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Paper 19
Entered: July 9, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.,
Petitioner,

v.

SHOCKWAVE MEDICAL, INC.,
Patent Owner.

Case IPR2019-00405
Patent 8,956,371 B2

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

WEATHERLY, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. §§ 42.4

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."). With authorization, Petitioner filed a Reply to the Preliminary Response (Paper 15, "Reply"), and Patent Owner filed a Surreply in response to the Reply (Paper 16, "Surreply").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Based on our review of the record, we conclude that Petitioner is reasonably likely to prevail with respect to at least one of the challenged claims.

Petitioner contends that the challenged claims are unpatentable as obvious under 35 U.S.C. § 103 based on the following grounds (Pet. 13–60):

References	Basis	Claim(s) challenged
Levy,[1] AAPA,[2] and Mantell,[3] Uchiyama,[4] or Willneff[5]	§ 103	1–6, 11, and 14–16
Levy, AAPA, and Mantell, Uchiyama, or Willneff, in further view of Hayes[6]	§ 103	7 and 12

[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").

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

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

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

[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").

References	Basis	Claim(s) challenged
Willneff, AAPA, and Levy or Mantell in further view of Bhatta	§ 103	13
Willneff, AAPA, and Levy or Mantell in further view of Schultheiss	§ 103	17

Generally, Patent Owner contends that the Petition should be denied in its entirety. On April 24, 2018, the Supreme Court held that, under 35 U.S.C. § 314, the Office may not institute review of fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that at least claim 1 is unpatentable. In accordance with the *SAS* decision and Office guidance,[12] we institute an *inter partes* review of all challenged claims of the '371 patent on all grounds alleged by Petitioner.

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);

[12] "Guidance on the impact of *SAS* on AIA trial proceedings" (Apr. 26, 2018), accessible at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (last accessed Oct. 2, 2018) ("At this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition," and "for pending trials . . . the panel may issue an order supplementing the institution decision to institute on all challenges raised in the petition.").

- 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)

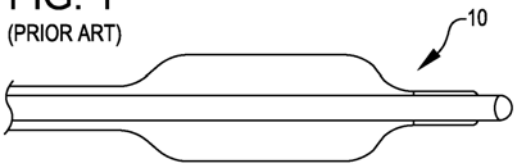

FIG. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter. *Id*. at 3:7–8.

FIG. 2

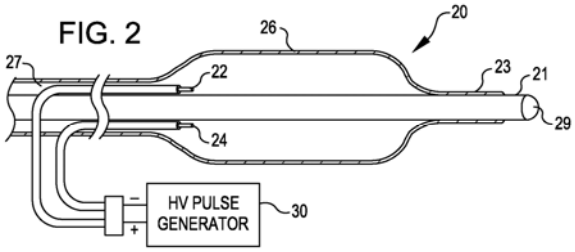

FIG. 2 is a side view of a dilating angioplasty balloon catheter with two electrodes within the balloon. *Id*. at 3:9–10.

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. The magnitude of the shock waves is controlled by altering the voltage, current, duration, and frequency of the signal sent from pulse generator 30 to electrodes 22, 24. *Id*. at 4:17–26.

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. EFFECTIVE PRIOR ART DATE OF MANTELL

Mantell published from an application filed May 6, 2009, and claims priority to a provisional application filed May 7, 2008 (the "Mantell Provisional"[13]). *See* Ex. 1004, 1 (INID codes (22), (60)). The '371 patent was filed June 11, 2009, and claims priority to a provisional application filed June 13, 2008 (the "'170 Provisional"[14]). *See* Ex. 1001, 1 (INID codes (22), (60)). Based solely upon the respective filing dates of the applications leading to publication (Mantell) or issuance ('371 patent), Mantell is prior art to the '371 patent under § 102(e)(1). Petitioner relies upon this relationship when alleging that Mantell is prior art. Pet. 6. Under *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1381 (Fed. Cir. 2015), we determine that Petitioner met its burden of raising the issue of whether Mantell is prior art.

[13] U.S. Provisional Patent Application No. 61/051,262.

[14] U.S. Provisional Patent Application No. 61/061,170.

