establishes only that angioplasty involves the permanent deformation of a vessel. Additionally, his testimony on cross-examination that "angioplasty" cannot refer to merely pressing plaque or a thrombus against the vessel wall, Ex. 1204, 13:7–13, 13:23–14:24, is irreconcilably inconsistent with prior art that was before the Examiner, O'Boyle and O'Connor. As discussed above, O'Boyle and O'Connor both describe angioplasty as pressing material *against* the vessel wall. Ex. 2109, 1:33–37, 3:53–62; Ex. 2110, 3:8–12. We simply do not consider Dr. Berger's opinion that angioplasty must involve displacing

plaque "into the vessel wall" is credible when considered against objective evidence that he cites.

Petitioner cites another patent, which was not before the Examiner that further establishes that an ordinarily skilled artisan would understand "angioplasty" as referring more broadly to both recanalization and dilation of a blood vessel. Reply 11 (citing Ex. 1041, 2).

c. Conclusion

For the reasons expressed above, we conclude that "angioplasty balloon" refers to "an inflatable sac that is configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels."

2. Other Disputed Terms

The parties expressly address and disagree about the meaning of two other phrases appearing in claim 1. Namely, "distal end of the balloon sealed to the carrier near the distal end of the carrier" and "carrier having a guidewire lumen extending therethrough." *Compare* Reply 12–13, *with* PO Resp. 16–18 *and* Sur-Reply 10–13. We adopt Patent Owner's interpretations of both terms for the reasons expressed in its briefing and because Patent Owner's interpretations comport more closely with the plain language of the phrases. PO Resp. 16–18; Sur-Reply 10–13. However, Petitioner establishes that the combined teachings of Levy and AAPA describe an angioplasty balloon sealed near the distal end of a carrier having a guidewire extending through the carrier as recited in these two phrases. *See* Part II.F.1.d.iii below.

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 1–17 as identified in the table in Part I.A above. Dec. 26–27. 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 20, 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 1–17 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).

To prevail in an *inter partes* review, Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing

"mere conclusory statements," but "must instead articulate specific reasoning, based on evidence of record" to support an obviousness determination. *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 IN THE ART

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

> knowledge roughly equivalent to the knowledge and/or training of a person holding the degree of Bachelor of Science in Mechanical Engineering, 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. 11; Ex. 1002 ¶¶ 63–66.

Patent Owner disagrees and contends that the level of ordinary skill in the art would have been a "multidisciplinary individual or team that included"

> i) at least one person with a medical degree and relevant clinical experience concerning the management of patients with vascular disease, and ii) at least one person with an electrical engineering, biomedical engineering or equivalent degree and at least two

> years of experience in the engineering, design, testing or development of catheter-based medical devices.

PO Resp. 4 (citing Ex. 2100 ¶ 3–14).

The parties' positions primarily differ in that Patent Owner suggests that a medical degree is required along with an engineering degree. Petitioner notes that none of the inventors of the '371 patent, a great majority of the inventors listed on the prior art asserted here or applied by the Examiner during prosecution, and Patent Owner's Vice President of Research and Development has a medical degree. Reply 5 (citing Ex. 1200 ¶¶ 12–15; Ex. 1216, 6:15–7:1, 10:10–13:18). However, Petitioner contends that three to five years of practical experience with medical devices and techniques for treating plaque buildup is needed. Pet. 11; Ex. 1002 ¶¶ 65–66. We consider Petitioner's stated level of experience to supply similar relevant knowledge to the medical degree that Patent Owner contends to be needed to attain a level of ordinary skill in the art.

For purposes of this Decision, and based on the record, we consider an ordinarily skilled artisan to possess skill attained by education via a bachelor's degree in mechanical, electrical, or biomedical engineering combined with knowledge of medical devices and techniques for treating plaque buildup in blood vessels that is attained either by education (a medical degree) or three to five years of practical experience. Further, we find that the prior art of record reflects the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Patent Owner contends, however, that "Dr. Jensen [ ] lacks a medical degree and relevant clinical experience and would not qualify as one skilled

in the art." PO Resp. 4–5. Patent Owner also criticizes Dr. Jensen for failing to understand certain concepts and figures in the prior art. *Id*.

We disagree with Patent Owner's contentions about Dr. Jensen's qualifications. Dr. Jensen holds a bachelor's degree in electrical engineering, master's degree in biomedical engineering, doctorates in medical science and medicine. Ex. 1002 ¶¶ 8–13, Appendix A (curriculum vitae). His doctorate of medicine (Dr.Med.) was awarded by the University of Aarhus School of Medicine in Denmark in 2008, and this degree is typically given only to medical doctors. Ex. 1200 ¶ 21. Furthermore, a declarant's expertise and experience need not match perfectly the experience and education of a person of ordinary skill in the art in order to provide testimony so long as there is an adequate relationship between the declarant's education and experience when compared to the claimed invention. *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010). Accordingly, we find that Dr. Jensen is qualified to testify about the perspective of one of ordinary skill in the art at the time of the invention.

E. OVERVIEW OF THE ASSERTED PRIOR ART

1. Levy

Levy describes a device for removing "deposits which form on the interior walls of passages, and in particular the removal, by disintegration, of plaque deposits, or atheromas, which form on the inner walls of the blood vessels." Ex. 1003, 1.[13] Levy's device is shown in Figure 1 (substantively reproduced below).

[13] We, like Petitioner, refer to the page numbering of the translation of the Levy reference itself rather than exhibit page numbers.

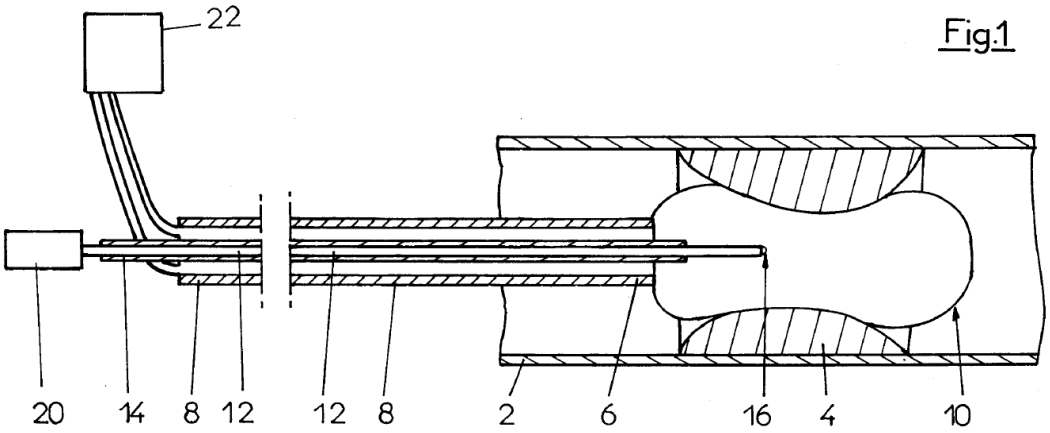


Fig.1

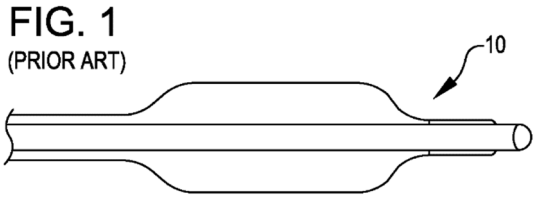
Levy's Figure 1 is a cross-sectional view of an embodiment of Levy's device for removing deposits from blood vessel walls.

Levy's devices includes balloon 10 protruding from distal end 6 of catheter 8. *Id*. at 3. Convergent lens 16 on optical fiber 12 protrudes into balloon 10 from distal end 6 of catheter 8. Balloon 10 is inflated with, e.g., saline, supplied by liquid source 22 through a suitable liquid coupling within the bore of catheter 8. *Id*. Laser source 20 emits light energy that is carried into the saline within balloon 10 by optical fiber 12. *Id*.

A user of Levy's device inserts catheter 8 into vessel 2 next to deposit 4 with balloon 10 deflated and then inflates balloon 10 with saline until it contacts deposit 4. *Id*. Laser energy is pulsed into the liquid within balloon 10 to create cavitation as gas bubbles which implode and agitate the fluid to disintegrate deposit 4. *Id*. at 4. According to Dr. Jensen, an ordinarily skilled artisan understands that Levy's laser pulses create shockwaves that cause the disintegration of deposit 4. Ex. 1002 ¶ 116.

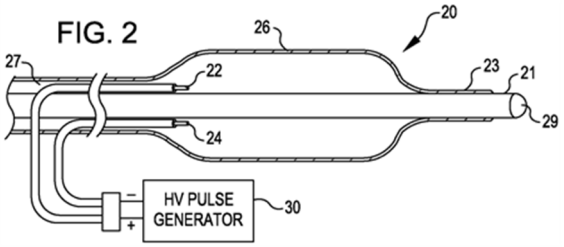
2. AAPA

Figure 1 of the '371 patent (reproduced right) is labeled and described as "PRIOR ART." Ex. 1001, Figure 1. The



Specification describes Figure 1 as "a view of the therapeutic end of a typical prior art *over-the-wire* angioplasty balloon catheter 10. Such catheters are usually non-complaint with a fixed maximum dimension when expanded with a fluid such as saline." *Id*. at 3:66–4:2 (emphasis added). Although Figure 1 does not illustrate a guidewire, the Specification implies its presence when describing catheter 10 as being "over-the-wire."

Figure 2, which illustrates the claimed catheter 20, also fails to illustrate a guidewire. *Id*. at Figure 2, 3:9–12. The Specification indicates that the guidewire is not shown but inserted through lumen 29 in carrier 21. *Id*. at 4:31–33. Although a carrier and lumen are not enumerated on Figure 1, similarities between Figures 1 and 2 imply, and we conclude, that Figure 1 illustrates a carrier and lumen that are essentially the same as carrier 21 and lumen 29 of Figure 2.



Accordingly, we understand that the AAPA includes the angioplasty balloon catheter comprising a carrier with a balloon postioned near the distal end and a guidewire lumen extending through the carrier and protruding from the distal end of the balloon as illustrated in Figure 1.

3. Mantell

Mantell is directed to "an invasive radially-firing electrohydraulic lithotripsy probe that creates a substantially annular shockwave for uses such as breaking up concretions that are at least semi-annular." Ex. 1004 ¶ 20.

> In one implementation, the EHL probes described below may be delivered to a proper channel of a heart by threading (or pre-loading) an EHL probe through a center lumen of a catheter or balloon device. The catheter may be threaded through appropriate veins or arteries to address concretions either

> forming in vessels or even in the valves of the heart or other organs.

Id. ¶ 21. One embodiment of Mantell's device is illustrated below.

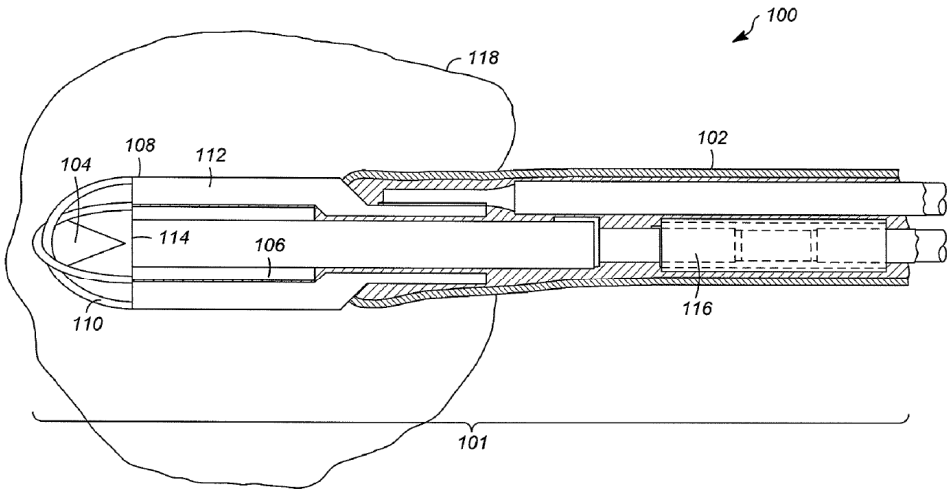


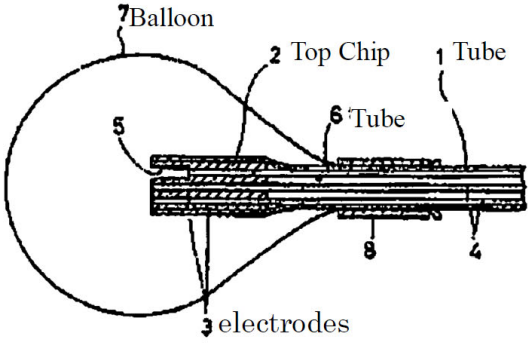
FIG. 2

> Figure 2 is a cross-sectional side view of an embodiment of Mantell's electrohydraulic lithotripsy probe. *Id*. ¶ 4.

Distal portion 101 of probe 100 includes insulating body 102 surrounding electrodes 104, 106, which are positioned within balloon 118. *Id*. ¶¶ 23–29. Balloon 118 "encapsulates a liquid such as saline" and an arc between electrodes 104, 106 "causes a steam bubble in the liquid [that] . . . rapidly expands and contracts back on itself" to generate "a shockwave." *Id*. ¶ 29. That shockwave "radiates away from the lithotripsy tip 101 in a substantially radial manner such that the shockwave is at least semi-annular." *Id*.