Patent Owner contends that the '170 Provisional fully supports every claim of the '371 patent and cites portions of that application as support. Prelim. Resp. 14. Whether a priority application supports claims as required under 35 U.S.C. § 112 presents factual and legal issues that must be resolved from the perspective of one of ordinary skill in the art. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012) (factual issue of written description support); *id*. at 1288 (legal issue of enablement). Patent Owner proffers no testimony from the perspective of an ordinarily skilled artisan to support its contentions that the '170 Provisional meets the written description and enablement requirements. *See* Prelim. Resp. 14 (merely listing locations in '170 Provisional allegedly meeting § 112 requirements for each limitation in challenged claims). On the current record, we determine that Patent Owner has not demonstrated that the claims of the '371 patent are entitled to priority based upon the filing date of the '170 Provisional.

In the Reply, Petitioner correctly noted that it did not have a burden of establishing in the Petition that Mantell is effective as prior art as of the filing date of the Mantell Provisional. Reply 1. Petitioner contends that the Mantell Provisional supports every claim in Mantell and lists specific portions of the Mantell Provisional in support of that contention. *Id*. at 2–4. Based on this listing, Petitioner argues that Mantell is effective as prior art as of the filing date of the Mantell Provisional. *Id*. at 2. Whether the Mantell Provisional meets the requirements of § 112 for its own claims is judged from the perspective of an ordinarily skilled artisan. *Dynamic Drinkware*, 800 F.3d at 1378. Petitioner proffers no testimony from the perspective of an ordinarily skilled artisan to support its contentions that the Mantell

Provisional supports the claims in Mantell. *See* Reply 3–4 (citing no testimonial evidence representative of the perspective of an ordinarily skilled artisan). Patent Owner does not respond to Petitioner's purported showing that Mantell is effective as prior art as of the filing date of the Mantell Provisional. *See* Surreply 1–5. On the current record, we determine that Petitioner has not demonstrated that Mantell is effective as prior art as of the filing date of the Mantell Provisional.[15]

Based on the current record, we determine that Mantell is effective as prior art as of May 6, 2009, and that the priority date for the claims of the '371 patent is June 11, 2009. Accordingly, for purposes of this Decision, we consider Mantell to be prior art to the '371 patent under 35 U.S.C. § 102(e). Differences, if any, in the record developed at trial may alter our decision on this issue.

B. 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) (2018).[16] Only terms that are in controversy need to

[15] Petitioner has also failed to demonstrate that the information in Mantell upon which it relies to challenge claims as unpatentable was also present in the Mantell Provisional. *See* Reply 3–4 (addressing only support under § 112). Such a showing is required under *In re Giacomini*, 612 F.3d 1380, 1383 (Fed. Cir. 2010). That is, Petitioner fails to compare the disclosure in the Mantell Provisional to the challenged claims.

[16] On October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court.

be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

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. Petitioner quotes a portion of the Specification as supporting its argument, which reads: "[t]he 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 12–13 (quoting Ex. 1001, 1:13–18).

Patent Owner argues that "'angioplasty balloon' would have been understood by any skilled artisan as referring to a specific prior art device that was configured to apply pressure to compress the plaque into the vessel." Prelim. Resp. 31. Patent Owner quotes the Specification's description of the disadvantages of prior art versions of "non-compliant" angioplasty balloons as support for its interpretation. *Id*. at 32 (quoting Ex. 1001, 1:25–36). However, we discern no limitation on "angioplasty balloon" relating to the compliance or non-compliance of the balloon. In fact, claim 8, which depends directly from claim 1 and requires that "the

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

balloon is formed of compliant material," Ex. 1001, 6:53–54, suggests that "angioplasty balloon" of claim 1 also covers compliant balloons.

Patent Owner also cites dictionary definitions in support of its contention that "angioplasty balloon" is limited to balloons that treat obstructions solely by compressing fatty matter. Prelim. Resp. 33–34 (citing Ex. 2018, 2019, 2020). The scope of "angioplasty balloon" as used in claim 1 cannot be so narrow, however, that it excludes the invention itself, which covers compliant (claim 8) and non-compliant (claim 7) balloons and treats obstructions "without the application of excessive pressure by the balloon on the walls of the artery." Ex. 1001, 4:39–41.