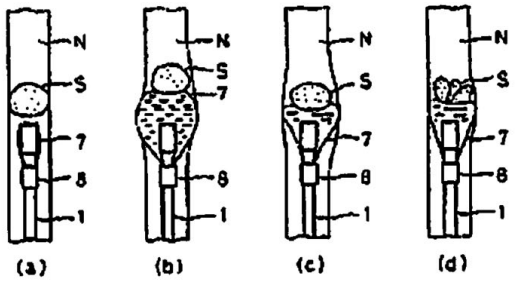
4. Uchiyama

Uchiyama describes an arc-based shockwave generator within an inflated balloon as illustrated in Figures 1–7. Ex. 1005, 298–99.[14] We reproduce Figures 1 and 3(a)–(d) below from the translation of Uchiyama.



Drawing1

Figure 1 is a cross section view illustrating the balloon inflated and some of the internal elements of the lithotripsy probe. *Id*. at 300.



Drawing3

Figures 3(a)–(d) are cross section views illustrating the process of using the probe of Figure 1 in the urinary duct. *Id*.

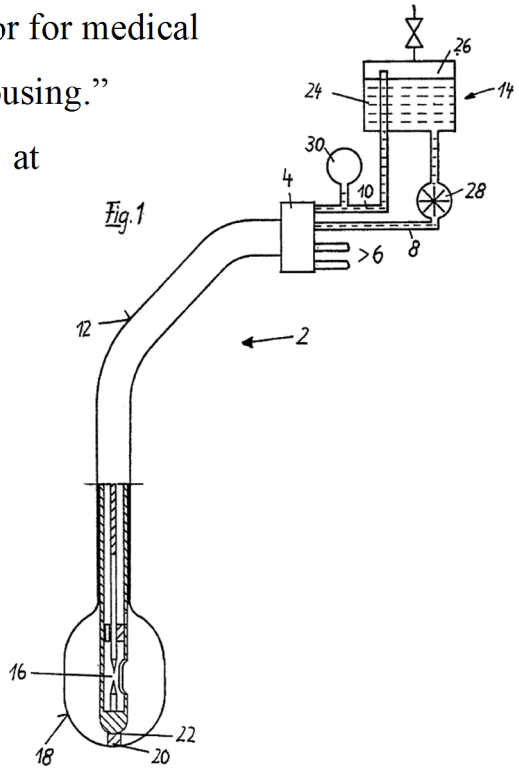
Electrodes 3 are positioned near the distal end of tube 1 that includes tube 6 for inflating balloon 7 with fluid through opening 5. *Id*. at 298. Figures 3(a)–(d) illustrate advancing the probe in a urinary duct N to a position close to calculus S (Figure 3(a)), inflating balloon 7 so that it contacts calculus S (Figure 3(b)), and using arcs between electrodes 3 to generate shockwaves that break up calculus S (Figures 3(c) and (d)). *Id*. at 298–99. The optimal gap between electrodes 3 and calculus S for making the shockwaves most effective at breaking up calculus S is managed by controlling the degree to which balloon 7 is inflated. *Id*.; *see also id*. Figures 3(b) and (c). Uchiyama indicates that arcs are generated within

[14] We, like Petitioner, refer to the page numbering of the translation of the Uchiyama reference itself rather than exhibit page numbers.

balloon 7 "so that there is no risk that the electric discharge sparks hit a human tissue directly." *Id*. at 299. Uchiyama notes that arcs directly contacting human tissue may damage the tissue. *Id*. at 297.

5. Willneff

Willneff describes a "shock wave generator for medical applications with a spark gap located within a housing." Ex. 1006, 2.[15] We reproduce Willneff's Figure 1 at right, which is a schematic illustration of Willneff's catheter with a partial cross section view showing the configuration of tip 22. *Id*. at 9. Supply tube 8, return tube 10, and current feed 6 pass through sheath 12. *Id*. Balloon 18 is inflated and deflated with fluid supplied and controlled via tubes 8, 10. *Id*. A mechanical connection 20 between tip 22 and balloon 18 holds spark gap 16 in a fixed relationship with balloon 18. *Id*. Spark gap 16 is centered to avoid unintended tissue damage or burns. *Id*. at 5. The shock waves generated by arcs across spark gap 16 can remove concretions from the urinary tract. *Id*. at 4–5.



F. CLAIMS 1–17: OBVIOUSNESS IN VIEW OF LEVY, AAPA, AND ONE OF MANTELL, UCHIYAMA, OR WILLNEFF, AND IN FURTHER VIEW OF VARIOUS OTHER REFERENCES FOR CERTAIN CLAIMS

Petitioner argues that claims 1–6, 11, 14–16 are unpatentable as obvious in view of the combined teachings of Levy, the AAPA, and any one

[15] We, like Petitioner, refer to the page numbering of the translation of the Willneff reference itself rather than exhibit page numbers.

of Mantell, Uchiyama, or Willneff. Pet. 13–42. Petitioner relies on one or more of the same references or additional references to argue that dependent claims 7–10, 12, 13, and 17 are also obvious. *Id*. at 34–43. For the reasons expressed below, Petitioner has demonstrated by a preponderance of evidence that claims 1–4 and 6–17 are obvious in view of the teachings of the asserted combinations of prior art. However, Petitioner has failed to demonstrate by a preponderance of evidence that claim 5 is obvious.

1. Independent Claim 1

a. Summary of Petitioner's Argument and Evidence

Petitioner relies upon Levy as describing most of the physical elements of the catheter of claim 1 (carrier 1a, balloon 1b, and shockwave generator 1c–e) except that Levy uses a laser to generate shockwaves instead of an electrical arc. Pet. 23–31 (citing Ex. 1003, 1, 3, Figure 1; Ex. 1002 ¶¶ 109–123). Petitioner also relies upon AAPA as teaching the carrier with a guidewire lumen (element 1a) and balloon (element 1b). *Id*. at 23–25 (citing Ex. 1001, 3:65–4:2, Figure 1; Ex. 1002 ¶¶ 109, 113). Petitioner argues that an ordinarily skilled artisan would have been motivated to substitute any one of the arc-based shockwave generators described by Mantell, Uchiyama, or Willneff for Levy's laser-based shockwave generator to save cost, reduce complexity, and reduce overheating risks. *Id*. at 28–29 (citing Ex. 1002 ¶ 120). Petitioner contends that an ordinarily skilled artisan would have considered arc generators and lasers to be interchangeable devices for generating shockwaves to disintegrate unwanted deposits within blood vessels. *Id*. (citing Ex. 1002 ¶ 120); *see also id*. at 19–21 (citing Ex. 1002 ¶ 98; Ex. 1012, 1:5–10; Ex. 1006, 3) (discussing similarity of laser-

and arc-based methods for generating shockwaves to remove unwanted deposits within the body).

Petitioner persuades us by preponderance of evidence that the combined teachings of Levy, AAPA, and one of Mantell, Uchiyama, and Willneff describe all limitations of claim 1 and that an ordinarily skilled artisan would have combined those teachings to arrive at the angioplasty catheter of claim 1. We address Patent Owner's arguments otherwise below.

b. Whether Levy's Balloon Is an Angioplasty Balloon

Petitioner relies upon Levy as describing an angioplasty balloon near a distal end of the carrier and AAPA as describing the distal end of the balloon being sealed to the carrier. Pet. 25–26 (citing Ex. 1001, 3:65–4:2, Fig. 1; Ex. 1003, 4, Fig. 1; Ex. 1002 ¶¶ 113, 114). Patent Owner argues that Levy fails to describe an angioplasty balloon because Levy's balloon "does not displace plaque into the vessel wall in order to widen the lumen of the vessel." PO Resp. 20 (citing Ex. 2100 ¶¶ 55–58, 163–170). Rather, Patent Owner contends that Levy "removes" plaque through "erosion" and "disintegration." *Id*. (citing Ex. 1003, 3, 6; Ex. 2100 ¶¶ 163–170).

Patent Owner's argument is unpersuasive in rebutting Petitioner's showing that the prior art describes the claimed angioplasty balloon for two reasons. First, even accepting Patent Owner's description of Levy as using "erosion" and "disintegration" to remove plaque from the wall of an artery, such processes still widen a narrowed or obstructed blood vessel by removing "plaque deposits, or atheromas, which form on the inner walls of the blood vessels." Ex. 1003, 1. Such widening through ablation is within the scope of "angioplasty balloon" as we have interpreted the term. *See* Part II.A.1 above. Second, Patent Owner's argument fails to address Petitioner's

showing, Pet. 25, that the AAPA describes an angioplasty balloon. *See* PO Resp. 20–22 (addressing only whether Levy describes claimed "angioplasty balloon").

Based on our review of the record, Petitioner persuades us by a preponderance of evidence that Levy and the AAPA each describe the claimed angioplasty balloon.

c. Whether Levy's Balloon Includes a Shockwave Generator

Petitioner contends that Levy's laser-based device generates shockwaves inside the balloon without touching the balloon, which remains intact during formation of the shockwaves. Pet. 26–30 (citing Ex. 1003, 3, Fig. 1; Ex. 1021 ("Levy '227"),[16] 3:58–61; Ex. 1002 ¶¶ 116, 121, 122). Patent Owner contends that Levy fails to describe a "shockwave generator" because Levy refers only to "cavitation bubbles" that lead to "vigorous agitation" that causes disintegration of the plaque deposits. PO Resp. 22. Patent Owner concedes that Levy '227 refers to shockwaves, but argues that Levy '227 describes using shockwaves only within a tooth canal and not within a blood vessel. *Id*. at 22–24 (citing Ex. 2100 ¶¶ 55–58). We disagree.

Levy indisputably incorporates Levy '227 by reference as describing the laser used within Levy's balloon (Ex. 1003, 3, 5), and we, therefore, consider Levy '227 to be part of Levy for our analysis. Levy '227 first describes that its laser generates an "implosion" of gas bubbles within a tooth canal that results in "shockwaves" that detach debris from the walls of the canal. Ex. 1021, 3:39–42. Levy '227 later indicates that the same

[16] Exhibit 1021 is U.S. Patent 5,116,227, also to Levy, which is incorporated by reference into Levy. Ex. 1003, 3.

technique can clean blood vessels by removing "plaque deposits, or atheromas." *Id*. at 4:37–5:2; *see also* 2:12–33 (describing cavitation-based implosions as cleaning tooth canals and blood vessels among other body passages).

Patent Owner also argues that Levy's description of cavitation bubbles refers to the generation of "hydraulic or acoustic" waves rather than shockwaves. PO Resp. 23–24 (citing Ex. 2105 ("de la Torre"), 3:25–52; Ex. 2100 ¶¶ 55–58). Patent Owner supports its argument with Dr. Berger's analysis of de la Torre's description of the manner in which it uses a laser to create cavitation bubbles that avoid creating shockwaves. *Id*. (citing Ex. 2105, 3:25–52). We discount Dr. Berger's testimony and de la Torre's disclosure because they are inconsistent with Levy's express description of using its laser to generate cavitation bubbles within a balloon to create shockwaves as we find immediately above. *See* Ex. 1003, 3, 5 (incorporating description of the laser of Levy '227 as laser used in its balloon); Ex. 1021, 2:12–33, 3:39–42, 4:37–5:2 (expressly describing using laser to generate cavitation bubbles leading to shockwaves).

Petitioner also relies upon each of Mantell, Uchiyama, and Willneff as describing an arc generator that creates shockwaves between electrodes positioned within a balloon as claimed. Pet. 26–30 (citing Ex. 1004 ¶¶ 21, 24, 29, Figs. 1, 2, 5–7; Ex. 1005, 298, Figs. 1–7; Ex. 1006, 5, 10, Figs. 1–3; Ex. 1002 ¶¶ 117–119). Patent Owner does not respond to Petitioner's showing that each of these three references describes using arcs between electrodes within a balloon to generate shockwaves. PO Resp. 20–24 (arguing only that Levy does not describe generating shockwaves inside a balloon).

For the reasons above, Petitioner persuasively demonstrates by a preponderance of evidence that each of Levy, Mantell, Uchiyama, and Willneff describes generating shockwaves within a balloon, with Levy using a laser and the other references using electrical arcs between electrodes to do so.

d. Motive to Combine Teachings of the Prior Art

i. Whether EHL Probes[17] Would Have Been Considered Too Dangerous to Use in Blood Vessels

Patent Owner argues that danger to healthy tissue stemming from using EHL-generated shockwaves within blood vessels would have prevented an ordinarily skilled artisan from being motivated to incorporate the EHL probes of Mantell, Uchiyama, or Willneff into Levy's balloon. PO Resp. 24–44.

Patent Owner relies primarily upon Chernenko (Ex. 2046) as proving that EHL-generated shockwaves cannot be used safely within 5 mm of "soft tissues" such as the walls of a blood vessel. *Id*. at 24–25 (citing Ex. 2046 ¶ 11). Chernenko relates to a lithotripsy device for breaking calcified stones in the urinary system. Ex. 2046 ¶ 1. Chernenko's admonition against using EHL devices within 5 mm of soft tissue appears in its description of known devices. *See id*. ¶ 11 (in Background of the Invention section). Chernenko indicates that at least one prior art device includes a nozzle to direct shockwaves to a focal point. *Id*. ¶ 13. Dr. Berger relies heavily upon Chernenko's broad statements about other prior art that 5 mm is as close as an EHL probe can be located to soft tissue without damaging it and that

[17] Mantell and the parties refer to electrohydraulic lithotripsy probes as "EHL probes." Ex. 1004 ¶ 21; Pet. 1; PO Resp. 1.

shielding is necessary to focus shockwave energy. Ex. 2100 ¶¶ 32–38 (citing Ex. 2046 ¶¶ 11, 13, 88, Fig. 6).

We discount Dr. Berger's conclusions about the minimum safe distance between EHL probes and healthy tissue for two reasons. First, Chernenko advises that its EHL probe should be moved closer to its target such that at least one and preferably both electrodes directly contact the stone to be broken to ensure that arcing passes through the target stone. *Id*. ¶¶ 89–91, 105, Figs. 6b, 6c, 7a–d, 8a. Second, none of the other prior art summarized by Chernenko places an EHL probe inside a balloon or forms part of Petitioner's proposed combination. Chernenko and the prior art that it discusses relates to intracorporeal EHL probes that are not placed within balloons. *Id*. ¶¶ 1–13. Although Chernenko claims that its device can be used for "fragmentation of any foreign object[], which might appear in other locations of the body, e.g. in blood vessels etc.," *id*. ¶ 3, Chernenko never provides any further details on how so, *see generally id*.

Petitioner persuasively argues that:

> The prior art must be considered ***as a whole*** for what it teaches." *Medichem, S.A. v. Rolabo*, 437 F.3d 1157, 1166 (Fed. Cir. 2006); *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991). Although a reference teaches away from the claimed invention when it "suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant" (*id.*, at 1165 (citing *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)), there is no rule "that a single reference that teaches away will mandate a finding of nonobviousness" (*Medichem*, 437 F.3d at 1165; *In re Dome Patent*, 799 F.3d 1372, 1381 (Fed. Cir. 2015)).

Reply 19. Each of Mantell, Uchiyama, and Willneff generates shockwaves within a balloon that are used to erode an unwanted deposit within a cavity of the body. Pet. 26–30 (citing Ex. 1004 ¶¶ 21, 24, 29, Figs. 1, 2, 5–7;

Ex. 1005, 298, Figs. 1–7; Ex. 1006, 5, 10, Figs. 1–3; Ex. 1002 ¶¶ 117–119). Furthermore, Petitioner establishes that Levy generates shockwaves within an angioplasty balloon using a laser rather than electrodes. *See* Parts II.F.1.b–c above.

At most, Chernenko is relevant through its summary that the Canadian counterpart (Ex. 2102) to Bhatta (Ex. 1012) describes focusing shockwaves emanating from an EHL probe to increase the effectiveness of the device. Regarding safety, Bhatta suggests that damage to healthy tissue may result from direct impact of plasma generated by an EHL spark or laser or inadvertent puncturing by sharply pointed laser delivery fiber. Ex. 1012, 1:46–51. Bhatta comments that its nozzle 30 shapes shockwaves toward a focal point while also protecting surrounding tissue from problems associated with tip impacts and damaging effects of plasma. *Id*. at 3:22–25, 3:48–4:6. On balance, we find Patent Owner's argument that Chernenko forecloses any motivation to incorporate the EHL probes of Mantell, Uchiyama, or Willneff into Levy's angioplasty balloon unpersuasive.

ii. Petitioner's Alleged Motives to Replace Levy's Laser with an EHL Probe from Mantell, Uchiyama, or Willneff

Petitioner, through Dr. Jensen's testimony, contends that an ordinarily skilled artisan would have been motivated to substitute an EHL shockwave generator such as those described in Mantell, Uchiyama, or Willneff for Levy's laser-based shockwave generator for three reasons, including: (1) reducing complexity, (2) reducing cost and (2) generating less heat, which Levy recognized as an issue with its laser-based shockwave generator. Pet. 28 (citing Ex. 1002 ¶ 120). We analyze each reason below and conclude that Petitioner has proven by a preponderance of evidence that an ordinarily skilled artisan would have been motivated for at least two reasons

(reducing cost and complexity) to substitute an EHL shockwave generator for Levy's.

a) Complexity

Patent Owner argues that we should disregard Dr. Jensen's testimony that EHL systems are less complex than laser-based systems because he fails to cite objective evidence in support. PO Resp. 53. Patent Owner also argues, based on testimony from Dr. Berger and Dr. Jensen, that creating shockwaves using the sparks of EHL devices is "complicated" and not well understood. PO Resp. 54 (citing Ex. 2100 ¶¶ 138–139; Ex. 2156, 70:4–6, 83:13–14). Patent Owner, based on testimony from Dr. Berger, further argues that "electrical connections" of EHL systems are "more complex than the simple optical fiber technology of Levy." PO Resp. 54 (citing Ex. 2100 ¶ 140). The cited testimony from Dr. Berger fails to support the proposition for which Patent Owner cites it because it wholly fails to express any opinion about the circuitry that drives EHL or laser-based shockwave generators. Petitioner responds that the physics of spark formation are not claimed and that circuits for reliably creating sparks are well known. Reply 32 (citing Ex. 1200 ¶ 138).

Based on our review of the record, we determine that Petitioner has proven by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to substitute an EHL probe for a laser lithotripsy probe to reduce complexity.

b) Cost

Petitioner contends that using a "laser to generate shockwave energy is well known to be expensive — approximately 10 times more expensive than a system employing electrohydraulic (i.e., pair of electrodes) system to

generate shockwaves." Ex. 1002 ¶ 95. During his deposition, Dr. Jensen stated that his opinion was based upon a journal article. Ex. 2111, 61:8–17 (identifying Huang article (Ex. 2157)).

Patent Owner does not dispute that Huang concludes that laser-based lithotripsy systems are greater than ten times more expensive to use than EHL systems, but rather argues that Huang's conclusion is improperly based upon total system costs including capital and maintenance costs. PO Resp. 56. Patent Owner argues, based on Dr. Berger's testimony, that comparing cost "at a catheter level" (i.e., the cost of the catheter alone) is more appropriate. *Id*. (citing Ex. 2100 ¶ 144). Dr. Berger fails to cite evidence to support his opinion or state how much more expensive and EHL catheter would be than a laser lithotripsy catheter. Ex. 2100 ¶ 144.

By contrast, Huang explains the basis of its cost analysis to conclude that the cost per case of using EHL is $336 versus $4,220 for laser-based lithotripsy. Huang explains:

> The large discrepancy in costs can be ascribed not only to the large initial capital outlay for the Candela LaserTripter, but also to the substantial amount that must be spent yearly on maintenance and supplies. Indeed, this yearly cost of the LaserTripter is more than the capital cost of the EHL machine. In effect, a new EHL machine could be purchased each year we operate the LaserTripter.

Ex. 2157, 238.[18] Huang also includes a table summarizing the costs by category that reflects the amortized costs of the probes (i.e., "fibers") per case that reveals that laser probes are almost five times more expensive per case than EHL probes. *Id*. at 239. Based on our review of Huang, we find

[18] We cite the native page numbers reflected in Huang rather than the exhibit page number.

that the analysis fairly reflects the comparative operating cost per case for each type of system.

Patent Owner also criticizes Dr. Jensen's reliance upon Huang's analysis because the comparatively poor safety of EHL versus laser lithotripsy outweighs the cost savings. PO Resp. 57–58. Patent Owner quotes Huang, *id*. at 57, which states that "[t]he perforation rates of lasertripsy are 1% to 12%, whereas that of EHL has been shown to be as high as 17% to 25%." Ex. 2157, 237. Huang's statement describes the safety of prior versions of EHL, however, not the EHL probe that Huang analyzed, which Huang described as "similar in freedom from significant complications" to the laser lithotripsy devices that were studied. *Id*. at 238. Huang also concludes that "EHL can be used safely for distal ureteral stones and is more cost effective than lasertripsy." *Id*. at 239. Huang recognized that the EHL and laser lithotripsy "modalities have inherent advantages and disadvantages." *Id*. However, if a hospital "must choose one lithotripter," the "EHL unit with the smaller-caliber probes would be the logical choice, because this is a safe, effective, and cost effective modality." *Id*.

Based on our review of the entire record, Petitioner has proven by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to substitute an EHL probe for a laser lithotripsy probe to save cost.

c) Reduce Heat

Petitioner contends that Levy itself identifies heat generated by its laser as enough of a concern that its balloon could be cooled by circulating liquid through the balloon. Pet. 18, 29 (citing Ex. 1002 ¶¶ 96, 120); Reply 31 (citing Ex. 1003, 3–5). However, Petitioner fails to adduce

evidence that an EHL shockwave generator produces less heat than a laser-based shockwave generator such as Levy's. Accordingly, we determine that Petitioner has failed to prove by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to substitute an EHL probe for Levy's laser probe to reduce heat generated by the probe.

iii. Motive to Incorporate a AAPA Guidewire and Sealing Arrangement into Levy

As an initial matter, we address Patent Owner's argument that we may not consider AAPA during this proceeding because the AAPA is not a patent or printed publication under § 311(b). PO Resp. 64–65. We disagree.

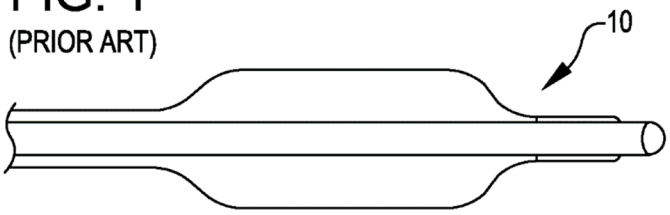
The Federal Circuit has affirmed Board decisions in *inter partes* review that claims were unpatentable based in part upon admitted prior art found in the challenged patent. *B/E Aerospace, Inc. v. C&D Zodiac, Inc*., No. 2019-1935, 2020 WL 3478651, at *5 (Fed. Cir. June 26, 2020); *Papst Licensing GMBH & Co. v. Samsung Elecs. Am., Inc.*, 924 F.3d 1243, 1255 (Fed. Cir. 2019). Additionally, the Board, and our reviewing Court, have long treated a patentee's admissions as prior art: "We see no reason why the patentee's representations in their application should not be accepted at face value as admissions that . . . may be considered 'prior art' for any purpose, including use as evidence of obviousness under 35 U.S.C. [§] 103." *In re Nomiya*, 509 F.2d 566, 570–71 (CCPA 1975). This is true, even though the admissions may not qualify as prior art under 35 U.S.C. § 102:

> [A] statement by an applicant, whether in the application or in other papers submitted during prosecution, that certain matter is "prior art" to him, is an admission that that matter is prior art for all purposes, whether or not a basis in [§] 102 can be found for its use as prior art.

Id. at 571 n.5. The AAPA upon which Petitioner relies is expressly characterized as prior art and appears in a patent. We consider the AAPA to constitute "prior art consisting of patents" as stated in 35 U.S.C. § 311(b). Accordingly, we find Patent Owner's argument unpersuasive and consider the AAPA relied upon by Petitioner.

On the merits, no dispute exists that a guidewire extending through a carrier to which an angioplasty balloon is sealed near its distal end was well known. The '371 patent labels such an arrangement "PRIOR ART" as shown in Figure 1, reproduced at right. Although the guidewire is not shown in Figure 1 or any figure illustrating the claimed invention, the Specification describes Figure 1 as illustrating "a typical prior art over-the-wire angioplasty balloon catheter 10." *Id*. at 3:66–67; *see also id*. 4:31–33 (describing guidewire not shown in Figure 2 illustration of invention).

FIG. 1
(PRIOR ART)



Petitioner relies upon Figure 1 of the '371 patent and its accompanying text as constituting AAPA. Pet. 23–25 (citing Ex. 1001, 3:65–4:2, Fig. 1; Ex. 1002 ¶ 113). Petitioner contends that a similar arrangement is also shown in other prior art, Healy (Ex. 1047). *Id*. Prior art of record confirms that the arrangement of a balloon sealed near the distal end of a carrier through which a guidewire extends was well known. Ex. 1008 ¶¶ 21–22, Figs. 1–3; Ex. 1047, Abstract, 3:17–27, Fig. 2; Ex. 1268 ("Lennox"), 4:63–5:8; Figs. 1, 3; Ex. 2110, 3:26–51, Figs. 2, 3. The prosecution history of the '371 patent confirms the same. The Examiner found that the prior art taught the claimed structural arrangement between

the balloon, carrier, and guidewire, Ex. 1013, 304 (applying Lennox), and Patent Owner did not contest the Examiner's finding, *id*. at 290–297.

Petitioner argues that it was known to an ordinarily skilled artisan to use a guidewire extending through an elongated bore to assist a physician to navigate the catheter to reach the area for treatment. Pet. 24 (citing Ex. 1002 ¶ 112). Petitioner also argues that it would have been obvious to "implement the AAPA with the angioplasty balloon described in Levy" as a "routine design choice" because the arrangement was "the most common angioplasty catheter and balloon design, with predictable and expected results." Pet. 26 (citing Ex. 1002 ¶ 115).

Patent Owner argues that Petitioner did not establish that an ordinarily skilled artisan would have been motivated to modify Levy by incorporating the guidewire extending through the carrier as described by the AAPA. PO Resp. 59–62. Patent Owner also argues that Petitioner failed to establish that an ordinarily skilled artisan would have been motivated to modify Levy to seal its balloon near the distal end of Levy's catheter as described by the AAPA. *Id*. at 62–63.

In response to both arguments, Petitioner points out that an ordinarily skilled artisan would understand Levy to be adapted for angioplasty procedures. Reply 34 (citing Ex. 1002 ¶¶ 114, 156; Ex. 1003, 5 ("[T]he balloon may have the shape of a balloon of the kind that is used with catheters used to perform treatments in [b]lood vessels."); Ex. 1200 ¶ 142). Petitioner also contends, based on testimony of Dr. Jensen, that an ordinarily skilled artisan

> looking to adapt Levy's catheter and/or balloon design to increase the types of treatments Levy could perform, would have been motivated to look to other catheters/balloons used to

> perform treatments in blood vessels, including the AAPA—i.e., the "most common angioplasty catheter and balloon design" as Dr. Jensen described in his original declaration.