Patent Owner also contends that "angioplasty balloon" cannot be interpreted to cover the balloon described in Mantell because "angioplasty balloon" was added to claim 1 to distinguish Mantell during prosecution. Prelim. Resp. 34–35 (citing Ex. 2022, 291, 295–96). Even if the amendment of claim 1 were to exclude Mantell's balloon, however, Petitioner relies upon Levy and AAPA, not Mantell, as describing the claimed balloon. Pet. 23–31 (citing Ex. 1003, 1, 3, Figure 1; Ex. 1001, 3:65–4:2, Figure 1; Ex. 1002 ¶¶ 109–123). Accordingly, we find it unnecessary to resolve the specific extent of potential disclaimer of scope associated with "angioplasty balloon" through the amendment of claim 1 allegedly to distinguish Mantell.

At this stage of the proceeding, we apply Petitioner's proposed meaning of "angioplasty balloon" as being more consistent with the plain language of claims 1, 7, and 8 and the general description of the invention in the Specification. Our interpretation is preliminary, however, and the parties are encouraged to provide additional argument and evidence during the trial regarding the meaning of "angioplasty balloon."

C. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1–17 on the grounds that the claims are obvious. 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 reasonably likely to be 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. With these standards in mind, we address each challenge below.

D. CLAIMS 1–6, 11, 14–16: OBVIOUSNESS IN VIEW OF LEVY, THE AAPA, AND MANTELL, UCHIYAMA, OR WILLNEFF

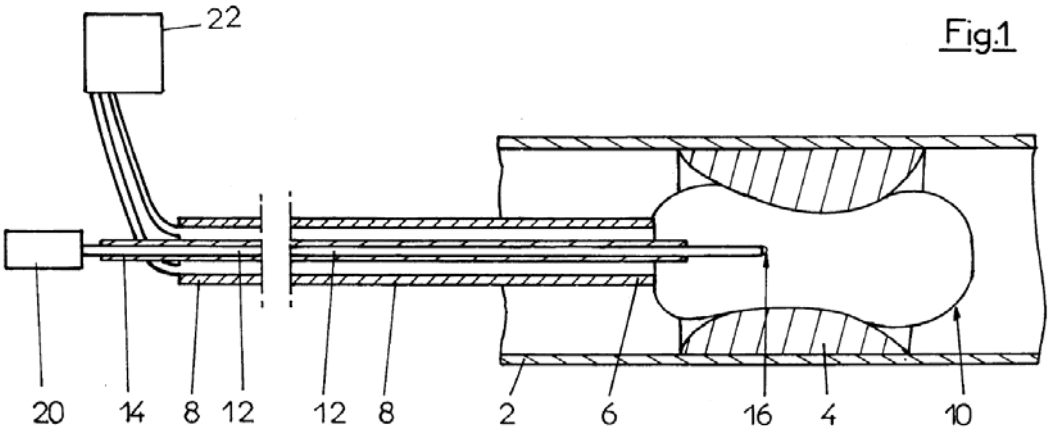
Petitioner argues that claims 1–6, 11, 14–16 are unpatentable as obvious in view of the combined teachings of Levy, the AAPA, and any one of Mantell, Uchiyama, or Willneff. Pet. 13–43. For the reasons expressed below, Petitioner has demonstrated a reasonable likelihood of establishing that these claims are obvious in view of the teachings of the asserted combinations of prior art.

1. Overview of the Asserted Prior Art

a) 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.[17] Levy's device is shown in Figure 1 (substantively reproduced below).



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.

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

b) AAPA

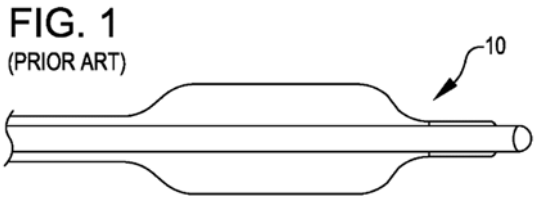


Figure 1 of the '371 patent (reproduced right) is labeled and described as "PRIOR ART." Ex. 1001, Figure 1. The Specification describes Figure 1 as "a view of the therapeutic end of a typical prior art *over-the-wire* angioplasty balloon catheter 10. Such catheters are usually non-complaint with a fixed 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."

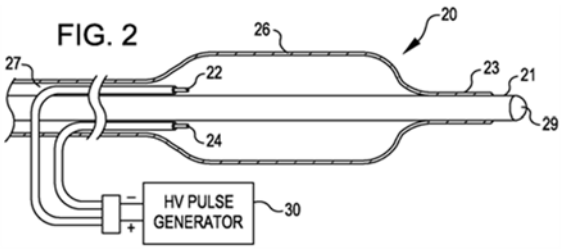


Figure 2, which illustrates the allegedly inventive catheter 20, also fails to illustrate a guidewire. *Id*. at Figure 2. The Specification indicates that the guidewire is not shown but inserted through lumen 29 in carrier 21. *Id*. at 4:31–33. Although a carrier and lumen are not enumerated on Figure 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.

c) 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.

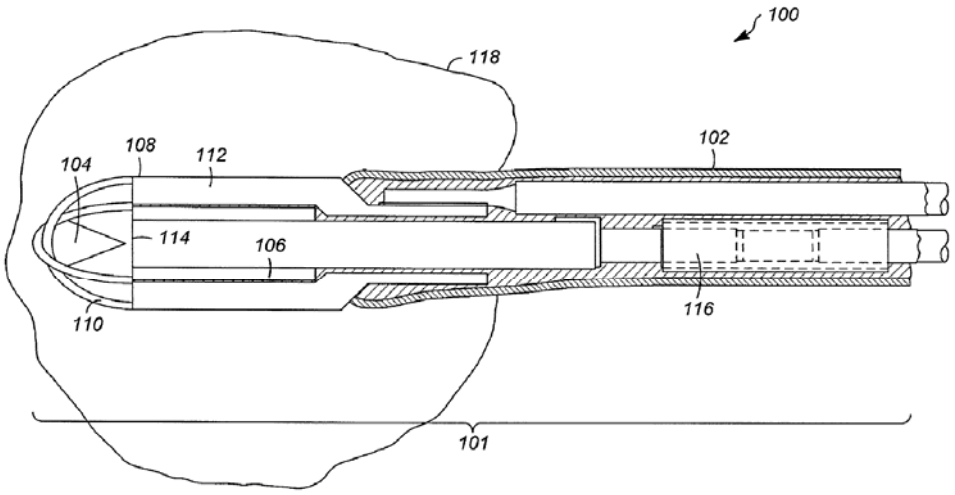


FIG. 2

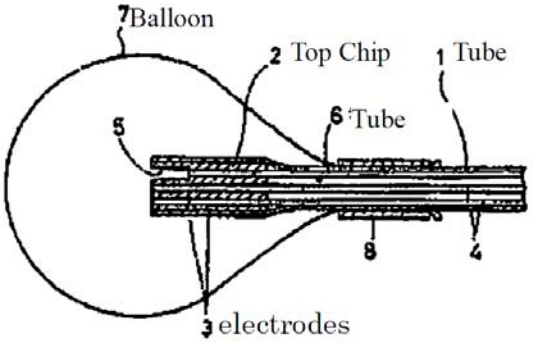
> Figure 2 is a cross-sectional side view of an embodiment of Mantell's electrohydraulic lithotripsy probe. *Id*. ¶ 4.

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*.

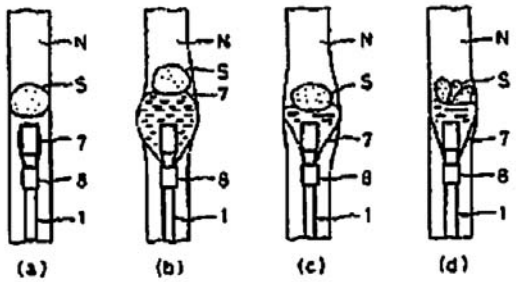
d) Uchiyama

Uchiyama describes an arc-based shockwave generator within an inflated balloon as illustrated in Figures 1–7. Ex. 1005, 298–99.[18] 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*.

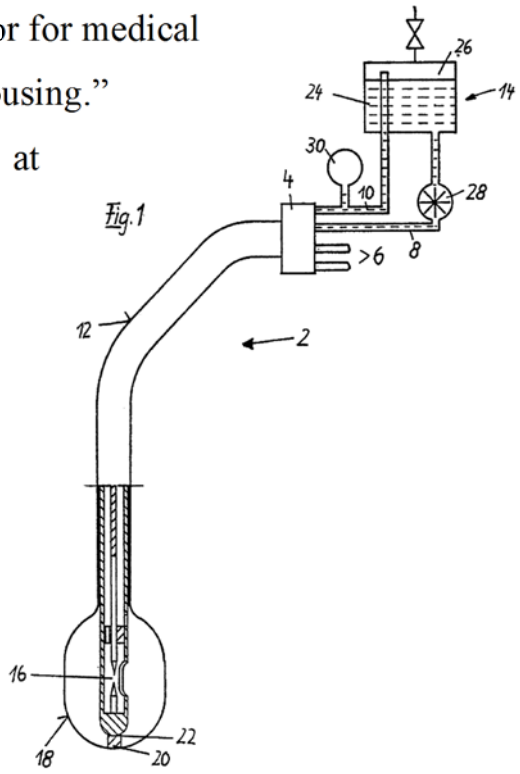
Electrodes 3 are positioned near the distal end of tube 1 that includes tube 6 for inflating balloon 7 with fluid through opening 5. *Id*. at 298. Figures 3(a)–(d) illustrate advancing the probe in a urinary duct N to a position close to calculus S (Figure 3(a)), inflating balloon 7 so that it contacts 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