Reply 34 (citing Ex. 1002 ¶¶ 115, 157). Petitioner also argues that configuring Levy according to well-known principles reflected by the AAPA "would have been a routine design choice well within the [artisan's] skill set and would have yielded predicable results." *Id*. (citing Ex. 1002 ¶¶ 115, 157; *KSR*, 550 U.S. 398 at 416).

In its Sur-reply, Patent Owner argues that Dr. Jensen's testimony is insufficient because he fails to explain how or why an ordinarily skilled artisan would have modified Levy's catheter. Sur-reply 31–32. However, we find this argument unpersuasive because the prior art and prosecution history of the '371 patent indisputably establishes that the configuration of an angioplasty catheter with a balloon sealed to the distal end of a carrier through which a guidewire extends was so well known. Ex. 1001, 3:65–4:2, Fig. 1; Ex. 1008 ¶¶ 21–22, Figs. 1–3; Ex. 1047, Abstract, 3:17–27, Fig. 2; Ex. 1268, 4:63–5:8; Figs. 1, 3; Ex. 2110, 3:26–51, Figs. 2, 3; Ex. 1013, 290–297, 304.

For all the reasons identified by Petitioner above and the testimony by Dr. Jensen, we find that Petitioner has proven by a preponderance of evidence that an ordinarily skilled artisan would have had motive to combine teachings of Levy and AAPA to arrive at the claimed configuration of the balloon sealed near the distal end of a carrier through which a guidewire extends.

e. Reasonable Expectation of Success

Petitioner contends that an ordinarily skilled artisan would have understood how to substitute an EHL shockwave generator from Mantell,

Uchiyama, or Willneff for Levy's laser-based shockwave generator because electrodes and lasers were known and interchangeable alternative mechanisms for generating shockwaves. Pet. 1–2 (citing Ex. 1012), 19–20 (citing Ex. 1012, 1:5–10, 1:15–30, Ex. 1002 ¶ 98), 28–29 (citing Ex. 1002 ¶ 120). Patent Owner contends that an ordinarily skilled artisan would not have reasonably expected to successfully substitute electrodes of Mantell, Uchiyama, or Willneff for Levy's laser for four reasons. PO Resp. 44–53. We address each reason below.

i. Whether EHL and Laser Lithotripsy Are Known Alternatives

Patent Owner argues that Dr. Jensen wrongly concludes that Levy's laser generate shockwaves in the same manner as electrodes. PO Resp. 44–45. More specifically, Patent Owner argues that Levy does not generate shockwaves at all, but merely generates "less powerful and harmful acoustic waves." *Id*. at 45 (citing Ex. 2100 ¶ 131). For the reasons expressed in Part II.F.1.c above, we disagree and find that Petitioner has proven by a preponderance of evidence that Levy, Mantell, Uchiyama, and Willneff all generate shockwaves in the same manner, by creating cavitation bubbles in the fluid whose collapse creates shockwaves.

Patent Owner also argues that Bhatta does not establish that lasers and electrodes are known interchangeable alternatives for generating shockwaves. *Id*. at 45–46. More specifically, Patent Owner contends that Bhatta refers to waves generated by lasers as "stress waves" but waves generated by electrodes as "shockwaves." *Id*. (citing Ex. 1012, 1:17–18, 2:5–11; Ex. 2100 ¶¶ 46, 55–58). Patent Owner's argument is unpersuasive because we see no meaningful distinction drawn by Bhatta between "stress waves" and "shockwaves." Bhatta expressly equates laser and electrodes as

mechanisms for breaking biliary calculi when it explains that: "Electrohydraulic lithotripsy and laser lithotripsy systems frequently are used to fragment urinary and biliary stones. Both systems utilize plasma-induced stress waves to fragment calculi." Ex. 1012, 1:16–19. Furthermore, when Bhatta describes its own electrode-based invention, it sometimes refers to the electrodes as generating "energy pulse waves," which Bhatta equates with "shockwaves." *Id*. at 2:5–11, Abstract. Patent Owner's argument that Bhatta's choice of "stress" or "shock" refers to different types of waves is simply not supported by Bhatta considered as a whole. Bhatta also expressly states that its device is suited for treating arteriosclerotic plaque. *Id*. at 1:5–9. We find that the record establishes that an ordinarily skilled artisan would have understood lasers and electrodes to be alternative forms of generating shockwaves for treating plaque in vessels.

ii. Whether an Artisan Would Have Expected Electrodes to Burst the Angioplasty Balloon

Patent Owner argues that an ordinarily skilled artisan would have expected an EHL probe placed in an angioplasty balloon to fail by bursting the balloon. PO Resp. 46–51. Patent Owner relies primarily upon testimony from Dr. Berger and his review of other evidence including declarations from other witnesses and objective evidence. *Id*. (citing Ex. 2100 ¶¶ 148–161 (citing Ex. 2033, 3[19] ("Zhong"); Ex. 2048; Ex. 2111; Ex. 2115; Ex. 2117; Ex. 2118; Fig. 5; Ex. 2119; Ex. 2170; Ex. 2173; Ex. 2174; Ex. 2175). Dr. Berger's opinion rests upon his understanding that EHL steam bubbles create "peak pressures of 50-250 ATM" (Ex. 2100 ¶ 154

[19] Our citations refer to the exhibit page number rather than Zhong's internal numbering.

citing Ex. 2033, 5, Fig. 8), which exceed typical burst pressures of angioplasty balloons of "around 25–30 ATM" (Ex. 2100 ¶ 153 (citing Ex. 2048, 2; Ex. 2111, 162:14–163:5; Ex. 2115, 4, Table 2)).

Petitioner responds that Dr. Berger's testimony is inconsistent with the teachings of the prior art that Petitioner cites as a basis for its challenge because each of Mantell, Uchiyama, and Willneff describes using an EHL probe within a balloon without bursting the balloon. Reply 27. Petitioner also notes that Willneff explains that steep pressure spikes pass through the balloon and healthy tissue to act upon target concretions. *Id*. at 28 (citing Ex. 1006, 4[20]); *see also* Ex. 1006, 7. Petitioner also points out that Dr. Berger's reliance on testimony from Drs. Soukas, Kereiakes, and Armstrong expressing skepticism that Patent Owner's device would work without bursting the balloon is flawed for three reasons. Reply 28. More specifically, Petitioner argues that: (1) Drs. Soukas, Kereiakes, and Armstrong are not proven to be ordinarily skilled artisans, (2) they did not review the '371 patent or the asserted prior art, and (3) their skepticism has not been shown to have existed at the time of invention. *Id*.

Based on our review of the entire record, Petitioner persuades us that an ordinarily skilled artisan would have had a reasonable expectation that substituting an EHL probe as taught by Mantell, Uchiyama, or Willneff for Levy's laser probe would not have burst Levy's balloon.

[20] Our citations to Willneff refer to Willneff's internal numbering rather than the exhibit page number.

iii. Whether the Proposed Combination Results in an Unacceptably Large Balloon Diameter

Patent Owner argues, based on Dr. Berger's testimony, that an ordinarily skilled artisan would have expected that adding electrical components to the interior of the AAPA angioplasty balloon would be unsuccessful because it would increase the diameter of the balloon. PO Resp. 51–52 (citing Ex. 2100 ¶¶ 121, 133, 150, 151, 171–173). We discount Dr. Berger's testimony because it is: (1) poorly supported by objective evidence (citing no evidence of the size of EHL, ultrasound, or laser-based angioplasty devices in the prior art), (2) is inconsistent with the express teachings of at least Levy (Ex. 1003, Fig. 1), O'Boyle (Ex. 2109, 3:20–21, 3:53–62), O'Connor (Ex. 2110, 3:36–57), and Bhatta (Ex. 1012, 2:52–3:11, Fig. 1), which all describe devices used to treat blood vessels that include probes inside a balloon, and (3) based upon a flawed legal premise that demonstrating obviousness requires proof that one device may be bodily incorporated into another.

Based on our review of the entire record, Petitioner persuades us that an ordinarily skilled artisan would have expected to succeed at placing an EHL probe inside a balloon without resulting in an acceptably large diameter of the balloon.

iv. Whether the Proposed Combination Would Lead to Restenosis and Embolism

Patent Owner contends, based on Dr. Berger's testimony, that an ordinarily skilled artisan would have feared that placing a shockwave generator inside an angioplasty balloon would "likely have result[ed] in embolism" and "lead to restenosis caused by thermal damage." PO Resp. 52–53 (citing Ex. 2100 ¶¶ 174–176, 206). Petitioner points out that

balloon angioplasty without a shockwave generator includes a low risk of embolism and contends that an ordinarily skilled artisan would expect a similarly low risk using a balloon with a shockwave generator. Reply 29–30 (citing Ex. 1200 ¶ 133). Petitioner also points out that a saline-filled balloon would protect the patient from thermal damage. *Id*. at 30 (citing Ex. 1200 ¶ 133).

Both Dr. Berger and Dr. Jensen appear to draw their respective conclusions without any objective evidence to support them. *See* Ex. 2100 ¶¶ 174–176, 206; Ex. 1200 ¶ 133. O'Boyle and O'Connor from the prior art also express concerns about embolism associated with balloon angioplasty. Ex. 2109, 1:32–43; Ex. 2110, 1:14–20. We also note that a risk of embolism is present even in Patent Owner's commercial device. *See* Ex. 2028, 3 (listing "Emboli (air, tissue, thrombus, or atherosclerotic emboli" and stating that "[p]ossible adverse effects are consistent with standard angioplasty"). Therefore, because embolism is a generalized concern with all balloon angioplasty, we fail to see why an ordinarily skilled artisan would have believed no reasonable chance of success existed if the prior art teachings were combined as proposed by Petitioner.

Regarding restenosis from thermal damage, Levy refers to the saline in its balloon as "coolant," which can be circulated or may be of low enough temperature or high enough heat absorption capacity to address any concern about damaging the vessel with excessive heat. Ex. 1003, 4–5. Moreover, even if we were to credit Patent Owner's proof, we do not consider the alleged concern to be of the type that would obviate Petitioner's motivations to substitute the EHL devices of Mantell, Uchiyama, or Willneff for Levy's laser probe. Our reviewing court has recognized that a given course of

action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.").

We determine that Petitioner has demonstrated that an ordinarily skilled artisan would have reasonably believed that Petitioner's proposed combination of teachings from the prior art would be successful.

f. Objective Indicia of Nonobviousness

i. Nexus

Patent Owner argues, based solely upon testimony of Dr. Berger, that it has proven that it is entitled to a presumption of nexus between the claimed invention and all objective evidence of non-obviousness because "the claims" are "essentially coextensive with the Shockwave IVL system." PO Resp. 68–69 (citing Ex. 2100 ¶ 201). Dr. Berger's cited testimony states:

> The claims are also not merely directed to a small component of a larger system; rather, they are directed to the essence of the innovation that was identified by analysts as one of the major drivers of Shockwave's success. The analysts identified Shockwave's "elegant," "easy-to-use," "unique" and "innovative" technology as one of the most important factors in Shockwave's stock performance.

Ex. 2100 ¶ 201. Dr. Berger does not link the claims to the structure of Patent Owner's commercial device in this testimony. Rather, he links the claims to "the essence of the innovation" and the "major drivers of [Patent

Owner's] success." *Id*. Dr. Berger's immediately preceding paragraph reflects his comparison of the claims to Patent Owner's commercial product. *Id*. ¶ 200. We interpret Patent Owner to have intended to cite paragraph 200 of Dr. Berger's testimony.

Petitioner appears to have interpreted Patent Owner's argument the same way. *See* Reply 36 (referring to Dr. Berger's testimony as ¶ 200 as the evidence of nexus). Petitioner contends that Dr. Berger cannot render an opinion that the claims cover Patent Owner's Shockwave IVL[21] product because he has seen only photos of the Shockwave IVL, does not know who prepared the claim chart that appears in his Declaration, and merely reviewed written materials to verify that the words and pictures appearing in the chart were present in the cited documents. *Id*.

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

[21] IVL refers to intravascular lithotripsy. Ex. 2100 ¶ 190.

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*.

Based on our review of Dr. Berger's testimony about the "claim chart" appearing in his Declaration, we find that Patent Owner fails to prove by a preponderance of evidence that "the Shockwave IVL devices include each feature recited in the claims" as Dr. Berger opines. Ex. 2100 ¶ 200. First, the claim chart does not include any claim language at all. *Id*. Rather, it merely refers to claim language using shorthand [1a]–[1e], which the parties use in their briefing. *Id*. However, Dr. Berger never explains his understanding of what that shorthand means. *See generally*, Ex. 2100.

More importantly, based on our own review of the chart, many details of the claimed invention are left unaddressed. For example, the chart fails to address expressly whether the Shockwave IVL devices include:

> a "distal end of the balloon being sealed to the carrier near the distal end,"
>
> a "proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon,"
>
> a "pair of electrodes," or
>
> the "arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon."