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

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 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.

e) Willneff

Willneff describes a "shock wave generator for medical applications with a spark gap located within a housing." Ex. 1006, 2.[19] 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.



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

2. Claim 1

a) 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 23–24 (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).

b) Analysis of Patent Owner's Counterarguments

Patent Owner argues that Petitioner's challenges to claim 1 based on Levy as the primary reference fail for a number of reasons, none of which is persuasive at this stage of the proceeding.

(1) Element 1a: carrier with guide wire lumen

Element 1a refers to the following portion of claim 1: "an elongated carrier sized to fit within a blood vessel, said carrier having a guide wire lumen extending therethrough." Patent Owner contends that neither Levy nor AAPA describes the "claimed guidewire." Prelim. Resp. 40. We disagree.

At the outset, we note that claim 1 does not recite a "guidewire" but rather a "guide wire lumen." Ex. 1001, 6:21–23. Patent Owner argues that Petitioner's challenge fails because "[u]nlike a guidewire lumen, Levy's element 8 does not extend beyond the far end of the balloon." Prelim. Resp. 41. This argument is unpersuasive. First, Petitioner persuasively relies upon the AAPA's description of a carrier having a guide wire lumen (and a guidewire in that lumen) as a "typical prior art over-the-wire angioplasty balloon" in the proposed combination of prior art teachings. Pet. 23–24 (citing Ex. 1001, 3:65–4:2, Figure 1; Ex. 1002 ¶ 109). The AAPA describes a guide wire lumen that extends past the distal end of a balloon. Ex. 1001, Figure 1.

Second, Patent Owner's argument rests upon the premise that claim 1 requires the guide wire lumen to extend past the distal end of the balloon. The plain language of element 1a arguably does not require such an arrangement, and Patent Owner has not expressly analyzed the language of element 1a or the intrinsic record to demonstrate that it does. Instead, the claim plainly requires only that the guide wire lumen extend through the carrier without limiting how far the lumen extends within or past the carrier. The language of element 1a, at least in isolation, does not require the guidewire lumen to extend past the end of the carrier. We invite the parties

to address expressly whether claim 1 as a whole requires the guide wire lumen to extend past the end of the carrier or balloon and cite appropriate evidence in support of their respective positions.

For these reasons, we are persuaded that, on the current record, at least the AAPA and possibly also Levy describe element 1a.

(2) Element 1b: angioplasty balloon

Element 1b refers to the following portion of claim 1:

> 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.

Patent Owner argues that Levy fails to describe an "angioplasty balloon" because Levy never mentions angioplasty, and Levy's flexible balloon is inconsistent with an angioplasty catheter, which "typically involves an inextensible balloon that inflates to a predetermined diameter." Prelim. Resp. 39–40.

First, Patent Owner's argument presumes that the claim requires the angioplasty balloon to be "inextensible." Claim 8, which depends directly from claim 1 and requires that "the balloon is formed of compliant material," Ex. 1001, 6:53–54, arguably requires us to interpret claim 1 broadly enough to cover compliant balloons such as the one Levy describes. Second, Petitioner persuasively relies on the AAPA as describing a "non-compliant" angioplasty balloon. Pet. 25 (citing Ex. 1001, 3:65–4:2, Figure 1; Ex. 1002 ¶ 113). Accordingly, on the current record, we are persuaded that the AAPA describes element 1b.

(3) Elements 1c–e: the arc generator and its operation

Elements 1c–1e collectively refer to the following language of claim 1:

> [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.

Patent Owner argues that changing Levy's laser-based shockwave generator to an arc-based shockwave generator is improper for two reasons, neither of which is persuasive on the current record. Prelim. Resp. 44–52.

First, Patent Owner argues that Petitioner fails to explain how any one of the arc-generators of Mantell, Uchiyama, or Willneff could be incorporated into a catheter having a guidewire that extends from the distal end of the balloon. *Id*. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted). Patent Owner's argument consists of a list of rhetorical questions without any evidence to support Patent Owner's implicit premise—that an ordinarily skilled artisan would consider the questions to be relevant or difficult to answer. *See*, *e.g.*, Prelim. Resp. 45 (regarding Mantell), 49 (regarding Uchiyama), 50 (regarding Willneff). Petitioner persuasively argues, based

on Dr. Jensen's testimony, that an ordinarily skilled artisan would understand how to implement an arc-based shockwave generator in Levy's catheter as modified by the AAPA. Pet. 28–29 (citing Ex. 1002 ¶ 120). Patent Owner's unsupported rhetorical questions do not overcome the probative weight of Dr. Jensen's testimony.

Second, Patent Owner argues that changing Levy's laser-based shockwave generator to an arc-based generator as described by Mantell, Uchiyama, or Willneff changes Levy's principle of operation. Prelim. Resp. 47 (Mantell), 50 (Uchiyama), 52 (Willneff). More specifically, Patent Owner contends that Levy's principle of operation would change from "cavitation induced vibrations by laser heat to shockwaves generated by a plasma arc discharge." *Id*. at 47. The evidence fails to support Patent Owner's argument because at least Levy's and Mantell's shockwave generators operate on the common principle of creating cavitation in the liquid within a balloon. Ex. 1003, 1; Ex. 1004 ¶ 29. Uchiyama and Willneff do not specifically describe cavitation of the fluid as the mechanism for generating shockwaves, but they both, like Levy, describe using the fluid inside a balloon as the medium for transmitting shockwaves from the arc to the target deposit. Ex. 1005, 299; Ex. 1006, 7. Petitioner persuasively argues, based on Dr. Jensen's testimony and other evidence, that an ordinarily skilled artisan would have considered arc-based systems for generating shockwaves to be interchangeable with laser-based systems for doing so. Pet. 19–20 (citing Ex. 1002 ¶¶ 97–102; Ex. 1012, 1:5–10, 1:15–30). By contrast, no testimony supports Patent Owner's argument.

For all these reasons, Petitioner persuades us that the combined teachings of Levy, the AAPA, and at least Mantell describe or suggest elements 1c–1e.

(4) Teaching Away by Bhatta and Mantell

Patent Owner argues that each of Bhatta (Exhibit 1012) and Mantell teach away from combining arc-based shockwave generators with Levy. Patent Owner contends that Bhatta warns that a metal shield is necessary to protect surrounding tissue from the arc, but that the metal shield was "prone to fragmentation." Prelim. Resp. 52–53 (citing Ex. 1012, 1:19–24, 1:31–53). Patent Owner's argument is unpersuasive because Petitioner relies on Bhatta only as reflecting an ordinarily skilled artisan's general understanding that laser-based systems and arc-based systems both generate shockwaves that can be used to break up "arteriosclerotic plaque." Pet. 19–20 (citing Ex. 1012, 1:5–10, 1:15–30).

Patent Owner argues that Mantell "*teaches directly away* from using the Mantell EHL probe in a device intended to *enlarge* small vessels, such as the angioplasty balloon of the AAPA." Surreply 2. Patent Owner's argument is unpersuasive. Patent Owner quotes at length from Mantell's paragraph 22 to support its argument. *Id*. (quoting Ex. 1004 ¶ 22). However, that paragraph describes a single embodiment of Mantell's device that is intended to collapse a small vessel in the body (a fallopian tube). Ex. 1004 ¶ 22. Patent Owner ignores Mantell's description of a more relevant embodiment intended to clear blockages within vessels of the heart without otherwise damaging those vessels. *Id*. ¶¶ 21, 29. We, therefore, find Patent Owner's argument to be unpersuasive.