Compare Ex. 2100 ¶ 200 (descriptions in claim chart), *with* Ex. 1001, 6:21–39 (claim 1). We have reviewed the entirety of the evidence cited in the chart and found that none of it ever refers to "electrodes," "arc," or "plasma." The evidence adduced by Patent Owner simply fails to carry its

burden of persuasion that the claims cover its product, much less that the two are sufficiently coextensive to be entitled to a presumption of nexus. Nevertheless, for purposes of the analysis below, we will assume that Patent Owner has demonstrated that the claims cover its commercial product and some degree of nexus between its objective evidence of nonobviousness and the claimed features.

ii. Long Felt Need

Patent Owner contends that its device, Shockwave IVL, filled a long felt need for a device that could effectively treat medial calcified lesions. PO Resp. 69–75. Patent Owner supports its argument with testimony from Dr. Berger (Ex. 2100 ¶¶ 190–203) and testimony from clinicians, Drs. Kereiakes (Ex. 2174), Lyden (Ex. 2171), Hill (Ex. 2172), Soukas (Ex. 2170), and Armstrong (Ex. 2173), and statements appearing in documents distributed by financial analysts at Wells Fargo (Exs. 2003, 2004, 2016, 2017). PO Resp. 69–75. Dr. Berger relies on many of the same items of evidence but also considers journal articles. We analyze each type of evidence below.

a) Clinicians' Testimony

Dr. Kereiakes explains that medial plaque occurs within the walls of arteries and can "cause narrowing of the lumen of the artery" and opines that "there has been no known way to treat a medial calcified lesion." Ex. 2174 ¶ 9. Dr. Lyden testifies that "medial calcified lesions" prevented angioplasty balloons from expanding a vessel sufficiently to enable the placement of a stent to hold the vessel open. Ex. 2171 ¶ 15. Dr. Hill testifies that "the community struggled to achieve full lesion expansion that would allow the lumen of the artery to be expanded to the desired diameter" often because of

"medial calcified lesions." Ex. 2172 ¶ 7. Dr. Soukas testifies that "Shockwave IVL was the first, and remains the only, effective treatment for medial calcified lesions. . . . [N]either atherectomy nor an angioplasty balloon are effective at breaking up medial plaque." Ex. 2170 ¶ 15.

We note that none of the Patent Owner's clinicians support any of their testimony about the benefits of Shockwave IVL over competitive devices with citations to objective evidence. *See* Exs. 2170–2174 (citing no outside evidence objective or otherwise). We consider this fact to slightly reduce the weight of the testimony from these clinicians, but we also recognize them as having firsthand knowledge of outcomes in certain cases involving the use of Patent Owner's Shockwave IVL device. Those experiences, however, are merely ad hoc examples of success that we do not consider to definitively prove that the Shockwave IVL is the first and only way to treat occluded vessels that also exhibit medial calcification. Accordingly, we consider the testimony from clinicians to be of modest, but meaningful, probative value on whether IVL is more effective than pre-existing options for treating calcified plaque that includes plaque within the medial tissues of arteries.

Petitioner argues that no "unmet need to effectively treat medial calcified lesions" exists because medial calcium rarely obstructs blood vessels and rarely causes symptoms that require medical treatment. Reply 37. Petitioner supports its argument with deposition testimony of Drs. Soukas, Hill, and Kereiakes (clinicians proffered by Patent Owner) and declarations from Drs. Chambers and Finn (clinicians proffered by Petitioner). *Id*. at 37–38 (citing Ex. 1212, 34:8–14, 37:24–39:5; Ex. 1211, 86:19–87:19, Ex. 1213, 38:12–23; Ex. 1350 ¶¶ 8–9; Ex. 1362 ¶¶ 9–15). We

find that this cited testimony establishes that all five clinicians agree that the presence of medial calcium alone does not call for treatment by cardiovascular intervention. We have carefully reviewed Petitioner's cited evidence and find it persuasive on this point.

Patent Owner attempts to rebut Petitioner's cited evidence by citing deposition testimony from Dr. Finn for the proposition that he defined "medial calcification" as a condition not associated with atherosclerotic plaque that obstructs blood vessels. Sur-reply 41 (citing Ex. 2253, 25:13–25, 26:5–29:16). Based on our review of this cited testimony from Dr. Finn, we find that it fails to support Patent Owner's position. Rather, the testimony reveals that Dr. Finn uniformly distinguishes "medial calcification" from atherosclerotic plaque, which occurs in the intimal layer of a vessel and is a different form of calcification. Ex. 2253, 25:13–25, 26:5–16. The objective evidence about which Patent Owner questioned Dr. Finn, which relates to the progression of calcification in arteries, similarly distinguishes between medial calcification and atherosclerotic plaque. *See, e.g.*, Ex. 2247 ("atherosclerotic intimal calcification is different from medial Monckeberg calcification, and the latter occurs independently from intimal calcification").

Patent Owner also argues that Dr. Chambers uses "medial calcification" to refer to "deep atherosclerotic plaque that occludes the vessel and requires treatment by angioplasty or otherwise." Sur-reply 41–42 (citing Ex. 2251, 39:2–19, 40:2–4, 132:6–11). However, we find that Dr. Chambers' cited testimony merely confirms his originally stated view that "medial calcium" alone does not require treatment unless calcium is also present in the intima. Ex. 2251, 39:2–40:22. Petitioner contends, based

upon Dr. Chambers' testimony, that orbital atherectomy was a successful method of treating heavily calcified plaque that included medial plaque. Reply 38 (citing Ex. 1350 ¶ 9–21). Dr. Chambers' testimony is supported by citations to objective evidence. Ex. 1350 ¶¶ 16–19 (citing Exs. 1351–1353). His testimony is also consistent with the conclusions about the efficacy of rotational atherectomy reflected in the Dill paper discussed in Part II.F.1.f.ii.b) below, which we consider to be highly probative evidence on this point.

b) Articles Cited by Dr. Berger

Dr. Berger relies, in part, upon reports from financial analysts and three journal articles for his opinion that Shockwave IVL was more effective at treating vessels that included medial calcified lesions than either traditional balloon angioplasty or rotational atherectomy. Ex. 2100 ¶¶ 193–196 (citing Ex. 2126;[22] Ex. 2127; Ex. 2128). Exhibit 2126 ("Dill") is a paper reporting results of a randomized study of about 500 total patients on the comparative efficacy of using either a rotational atherectomy device or traditional angioplasty balloons for treating "complex, calcified, and long lesions" in small coronary arteries. Ex. 2126, 1. Dill concludes that both treatment methods were relatively successful in treating the "difficult morphologies" of the studied complex lesions with success rates of 78% (angioplasty) and 85% (atherectomy). *Id*. at 6–7. Dill concluded that rotational atherectomy may be required to treat lesions "resistant to high balloon pressures." *Id*. at 7.

[22] Dr. Berger erroneously cites Exhibit 2136, but context makes clear that he intended to cite Exhibit 2126. Ex. 2100 ¶ 194.

We view Dill to be among the most probative evidence on the issue of whether rotational atherectomy was effective for treating complex calcified lesions in coronary arteries. Dill establishes that rotational atherectomy was more effective than traditional angioplasty balloons for such lesions and undermines Patent Owner's contention that Shockwave IVL was the only treatment available for such lesions.

Exhibits 2127 and 2128 ("CAD I" and "CAD II" respectively, and collectively, the "CAD Studies") reflect results of tests focusing solely upon whether the Shockwave IVL device is safe and effective at treating "heavily calcified atherosclerotic plaques," Ex. 2127, 1, or "severe CAC [coronary artery calcification]," Ex. 2128, 2. CAD I involved treatment of 60 patients. Ex. 2127, 2. CAD II involved treatment of 120 patients. Ex. 2128, 4. The CAD Studies conclude that Shockwave IVL was "a feasible frontline tool for CAC plaque modification." Ex. 2128, 6. The CAD II study indicates that using Shockwave IVL resulted in "intraplaque calcium fracture, thereby modifying vascular compliance and facilitating stent expansion." *Id*. The success rates of IVL determined in CAD I and CAD II were 95% and 94.2% respectively with very few side effects noted during each 30-day study period. Ex. 2127, 2; Ex. 2128, 5, Table 4. Neither of the CAD Studies presented detailed information of the precise radial depth of calcification within the tissues of the arteries that were treated (i.e., whether the calcification was in the intimal or medial tissues), but CAD II indicated that maximum calcium fracture depth of 0.6±0.3 mm and maximum calcium thickness at fracture site of 0.8±0.3 mm was observed in the 37 patients for whom such data was gathered. Ex. 2128, 7, Table 7.

We similarly view the CAD Studies as objective and reliable evidence of the potential efficacy of using IVL to treat severe coronary artery calcification. However, one limitation that we note is that neither of the CAD Studies reflect whether IVL had detrimental side effects after the 30-day study period.

Petitioner contends, based on testimony by Dr. Chambers, that IVL has been shown to have a primary patency rate (i.e., the rate at which a treated vessel remains open) that is lower than that expected for balloon angioplasty and drug eluting angioplasty. Reply 39 (citing Ex. 1350 ¶¶ 25–26). Dr. Chambers relies upon articles that reported 12-month patency rates for patients treated with IVL in peripheral arteries (in the "PAD II" trial) was 54% while patients in a different study that were treated with balloon angioplasty or drug eluting balloons exhibited patency rates of 75% and 94.7% respectively. Ex. 1350 ¶¶ 25–26 (Ex. 1355; Ex. 1356). We consider Dr. Berger's testimony on this point to be credible.

c) Statements by Financial Analysts

Patent Owner and Dr. Berger rely upon unsupported statements in documents written by unidentified employees of various financial advisers describing the Shockwave IVL was more effective than "[a]therectomy and other plaque modification devices" at treating medial calcium. *See, e.g.*, Ex. 2100 ¶ 193 (quoting Ex. 2006, 17).

We discount the probative weight of all the statements from financial analysts as being from authors who have not been established to either have relevant medical or scientific training or may have biases based on financial interest. For example, Wells Fargo warns readers of its "analysis" of Patent Owner's stock that: "investors should be aware that the firm may have a

conflict of interest that could affect the objectivity of the report and investors should consider this report as only a single factor in making their investment decision." Ex. 2006, 1. Wells Fargo also refers readers of the report to "page 31 for . . . important disclosures" that reflect five different ways in which Wells Fargo has financial interests in or received compensation from Patent Owner in the past or going into the future. *Id*. at 1, 31–32. The probative weight of such evidence is not increased merely by having Dr. Berger read it and recount the conclusions drawn by such analysts. Accordingly, we ascribe little weight to statements by the financial analysts or Dr. Berger's testimony that relies upon such statements.

d) FDA Breakthrough Designation

Patent Owner argues, based on testimony from Dr. Berger, that the designation of the Shockwave IVL as a "breakthrough device" by the FDA establishes that its device treats a condition for which "no approved or cleared alternatives exist." PO Resp. 73–74 (citing Ex. 2100 ¶¶ 197–199). The documents upon which Dr. Berger bases his testimony are the letter from the FDA informing Patent Owner of its designation (Ex. 2124) and "Guidance for Industry" from the FDA on the "Breakthrough Devices Program" (Ex. 2125). Ex. 2100 ¶¶ 197–199 (citing Ex. 2124; Ex. 2125).

A "breakthrough device" designation as defined in section 515B(b) of the FD&C Act refers to devices:

> (1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and
>
> (2)(A) that represent breakthrough technologies;
>
> (B) for which no approved or cleared alternatives exist;

> (C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
>
> (D) the availability of which is in the best interest of patients.

Ex. 2125, 8.

FDA guidance explains that a breakthrough designation may be granted for devices that meet the requirement of section (1) and *one* of the four subparagraphs listed in section (2) (i.e., one of (2)(A)–(D)). Meeting section (1) requirement can occur when the manufacturer shows "a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use." *Id*. at 9. This showing may be made based upon "literature or preliminary data." *Id*.

Without further explanation or identifying specific evidence, Dr. Berger concludes that "[b]ased on the evidence discussed above, I believe that the Shockwave IVL meets each of the criteria 2(A) through 2(D)." Ex. 2100 ¶ 199. Petitioner correctly notes that Patent Owner has submitted no evidence revealing the content of its request for a breakthrough designation or any correspondence with the FDA relating to its application for the designation other than the FDA's letter granting the breakthrough designation. Reply 40. Petitioner also contends that the FDA grants breakthrough designations about 71% of the time. *Id*.

Based on FDA guidance discussed immediately above, we conclude that Patent Owner could have obtained the designation by merely

demonstrating a "reasonable expectation" based on "literature or preliminary data" that the Shockwave IVL is more effective at treating a life threatening or debilitating condition. We discern no reliable basis for Dr. Berger to have concluded that the Shockwave IVL met all four of the section (2) criteria for devices that are "breakthrough devices" because none of the items upon which Dr. Berger relies reflects personal knowledge of underlying facts needed to draw such a conclusion. Accordingly, we ascribe little probative weight to the FDA's "breakthrough device" designation because: (i) Patent Owner failed to supply evidence of the precise basis for its request for designation or the FDA's precise basis for granting it, (ii) manufacturers need only demonstrate a "reasonable expectation" of meeting the criterion of section (1) based on "literature or preliminary data," and (iii) about 71% of those seeking the designation get it.

e) Evidence First Introduced with the Sur-Reply

Patent Owner presents Exhibit 2131 ("Kassimis") for the first time with its Sur-reply. Sur-reply 42 (citing Ex. 2131). Patent Owner argues that Kassimis reports a head-to-head comparison of orbital atherectomy and IVL treatments and concludes that IVL is superior based on the following quote:

> Moreover, ***shock-wave pulses affect calcium sheets located within the target field regardless of their depth in the vessel wall, which contrasts with inefficacy of PTRA or OA [rotational or orbital atherectomy] to modify deep-seated calcium***. . .
>
> IVL is unique among all technologies in its ability to modify calcium circumferentially and transmurally thus, modifying transmural conduit compliance. [. . .] ***We believe that IVL balloon is going to transform the market***, as it is easy to use, with predictable results and in most centers will replace cutting and scoring balloons for the treatment of calcific disease.

Id. (quoting and emphasizing text of Ex. 2131, 11).

This passage speaks glowingly about IVL, but the statement is prospective and not definitive, which is apparent from the following section of Kassimis, labeled "Conclusion," which reads:

> The optimal therapy for calcified CAD [coronary artery disease] is multi-adjunctive and *several strategies should always be available in the catheter laboratory* (Fig. 10). The outcome is less favourable compared to non-calcified lesions, but with increased understanding of calcification, more sophisticated, individualized treatment regiments will likely evolve to make optimal use of the variety of dedicated technologies and success. The advent of the IVL balloon *may* revolutionise this indication *but* cost-effectiveess of these advanced technologies will need to be considered.

Ex. 2131, 11 (emphasis added). The "several strategies" of "Fig. 10" includes orbital atherectomy. *Id*. at 10, Fig. 10. Thus, Kassimis recognizes that IVL is not yet proven to be a superior treatment for calcified coronary artery disease, but is likely to be an important option added to existing options for treating the entire population of potential patients. On balance, Kassimis supports Patent Owner's argument that IVL has promise to be an improved mode of treating certain types of coronary artery disease.

f) Conclusion

Based on our analysis of the evidence adduced by both parties, we conclude that Patent Owner has demonstrated that IVL is a promising treatment for stenoses in arteries with complex coronary artery calcification. However, Petitioner has also established that previous methods for treating the same type of stenoses, e.g., rotational and orbital atherectomy, remain viable treatment options that may have advantages in certain circumstances. We also conclude that the medical community at large has recognized that

severe calcification of arteries makes successful short and long term treatment more difficult to attain. We also find that neither party has provided conclusive evidence of what, if any, long term detrimental side effects result from treatment with IVL, but Petitioner has submitted credible evidence that IVL does or is likely to lead to long term side effects. Accordingly, whether IVL is more meaningfully effective than prior methods of treating arteries with complex coronary artery calcification remains an open question.

iii. Failure of Others

Patent Owner's argument that all other treatments for coronary artery disease accompanied by complex calcification have failed is based upon the same testimony that we have reviewed in detail in Part II.F.1.f.ii above. PO Resp. 74–79. We are not persuaded by Patent Owner's evidence because Petitioner has adduced persuasive evidence that prior treatments have been used with an acceptable level of success. The evidence supporting our conclusion is also described and analyzed in Part II.F.1.f.ii above. Although IVL may show signs of being able to treat certain types of coronary artery disease in a measurably more effective manner than prior techniques, Patent Owner does not persuade us that those prior techniques are failures.

iv. Skepticism

The parties' arguments and evidence relating to skepticism closely follow their argument and evidence on the issue of whether an ordinarily skilled artisan would not have had a reasonable expectation of succeeding in substituting an EHL probe for Levy's laser probe because of risks of the balloon bursting and embolism. *Compare* PO Resp. 79–82 (citing Ex. 2100 ¶¶ 205–212; Ex. 2170; Ex. 2171; Ex. 2173; Ex. 2174), *with* PO Resp. 46–51

(citing Ex. 2100 ¶¶ 148–161 (citing Ex. 2170; Ex. 2173; Ex. 2174; Ex. 2175)). For the reasons expressed in Part II.F.1.e above, we found that an ordinarily skilled artisan would have had a reasonable expectation of successfully making a working device according to claim 1 that would not burst or result in unwarranted risks of embolism. Accordingly, we find that Patent Owner's evidence of skepticism is a weak indicator of non-obviousness.

v. Industry Praise

Patent Owner argues "first and foremost" that the FDA's designation of Shockwave IVL as a "breakthrough device" is "significant praise" from those in the industry. We have explained in detail why we do not consider the evidence adduced by Patent Owner to establish that the FDA's designation proves that Shockwave IVL was a breakthrough, or praiseworthy as a more effective treatment than existing options. *See* Part II.F.1.f.ii.d) above. For those same reasons, we do not consider the FDA's designation to demonstrate praise by the industry.

Patent Owner also relies upon testimony from the clinicians, Drs. Kereiakes, Hill, and Lyden. PO Resp. 83 (citing Ex. 2171 ¶ 12; Ex. 2172 ¶ 10; Ex. 2174 ¶¶ 10, 16). This testimony reflects unsubstantiated speculation about better efficacy, which has yet to be supported by objective evidence. *See* Part II.F.1.f.ii above. We do not, however, entirely discount what appears to be genuine excitement by clinicians about IVL.

We cannot draw the same conclusion regarding Patent Owner's evidence of "praise," introduced by Dr. Berger, because it merely recounts unsubstantiated and often forward-looking statements from financial analysts or hopeful statements from the Kassimis article. PO Resp. 83–84

(citing Ex. 2100 ¶¶ 216–223 (citing Ex. 2131; Ex. 2132; Ex. 2133, Ex. 2135; Ex. 2139)). We have explained why we consider statements of financial analysts to be of little probative value and the weight we accord the cited portion of Kassimis article, which does not reflect the conclusion drawn in Kassimis above. *See* Parts II.F.1.f.ii.c) and II.F.1.f.ii.e).

For all these reasons, we ascribe some, but not great, weight to Patent Owner's evidence of industry praise.

vi. Commercial Success

Patent Owner contends that its Shockwave IVL devices, Patent Owner's only commercial products, are commercially successful because 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." PO Resp. 85–86 (citing Ex. 2100 ¶¶ 224–225; Ex. 2175 ¶ 8; Ex. 2164).

Petitioner responds that Patent Owner's evidence fails to establish commercial success because it fails to reflect the market share achieved by Patent Owner's devices. Reply 44. Patent Owner does not cure this deficiency in its evidentiary showing despite having an opportunity to do so. *See* Sur-reply 38–39 (arguing that it need not provide evidence of market share).

Petitioner also points out that, based on testimony from Mr. Stephens and Patent Owner's 10-Q, Patent Owner increased its spending on its sales and marketing forces by 59% from 2018 to 2019, which at least partially accounts for the increase in revenue that Patent Owner alleges. Reply 45

(citing Ex. 1216, 30:20–37:7; Ex. 2141, 4, 20–23). Patent Owner does not contest that the increase of 59% in sales and marketing expenses did not occur, but rather argues that its expenditures were "relatively low" and not a "primary driver of the device's success." Sur-reply 40 (citing Ex. 2252, 256:11–259:3). We are persuaded that Patent Owner's increased spending on sales and marketing at least partially explains the increase in its revenues.

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. Berger and Mr. Stephens. PO Resp. 85–86 (citing Ex. 2100 ¶ 225; 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 ¶ 225 (citing Ex. 2176); 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.

Patent Owner also contends, based on testimony of Drs. Berger and Armstrong, that its success is more noteworthy because doctors have "a strong financial disincentive" to use Shockwave IVL devices. PO Resp. 86 (citing Ex. 2100 ¶ 227; Ex. 2173 ¶ 29). First, Dr. Berger's testimony simply quotes and relies upon the cited testimony of Dr. Armstrong; so, ultimately, Dr. Armstrong's testimony is the only evidence that might be probative. Ex. 2100 ¶ 227 (citing Ex. 2173 ¶¶ 28–29). Dr. Armstrong cites no evidence underlying his testimony, which limits its probative value. Second, even if we were to accept Dr. Armstrong's testimony as true, his cited testimony provides no evidence of market share or the quantitative effect of the "disincentive" that he describes. Ex. 2173 ¶¶ 28–29. However, he does testify that he has performed over 2,000 vascular interventions and about 300 such procedures per year with 200 being atherectomy procedures, but he has only performed "over 100" IVL procedures. *Id*. ¶ 5. This testimony implies that he uses directly competing atherectomy devices far more often than Shockwave IVL devices. *Id*. In any event, this testimony does not establish that doctors perform IVL procedures at an abnormally high rate despite financial disincentives.

Even if we were to conclude that Patent Owner's increases in revenue are tied to the claimed features, we find Patent Owner's showing of commercial success to be weak.

g. Weighing of Evidence of Obviousness and Conclusion

We conclude that Petitioner has proven that Guy Levy, a dentist, described a laser-based shockwave generator in an angioplasty balloon to

treat atheromas in blood vessels before Patent Owner conceived its claimed invention. We also conclude that Petitioner has persuasively proven that an ordinarily skilled artisan would have been motivated to modifying Levy's device by substituting a known EHL shockwave generator for the laser and adapting Levy's balloon and carrier to use a well-known configuration of a guidewire to place the balloon. We consider Petitioner's showing of obviousness to be rather straightforward and well supported.

Patent Owner's objective evidence of non-obviousness is voluminous, but largely weak for all the reasons that we express above even crediting Patent Owner for having established some nexus. Ultimately, we find that excitement about the *potential* efficacy of the Shockwave IVL or its *potential* commercial success simply does not warrant a conclusion that claim 1 remains patentable. 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 Levy, AAPA, and any one of Mantell, Uchiyama, or Willneff render claim 1 unpatentable as obvious.

2. Dependent Claims 2–14

Petitioner contends that the limitations introduced in each of dependent claims 2–6, 11, and 14, all of which ultimately depend from claim 1, are described by one or more of Mantell, Uchiyama, or Willneff or are simply well known by an ordinarily skilled artisan. Pet. 31–39. Except for dependent claim 5, Patent Owner does not distinguish the limitations introduced in these dependent claims from the teachings of the prior art or knowledge of an ordinarily skilled artisan that Petitioner identifies. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15). For the

reasons expressed below, we conclude that Petitioner has proven by a preponderance of evidence that dependent claims 2–4 and 6–14 are unpatentable as obvious, but has failed to do so for claim 5.

a. Claim 2

Claim 2 depends from claim 1 and further recites: "wherein the pair of electrodes includes a pair of metallic electrodes." Ex. 1001, 6:40–41. Petitioner argues that Mantell describes that the electrodes of its probe may be metallic. Pet. 31 (citing Ex. 1004 ¶ 23). Petitioner also contends, based on testimony by Dr. Jensen, that an ordinarily skilled artisan would have considered electrodes made of metallic material to have been an obvious design choice because electrodes must be conductive. *Id*. (citing Ex. 1002 ¶ 126). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and Mantell or the background knowledge of an ordinarily skilled artisan render claim 2 unpatentable as obvious.

b. Claim 3

Claim 3 depends from claim 2 and further recites: "wherein the electrodes are radially displaced from each other." Ex. 1001, 6:42–43. Petitioner argues that Mantell describes electrodes that are radially displaced from each other. Pet. 31–32 (citing Ex. 1004, Figs. 2, 7; Ex. 1002 ¶ 128). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and Mantell render claim 3 unpatentable as obvious.

c. Claim 4

Claim 4 depends from claim 2 and further recites: "wherein the electrodes are longitudinally displaced from each other." Ex. 1001, 6:44–45. Petitioner argues that Willneff describes electrodes that are longitudinally displaced from each other. Pet. 31–32 (citing Ex. 1006, Fig. 1 (spark gap 16 between two longitudinally displaced electrodes); Ex. 1002 ¶ 130). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, Mantell or the background knowledge of an ordinarily skilled artisan, and Willneff render claim 4 unpatentable as obvious.

d. Claim 5

Claim 5 depends from claim 2 and further recites: "wherein the pair of electrodes is disposed adjacent to and outside of the guide wire lumen." Ex. 1001, 6:46–47. Petitioner argues that Uchiyama describes "a shockwave generator including a pair of electrodes (3) that are disposed radially spaced away from the lumen of tube (8)." Pet. 32 (citing Ex. 1005, Figs. 1, 3, 4, 6, 7; Ex. 1002 ¶ 132). Petitioner also contends, based on testimony by Dr. Jensen, that an ordinarily skilled artisan would have found it obvious to

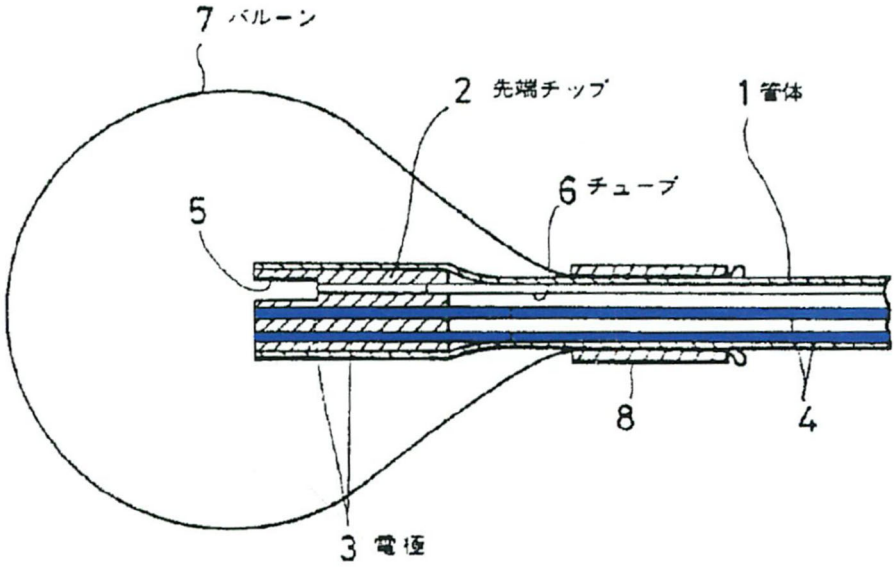
implement the routine design choice of configuring electrodes as described by Uchiyama. *Id*. at 33 (citing Ex. 1002 ¶ 133).

Patent Owner argues, based upon testimony by Dr. Berger, that an ordinarily skilled artisan would not have radially spaced electrodes from the longitudinal center of an EHL probe because doing so would unacceptably increase the risk of damaging healthy tissue by placing the electrodes too close to such tissue. PO Resp. 65 (citing Ex. 2100 ¶¶ 33–60, 169, 170, 178).