Patent Owner also argues that Mantell "teaches away from using an *inflatable* balloon as in Levy and the AAPA and as recited in the claims." Surreply 4. Patent Owner relies upon Mantell's illustration of balloon 118 as "limp and wrinkled" in Figures 1–6. *Id*. Patent Owner's argument contradicts the description of Mantell's balloon 118 as "encapsulat[ing] a liquid such as saline" so that an "electrical arc causes a steam bubble in the liquid." Ex. 1004 ¶ 29. Dr. Jensen's uncontroverted testimony that an ordinarily skilled artisan would understand Mantell's balloon to be "fluid-filled" supports our determination that Mantell's balloon is inflatable. Ex. 1002 ¶ 117. Accordingly, we find Patent Owner's argument unpersuasive.

c) Conclusion

For the reasons expressed above, we conclude that Petitioner has demonstrated a reasonable likelihood of proving that claim 1 is unpatentable as obvious in view of the combined teachings of Levy, the AAPA, and one of Mantell, Uchiyama, or Willneff.

3. Remaining Claims 2–6, 11, and 14–16

Patent Owner does not separately address Petitioner's challenges to any of the claims that ultimately depend from claim 1 (claims 2–6, 11, and 14) or independent claim 15 and its dependent claim 16. *See* Prelim. Resp. 36–54 (addressing only the challenge to claim 1). Based on our review of the Petition as it relates to these claims, we determine that Petitioner has demonstrated a reasonable likelihood of proving that these claims are also unpatentable as obvious in view of the combined teachings of Levy, the AAPA, and one of Mantell, Uchiyama, or Willneff.

4. Conclusion

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of proving that claims 1–6, 11, and 14–16 are unpatentable as obvious in view of the combined teachings of Levy, the AAPA, and one of Mantell, Uchiyama, or Willneff.

E. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Patent Owner argues that Petitioner "should address objective evidence of nonobviousness known to it prior to filing the petition." Prelim. Resp. 62 (citing *Praxair Distribution, Inc. v. Mallinckrodt Hospital Prods.*, Cases IPR2016-00777, IPR2016-00778, IPR2016-00779, IPR2016-00780, slip. op. 8–10 (PTAB Sept. 22, 2016) (Paper 10)). Patent Owner contends that Petitioner "is Shockwave's primary competitor" and "thus surely knew about most if not all the objective evidence of nonobviousness discussed" in the Preliminary Response. *Id*. at 62–63 (citing Ex. 2006, 6, 23). The evidence cited does not support the proposition for which Patent Owner offers it. Exhibit 2006 is a Wells Fargo Securities report explaining Wells Fargo's "price target" for shares in Patent Owner. Ex. 2006, 1. The cited portions merely identify Petitioner as the filer of this Petition and others challenging Patent Owner's patents, *id*. at 6, or the maker of one competing atherectomy device, *id*. at 23. The Wells Fargo report never characterizes Petitioner as "Shockwave's primary competitor." Even if it did, the report may be inadmissible hearsay for that proposition.

Additionally, Patent Owner presents no admissible evidence of Petitioner's subjective knowledge of Patent Owner's purported objective

evidence of non-obviousness.[20] Patent Owner recognizes its own failure to supply such evidence by equivocally arguing that Petitioner "surely knew" about "most if not all" of Patent Owner's evidence. We will not deny the Petition on the current record because Petitioner is entitled to an opportunity to meet Patent Owner's evidence in a trial setting.

For similar reasons, we do not weigh the evidence adduced by Patent Owner directly relating to purported objective indicia of non-obviousness. *See* Prelim. Resp. 24–30 (discussing industry praise for the invention). Petitioner is entitled to address the evidence adduced by Patent Owner in the Preliminary Response and any additional evidence presented in the Patent Owner Response during the trial. When the record regarding objective indicia of non-obviousness is complete, we will weigh the evidence as part of our consideration of Petitioner's challenges.

III. CONCLUSION

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of showing that claims 1–6, 11, and 14–16 of the '371 patent are unpatentable as obvious. In accordance with the Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) and Office guidance, we institute an *inter partes* review of all challenged claims of the '371 patent on all grounds of unpatentability alleged by Petitioner.

[20] A variety of fundamental evidentiary problems exist with the Wells Fargo report when offered to prove Petitioner's subjective knowledge that virtually nullify its probative value on that point.

IV. ORDER

For the reasons given, it is:

ORDERED that *inter partes* review is instituted of claims 1–17 of the '371 patent with respect to all grounds of unpatentability set forth in the Petition;

FURTHER ORDERED that *inter partes* review is not instituted with respect to any other grounds of unpatentability alleged in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '371 patent is instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial.

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