Petitioner responds that Uchiyama expressly describes that electrodes need not be radially centered within its balloon but could be spaced from the longitudinal center of the balloon. Reply 35 (citing Ex. 1200 ¶ 144). Petitioner also contends that an ordinarily skilled artisan would have understood from Uchiyama that placing the electrodes radially off-center would permit shockwaves to attain greater lateral coverage to reach calcifications that are not uniformly distributed around the circumference of a vessel. *Id*. (citing Ex. 1200 ¶ 144 (cross-referencing *id*. ¶¶ 32–34); Ex. 1204, 175:19–177:3). Petitioner also argues that an ordinarily skilled artisan would not have been dissuaded from placing the electrodes off center as shown in Uchiyama because Uchiyama teaches that placing the electrodes within a balloon would avoid undesirable tissue damage. *Id*. (citing Ex. 1200 ¶ 144 (cross-referencing *id*. ¶¶ 32–34)).

In its Sur-reply, Patent Owner argues that Dr. Jensen testifies that Uchiyama's electrodes are not disposed radially away from the lumen of tube 8. Sur-reply 36 (citing Ex. 2249, 38:4–40:15). Patent Owner also points out that Uchiyama's tube 8 is not a guidewire lumen as recited in the claim.

Based on our review of Uchiyama, we agree with Patent Owner that Uchiyama fails to describe "the pair of electrodes is disposed adjacent to and outside of the guide wire lumen" as recited in claim 5. The position of Uchiyama's pair of electrodes 3 is illustrated in the version of Figure 1 about which Dr. Jensen testified, which we reproduce below. Ex. 2240.



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Uchiyama's Figure 1 is a cross-sectional view of Uchiyama's lithotripter with the balloon 7 inflated. Ex. 1005, 299.

Electrodes 3 (blue) are shown offset downward from the longitudinal center of the device as it is shown in the figure. Ex. 2240. Uchiyama states: "The electrodes3 are electrically connected with a pair of electric cables4 inserted into the tube1 above." Ex. 1005, 298. Uchiyama also describes fluid channel 6 through which fluid is injected to inflate balloon 7 or removed to deflate balloon 7. *Id*. Regarding "tube (8)," which Petitioner identifies as corresponding to the claimed lumen through the carrier, Uchiyama states: "The duct end of the balloon7 is air-tightly fixed by a removable stopper ring8 attached on the putter [sic, outer] circumference of

the tip part of the tube1." *Id*. Thus, "tube (8)" is not a lumen for a guidewire or even a lumen in a "carrier." Rather, stopper ring 8 is the device for holding balloon 7 to tube 1. *Id*. In addition, Petitioner has not established that electrodes 3 are disposed both adjacent to and radially "outside" stopper ring 8, as Uchiyama describes them as connected to electric cables 4 radially inside both tube 1 and stopper ring 8. *Id.*; Pet. 32 (arguing that electrodes 3 are radially spaced away from stopper ring 8).

Based on our review of Uchiyama, we find that Petitioner has failed to prove that Uchiyama describes a pair of electrodes that are both "adjacent to and outside of the guidewire lumen" as required in claim 5. Petitioner identifies no other prior art that meets these limitations. Accordingly, we conclude that Petitioner has failed to demonstrate by a preponderance of evidence that claim 5 is unpatentable as obvious in view of the combined teachings of Levy, AAPA, Mantell, and Uchiyama or the combined teachings of Levy, AAPA, Uchiyama, and the background knowledge of an ordinarily skilled artisan.

e. Claim 6

Claim 6 depends from claim 2 and further recites: "wherein the catheter has a distal end and wherein the pair of electrodes is disposed proximal to the distal end of the catheter." Ex. 1001, 6:48–50. Petitioner argues that Willneff describes electrodes that are disposed proximal to the distal end of the catheter. Pet. 33 (citing Ex. 1006,[23] Fig. 1 (spark gap 16 formed between two electrodes disposed proximal to distal end of

[23] Petitioner mistakenly cites Ex. 1005 as is made clear by the context (spark gap 16) and as is consistent with the cited testimony from Dr. Jensen. *See* Ex. 1002 ¶ 135 (correctly citing Ex. 1006, Fig. 1).

catheter 22); Ex. 1002 ¶ 135). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, Mantell or the background knowledge of an ordinarily skilled artisan, and in further view of Willneff render claim 6 unpatentable as obvious.

f. Claim 7

Claim 7 depends from claim 1 and further recites: "wherein the balloon is formed of non-compliant material." Ex. 1001, 6:51–52. Petitioner correctly notes that the '371 patent acknowledges that prior art angioplasty balloons are typically made of non-compliant material to fix the maximum dimension of the balloon. Pet. 34 (citing Ex. 1001, 3:65–4:2). Petitioner argues that Hayes describes non-compliant angioplasty balloons. *Id*. (citing Ex. 1007, 1:5–10). Based on Dr. Jensen's testimony, Petitioner argues that an ordinarily skilled artisan would readily recognize that Levy as modified by AAPA includes a non-compliant balloon and that using a non-compliant balloon would have been easily implemented. *Id*. (citing Ex. 1002 ¶ 137). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and one of Mantell, Uchiyama, or Willneff and in further view of Hayes, render claim 7 unpatentable as obvious.

g. Claim 8

Claim 8 depends from claim 1 and further recites: "wherein the balloon is formed of compliant material." Ex. 1001, 6:53–54. Petitioner argues that compliant angioplasty balloons were well known as evidenced by Duchamp. Pet. 34–35 (citing Ex. 1008 ¶ 40; Ex. 1002 ¶ 138). Based on Dr. Jensen's testimony, Petitioner argues that an ordinarily skilled artisan would readily recognize that a compliant balloon could be readily and successfully substituted for the angioplasty balloon of Levy as modified by AAPA. *Id*. at 35 (citing Ex. 1008 ¶ 40). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and one of Mantell, Uchiyama, or Willneff and in further view of Duchamp, render claim 8 unpatentable as obvious.

h. Claim 9

Claim 9 depends from claim 1 and further recites: "wherein the balloon has a surface, and wherein the catheter further comprises at least one stress riser carried on the surface of the balloon." Ex. 1001, 6:55–57. Petitioner argues that angioplasty balloons with stress risers were well known as evidenced by Naimark in the form of micro-needles 21, 31 on the surface of its balloon. Pet. 35–36 (citing Ex. 1009,[24] Abstract, Figs. 2, 3 (illustrating micro-needles 21, 31); Ex. 1002 ¶ 140). Based on Dr. Jensen's

[24] Petitioner mistakenly cites Ex. 1008 as is made clear by the context (microneedles 21, 31). Ex. 1009, Abstract, 4:21–31, 5:18–20, Figs. 2, 3.

testimony, Petitioner argues that an ordinarily skilled artisan would readily recognize that a balloon with stress risers could be readily and successfully substituted for the angioplasty balloon of Levy as modified by AAPA. *Id*. at 35 (citing Ex. 1008 ¶ 40). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and one of Mantell, Uchiyama, or Willneff and in further view of Naimark, render claim 9 unpatentable as obvious.

i. Claim 10

Claim 10 depends from claim 1 and further recites: "further comprising a sensor that senses reflected energy." Ex. 1001, 6:58–59. Petitioner argues that sensors used with shockwaves created within a fluid-filled balloon were well known as evidenced by Beyar. Pet. 36 (citing Ex. 1010, ¶¶ 192, 243; Ex. 1002 ¶ 142). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and one of Mantell, Uchiyama, or Willneff and in further view of Beyar, render claim 10 unpatentable as obvious.

j. Claim 11

Claim 11 depends from claim 1 and further recites: "further comprising a reflector within the balloon that focuses the shock waves." Ex. 1001, 6:60–61. Petitioner argues that Willneff describes a wall 34 that reflects and focuses its shockwave. Pet. 37 (citing Ex. 1006, 10, Fig. 2 (pressure waves reflected by wall 34 toward focal point 36); Ex. 1002 ¶ 144). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, Mantell, Uchiyama, or Willneff render claim 11 unpatentable as obvious.

k. Claim 12

Claim 12 depends from claim 1 and further recites: "wherein the balloon electrically insulates the pair of electrodes from tissue external to the catheter." Ex. 1001, 6:62–64. Petitioner argues that balloon material was well known to generally be non-conductive and insulating to the electrodes within them. Pet. 37 (citing Ex. 1002 ¶ 146). For example, Uchiyama teaches that its balloon regulates the force emanating from its spark generator and prevents its spark from directly hitting human tissue. *Id*. (citing Ex. 1005, 298). Additionally, Duchamp and Hayes both describe non-conductive materials used to insulate the pair of electrodes from tissue. *Id*. at 38 (citing Exs. 1007, 1008; Ex. 1002 ¶ 146). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and one of Mantell, Uchiyama, or Willneff and in further view of Duchamp or Hayes render claim 12 unpatentable as obvious.

l. Claim 13

Claim 13 depends from claim 1 and further recites:

> wherein the pair of electrodes includes a first electrode and a second electrode, the second electrode being arranged to form an electrical arc with the first electrode to generate the mechanical shock wave and to generator including a pair of electrodes being positioned reflect the mechanical shock wave in a desired pattern.

Ex. 1001, 6:65–7:2. Petitioner argues that Bhatta describes a shockwave generator with a pair of electrodes in which one of the electrodes is a metallic nozzle that also reflects the shockwave in a desired pattern. Pet. 38 (citing Ex. 1012, 3:17–25). Based on Dr. Jensen's testimony, Petitioner argues that an ordinarily skilled artisan would have found it obvious to have modified Levy in view of Mantell to include Bhatta's nozzle-shaped electrode to focus the shockwave being generated. *Id*. at 38–39 (citing Ex. 1002 ¶ 148). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and one of Mantell, Uchiyama, or Willneff and in further view of Bhatta render claim 13 unpatentable as obvious.

m. Claim 14

Claim 14 depends from claim 1 and further recites: "wherein the balloon has a center axis and the guidewire lumen has a center axis in common with the balloon center axis; and wherein at least one electrode of the electrode pair is disposed in non-intersecting relation with respect to the balloon center axis." Ex. 1001, 7:3–8. Petitioner argues that "Uchiyama discloses a balloon with a center of axis that is collinear with the guidewire lumen." Pet. 39 (cross-referencing argument relating to claim 5). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

As explained in Part II.F.2.d above, we find that Uchiyama fails to describe a pair of electrodes that are outside of a guidewire lumen. However, Uchiyama does illustrate a pair of electrodes in which one of the electrodes is located off the center longitudinal axis of its balloon. Additionally, the AAPA that forms part of Petitioner's challenge to claim 1 describes a guidewire lumen that shares a common central longitudinal axis with the balloon. Ex. 1001, 3:65–4:2, Fig. 1.

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 Levy, AAPA, and one of Mantell or Willneff along with Uchiyama or the combined teachings of Levy, AAPA, and Uchiyama render claim 14 unpatentable as obvious.

3. Independent Claim 15

Independent claim 15 is directed to a system comprising an angioplasty catheter that is materially the same as the catheter of claim 1 and a "power source configured to provide a high voltage pulse to the arc

generator" that is not recited in claim 1. *Compare* Ex. 1001, 7:9–8:9, *with id*. at 6:21–39. Petitioner contends, and we agree, that all the arguments directed to claim 1 apply to claim 15. Pet. 40. With respect to the "power source," Petitioner argues that each of Levy, Mantell, Uchiyama, and Willneff describe a power source that is configured to provide a high voltage pulse to their respective arc generators. *Id*. at 40–41 (citing Ex. 1003, 4, Fig. 1 (laser light source 20); Ex. 1004 ¶ 24 (Autolith EHL generator); Ex. 1005, 299 (high voltage supplied to electrodes 3); Ex. 1006, 9 (current feed 6)). Petitioner argues, based in part on testimony by Dr. Jensen, that an ordinarily skilled artisan would have included a suitable generator to ensure that the pair of electrodes generates a spark resulting in the formation of shockwaves. *Id.* at 41 (citing Ex. 1002 ¶ 164).

Patent Owner argues, based on testimony by Dr. Berger, that the prior art cautions against deploying EHL electrodes within an angioplasty balloon. PO Resp. 65–66 (citing Ex. 2100 ¶ 178). We have fully considered and found unpersuasive Patent Owner's argument. *See* Part II.F.1 above. For the reasons, expressed in connection with our analysis of claim 1 and Petitioner's argument and evidence discussed immediately above, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Levy, AAPA, and any one of Mantell, Uchiyama, or Willneff render claim 15 unpatentable as obvious.

4. Dependent Claims 16 and 17

Petitioner contends that the limitations introduced in each of dependent claims 16 and 17, both of which directly depend from claim 15, are described by the prior art. Pet. 42–43. For the reasons expressed below,

we conclude that Petitioner has proven by a preponderance of evidence that dependent claims 16 and 17 are unpatentable as obvious.

a. Claim 16

Claim 16 depends from claim 15 and further recites: "wherein the power source is arranged to provide high voltage pulses having at least one of selectable pulse durations, selectable voltage amplitudes, and selectable pulse repetition rates." Ex. 1001, 9:10–13. Petitioner contends that both Levy and Mantell describe power sources meeting the requirements of claim 16. Pet. 42 (citing Ex. 1003, 3 (incorporating controllable power source described in Levy '227); Ex. 1005 ¶¶ 51, 82 (describing power source with selectable voltage amplitudes (e.g., power level) and pulse repetition rates (e.g., number of pulses)); Ex. 1002 ¶¶ 168–169). Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and any one of Mantell, Uchiyama, or Willneff render claim 16 unpatentable as obvious.

b. Claim 17

Claim 17 depends from claim 15 and recites: "further comprising an R wave detector that synchronizes the mechanical shock waves with a cardiac R waves." Ex. 1001, 9:14–16. Petitioner contends that Schultheiss describes "a shockwave applicator and an R wave detector that synchronizes the mechanical shockwaves with cardiac waves." Pet. 43 (citing Ex. 1011 ¶ 72; Ex. 1002 ¶ 171). Petitioner also contends, based on the same evidence,

that it would have been obvious to use Schultheiss' detector to avoid a fibrillation in the patient. *Id*. Patent Owner does not respond to Petitioner's showing. *See* PO Resp. 18–65 (presenting arguments only for claims 1, 5, and 15).

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 Levy, AAPA, and any one of Mantell, Uchiyama, or Willneff along with Schultheiss renders claim 17 unpatentable as obvious.

5. Conclusion

Based on our review of the entire record and the parties' arguments, we conclude that Petitioner has demonstrated by a preponderance of evidence that claims 1–4 and 6–17 are unpatentable as obvious.

G. CLAIMS 1–17: OBVIOUSNESS IN VIEW OF WILLNEFF, AAPA, AND LEVY OR MANTELL AND IN FURTHER VIEW OF VARIOUS OTHER REFERENCES FOR CERTAIN CLAIMS

As an alternative, Petitioner argues that the same prior art applied above, but with Willneff as a primary reference, renders claims 1–17 obvious. *Compare* Pet. 13–43 (addressing Levy as primary reference), *with id*. at 43–60 (addressing Willneff as primary reference). Because we have found that the challenges based on Levy as the primary reference render claims 1–4 and 6–17 unpatentable as obvious, we find the challenges to these claims based upon Willneff as the primary references moot and do not address them in this Decision. *See Boston Sci. Simed, Inc. v. Cook Grp. Inc.*, No. 2019-1594, 2020 WL 2071962, at *4 (Fed. Cir. Apr. 30, 2020) (holding that "the Board need not address issues that are not necessary to the resolution of the proceeding").

However, because we have found that Petitioner's challenge to claim 5 based upon Levy as the primary reference fails, we must determine whether Petitioner's challenges to claim 5 based upon Willneff, AAPA, Levy, and Uchiyama or Willneff, AAPA, Mantell, and Uchiyama render claim 5 obvious. Petitioner's challenges to claim 5 based upon Willneff as the primary reference fail for the same reasons explained in Part II.F.2.d above, because Petitioner relies on Uchiyama in the manner in this challenge as in the previous challenge, and Petitioner has not proven that Uchiyama discloses the limitations of claim 5 for the reasons explained above.

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 2002–2004, 2006, 2008, 2016, 2017, 2124, 2125, 2126, 2132, 2133, 2139, 2141, 2149, 2152, 2161, 2162, 2163, 2164, 2170–2176, 2196 and certain paragraphs from Dr. Berger's Declaration for various reasons. Paper 67 ("Motion" or "Mot."). Patent Owner opposes the Motion. Paper 68 ("Opposition" or "Opp."). Petitioner filed a reply brief in support of the Motion. Paper 70 ("Motion Reply" or "Mot. Reply"). For the reasons explained below, we deny the Motion as unpersuasive, moot, or both.

A. HEARSAY

Petitioner moves to exclude Exhibits 2002–2004, 2006, 2008, 2016, 2017, 2124, 2125, 2132, 2133, 2139, 2141, and 2164 as containing inadmissible hearsay under Federal Rules of Evidence 801, 802, and 805. Mot. 1–4. 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), and one of Patent Owner's 10-Q submissions (Ex. 2141). *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. 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. 69–89. Patent Owner does not rely on statements made in these exhibits for the truth of the matter asserted, for example, that the Shockwave device has a "unique ability" to treat medial calcium (Ex. 2017 1) or that it is "space-age technology" (Ex. 2002, 1). Rather, Patent Owner relies upon these statements to show that industry actors took notice of and commented on the Shockwave device. *Quanergy Sys., Inc. v. Velodyne Lidar, Inc.*, IPR2018-00256, Paper 66 at 5–6 (PTAB May 21, 2020) ("[S]tatements offered solely for the purpose of showing they were made are admissible."); *Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 59 at 59 (PTAB Apr. 2, 2018). To the extent that the evidence may have served a hearsay purpose, we assign it little if any weight. Further, experts like Dr. Berger 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. Berger 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. Therefore, we deny Petitioner's motion to exclude these Exhibits 2002–2004, 2006, 2008, 2016, 2017, 2124, 2125, 2132, 2133, 2139, 2141, and 2164 as being unpersuasive, moot, or both.

B. UNCITED EXHIBITS

Petitioner moves to exclude exhibits 2126, 2152, 2161, 2162, and 2163 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. Berger cites and relies upon Exhibits 2126 and 2161–2163. Opp. 6 (citing Ex. 2100 ¶¶ 194 (with a typo mistakenly referring to 2126 as 2136), 224 (referring to Ex. 2196, which cites Exs. 2161–2163)). We deny Petitioner's Motion because the exhibits are relied upon by Dr. Berger in offering his testimony.

However, Patent Owner does not identify where it or any of its declarants cite or rely upon Ex. 2152, and we find no such citations. *Id.* at 6–7. Exhibit 2152 is U.S. Patent 5,454,809 to Janssen, entitled "Electrosurgical Catheter and Method for Resolving Atherosclerotic Plaque by Radio Frequency Sparking." Ex. 2152, Title. We have not considered Ex. 2152 in rendering our Decision and, therefore, deny Petitioner's Motion as being moot.

C. PERSONAL KNOWLEDGE

Petitioner moves to exclude Exhibit 2196, which is a claim chart mapping certain claims to the Shockwave devices, because Mr. Stephens has no personal knowledge of who prepared the exhibit. Mot. 5. Patent Owner

argues that Petitioner failed to timely object to Exhibit 2196 and therefore waived any objection now raised. Opp. 7. Patent Owner further explains that Dr. Berger relies upon Exhibit 2196, not Mr. Stephens, and argues that an expert need not have personal knowledge about the facts and data upon which he relies. *Id*. Petitioner does not respond to Patent Owner's arguments. *See generally*, 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); Combined Trial Practice Guide, November 2019, 78–79 ("Combined TPG").[25] "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* Mot. 5. Our review of the Petitioner's Objections (Papers 22, 43), the testimony of Mr. Stephens (Ex. 1216), and the testimony of Dr. Berger (Exs. 1126, 1204) show that Petitioner failed to object to Exhibit 2196. Therefore, we deny Petitioner's motion to exclude Exhibit 2196.

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

D. AUTHENTICATION

Petitioner moves to exclude Exhibit 2149, a Japanese Patent with an included Abstract in English because Patent Owner failed to provide a complete certified translation. Mot. 5. Patent Owner served a certified translation of Exhibit 2149 (Ex. 2222), which it files with its Opposition as Exhibit 2256. Petitioner does not argue that Patent Owner's supplemental evidence failed to cure its objection to Exhibit 2149. *See generally*, Mot. Reply. We deny Petitioner's Motion to exclude Ex. 2149 because the service of Exhibit 2256 cured Petitioner's objection.

E. RELEVANCE OR PREJUDICE

Petitioner moves to exclude Exhibits 2003, 2004, 2006, 2125, 2139, 2141, and 2170–2176 as irrelevant or prejudicial under Federal Rules of Evidence 401, 402, and 403. Mot. 5–9. 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. 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 2003, 2004, 2006, 2125, 2139, 2141, and 2170–2176 must be excluded from the record. The evidence Petitioner seeks to exclude support Patent Owner's argument that the '371 patent is 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," Mot. 6, 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 Motion to exclude Exhibits 2003, 2004, 2006, 2125, 2139, 2141, and 2170–2176.

F. PORTIONS OF DR. BERGER'S TESTIMONY

Petitioner moves to exclude portions of the declaration testimony of Dr. Berger under Federal Rules of Evidence 702 and 703. Mot. 9–10. More specifically, Petitioner argues:

> paragraphs 18, 19, 59, 60, 66, 132 (testimony not based on sufficient facts or data, patent owner has not shown the '371 patent is entitled to a June 13, 2008 priority date), 143, 144

> (testimony not based on sufficient facts or data), 165 (testimony not based on sufficient facts or data), 170 (testimony not based on sufficient facts or data), 175 (testimony not based on sufficient facts or data), 199 (not qualified to opine on device meeting criteria), 201, 205, 205 [sic], 217, 218, 220, 221, 222, and 229 (testimony not based on sufficient facts or data) are inadmissible under FRE 702(b) and/or 703.

Id.

Patent Owner argues that Petitioner's basis for excluding certain paragraphs of Dr. Berger's declaration are conclusory and that Petitioner "does not explain which aspects of the opinions are unsupported or what facts or data could or should have been considered." Opp. 14.

Whether Dr. Berger'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. Berger. Thus, we deny Petitioner's motion to exclude the identified paragraphs of Dr. Berger's declaration (Ex. 2100).

IV. CONCLUSION[26]

In summary,

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–3, 15, 16	103	Levy, AAPA, Mantell	1–3, 15, 16	

[26] 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.

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
4, 6, 11	103	Levy, AAPA, Mantell, Willneff	4, 6, 11	
5, 14	103	Levy, AAPA, Mantell, Uchiyama	14	5
7, 12	103	Levy, AAPA, Mantell, Hayes	7, 12	
8, 12	103	Levy, AAPA, Mantell, Duchamp	8, 12	
9	103	Levy, AAPA, Mantell, Naimark	9	
10	103	Levy, AAPA, Mantell, Beyer	10	
13	103	Levy, AAPA, Mantell, Bhatta	13	
17	103	Levy, AAPA, Mantell, Schultheiss	17	
1, 2, 5, 14–16	103	Levy, AAPA, Uchiyama	1, 2, 14–16	5
4, 6, 11	103	Levy, AAPA, Uchiyama, Willneff	4, 6, 11	
7, 12	103	Levy, AAPA, Uchiyama, Hayes	7, 12	

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).

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
8, 12	103	Levy, AAPA, Uchiyama, Duchamp	8, 12	
9	103	Levy, AAPA, Uchiyama, Naimark	9	
10	103	Levy, AAPA, Uchiyama, Beyer	10	
13	103	Levy, AAPA, Uchiyama, Bhatta	13	
17	103	Levy, AAPA, Uchiyama, Schultheiss	17	
1, 2, 4, 6, 11, 15, 16	103	Levy, AAPA, Willneff	1, 2, 4, 6, 11, 15, 16	
7, 12	103	Levy, AAPA, Willneff, Hayes	7, 12	
8, 12	103	Levy, AAPA, Willneff, Duchamp	8, 12	
9	103	Levy, AAPA, Willneff, Naimark	9	
10	103	Levy, AAPA, Willneff, Beyer	10	
13	103	Levy, AAPA, Willneff, Bhatta	13	
17	103	Levy, AAPA, Willneff, Schultheiss	17	

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 2, 4, 6, 11, 15	103	Willneff, AAPA, Levy[27]		
3, 16	103	Willneff, AAPA, Levy, Mantell		
5, 14	103	Willneff, AAPA, Levy, Uchiyama		5
7, 12	103	Willneff, AAPA, Levy, Hayes		
8, 12	103	Willneff, AAPA, Levy, Duchamp		
9	103	Willneff, AAPA, Levy, Naimark		
10	103	Willneff, AAPA, Levy, Beyar		
13	103	Willneff, AAPA, Levy, Bhatta		
17	103	Willneff, AAPA, Levy, Schultheiss		
1–3, 15, 16	103	Willneff, AAPA, Mantell		

[27] For all challenges to claims 1–4 and 6–17 relying upon Willneff as a primary prior art reference, we do not reach a decision because those challenges are moot in view of our ruling on the challenges to these claims based upon Levy as the primary prior art reference. *See Boston Sci. Simed, Inc. v. Cook Grp. Inc.*, No. 2019-1594, 2020 WL 2071962, at *4 (Fed. Cir. Apr. 30, 2020) (holding that "the Board need not address issues that are not necessary to the resolution of the proceeding"); *cf. Ex parte Moncla*, Appeal No. 2009-006448 (PTAB June 22, 2010) (holding that it is premature to address a provisional rejection) (designated precedential).

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
5, 14	103	Willneff, AAPA, Mantell, Uchiyama		5
7, 12	103	Willneff, AAPA, Mantell, Hayes		
8, 12	103	Willneff, AAPA, Mantell, Duchamp		
9	103	Willneff, AAPA, Mantell, Naimark		
10	103	Willneff, AAPA, Mantell, Beyar		
13	103	Willneff, AAPA, Mantell, Bhatta		
17	103	Willneff, AAPA, Levy, Schultheiss		
		Overall Outcome	1–4, 6–17	5

V. ORDER

For the reasons given, it is:

ORDERED, based on a preponderance of evidence, that claims 1–4 and 6–17 of U.S. Patent 8,956,371 B2 are *unpatentable* as obvious under 35 U.S.C. § 103;

FURTHER ORDERED that Petitioner has not demonstrated that claim 5 of U.S. Patent 8,956,371 B2 is *unpatentable*; and

FURTHER ORDERED that Petitioner's Motion to Exclude Exhibits 2002–2004, 2006, 2008, 2016, 2017, 2124, 2125, 2126, 2132, 2133, 2139, 2141, 2149, 2152, 2161, 2162, 2163, 2164, 2170–2176, 2196, and 2100

(¶¶ 18, 19, 59, 60, 66, 132, 143, 144, 165, 170, 175, 199, 201, 205, 217, 218, 220, 221, 222, and 229) is *denied*;

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.

PETITIONER:

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

PATENT OWNER:

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

Michael Stallman
MORRISON & FOERSTER LLP
mstallman@mofo.com