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Paper No. 8
Entered May 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

PGR2017-00002
Patent 9,247,989 B2

Before MEREDITH C. PETRAVICK, WILLIAM V. SAINDON, and RICHARD E. RICE, *Administrative Patent Judges.*

PETRAVICK, *Administrative Patent Judge.*

DECISION
Instituting Post-grant Review
37 C.F.R. § 42.208

I. INTRODUCTION

A. Background

On November 2, 2016, Minerva Surgical, Inc. ("Petitioner") filed a Petition requesting post-grant review of claims 1–19 of U.S. Patent No. 9,247,989 B2 (Ex. 1001, "the '989 patent"). Paper 2 ("Pet."). Pursuant to 35 U.S.C. § 321(c), the Petition was filed not later than 9 months after the grant of the '989 patent on February 2, 2016. Hologic, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

Under 35 U.S.C. § 324, a post-grant review may be instituted only if "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."

Petitioner challenges the patentability of claims 1–19 of the '989 patent under 35 U.S.C. § 112(a). We determine that Petitioner has demonstrated that it is more likely than not that at least one of the claims challenged in the petition are unpatentable. For the reasons described below, we institute a post-grant review of claims 1–19.

B. Related Proceedings

The parties indicate that the '989 patent is at issue in *Hologic, Inc. v. Minerva Surgical, Inc.*, Case No. 1:15-cv-01031-SLR, in the U.S. District Court for the District of Delaware. Pet. 10, Paper 4, 2.

C. The ’989 Patent

The ’989 Patent is titled “Moisture Transport System for Contact Electrocoagulation.” Ex. 1001, (54). The ’989 patent discloses a method for ablating an organ using an ablation device, having “a metallized fabric electrode array which is substantially absorbent and/or permeable to moisture and gases such as steam and conformable to a body cavity.” *Id.* at Abstract. The ’989 patent discloses two exemplary embodiments. *Id.* at 4:55–57.

First Embodiment

Figure 7 of the ’989 patent is reproduced below.

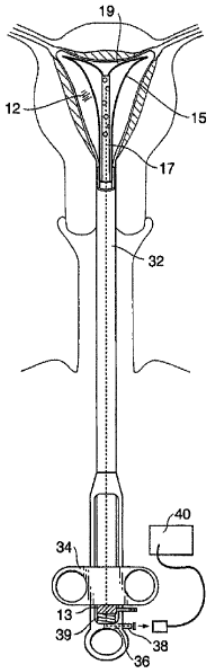

FIG. 7

Figure 7 depicts the ablation device of the first embodiment in an expanded state. *See id.* at 3:3–6. The ablation device includes RF applicator head 2 having electrode carrying means 12 mounted to shaft 10 (not depicted). *Id.* at 4:59–65. Electrode carrying means 12 is a sack formed of non-conductive

permeable material that has an array of electrodes on the surface. *Id.* at 5:57–6:3. Shaft 10 includes suction/insufflation tube 17, through which a gas or fluid may be introduced into or withdrawn from the tube via port 38 during the operation. *Id.* at 8:26–42. The gas or fluid travels into the uterine cavity through the permeable electrode carrying means. *Id.* at 8:39–42, 9:36–41, 10:16–19, 11:41–46. Water vapor or other fluid within the uterine cavity may also pass through permeable electrode carrying means 12 into suction/insufflation tube 17. *Id.* at 10:65–11:14.

Electrode carrying means 12 is compressed inside sheath 32 during insertion of the ablation device into the uterus. *Id.* at 7:42–54, Fig. 6. After insertion, sheath 32 is retracted, causing spring members 15 and 19 to expand electrode carrying means 12. *See id.* at 7:55–8:20, Figs. 6–7. The '989 patent discloses that additional components may be provided to add structural integrity to the electrode carrying means, through alternative spring members 15a, 19a as depicted in Figure 11; a pair of inflatable balloons 52 as depicted in Figure 20; or application of suction from the suction/inflation tube 17. *Id.* at 8:54–9:13, 10:21–25.

Second Embodiment

Figure 23 of the '989 patent is reproduced below.

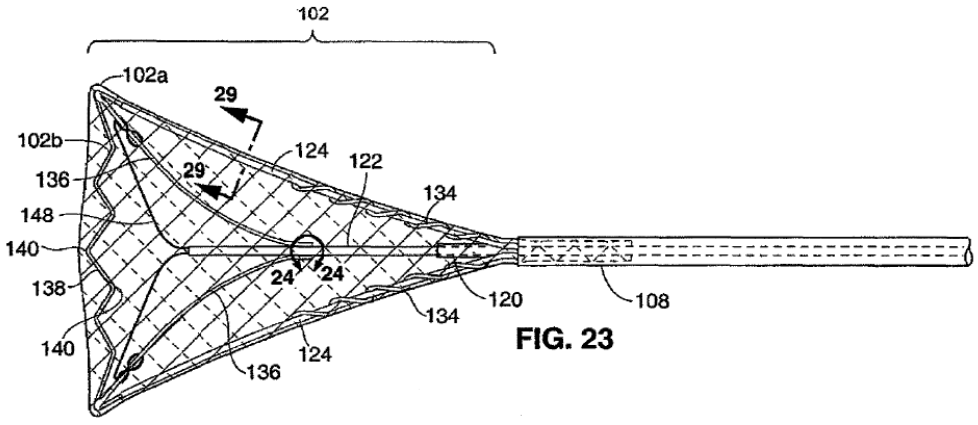

FIG. 23

Figure 23 depicts the applicator head of the ablation device of the second embodiment. *Id.* at 3:55–56. The '989 patent states:

> The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array. Naturally aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.

Id. at 11:59–64.

Applicator head 102 having a stretchable metallized fabric mesh electrode array 102a and an internal deflecting mechanism 102b, which expands the array. *Id.* at 12:12–18. Internal deflecting mechanism 102b includes flexures 124. *Id.* at 13:14–18. Flexures 124 have apertures 126 to allow moisture to be suctioned from the uterus and have conductive regions to deliver energy to electrode array 102a. *Id.* at 13:19–47. Internal deflecting mechanism 102b also include flexures 136 that extend laterally and longitudinally. *Id.* at 13:62–63.

D. Illustrative Claim

Claims 1 and 14 of the '989 patent are independent. Claims 2–13 depend from claim 1. Claims 14–19 depend from claim 14. Claim 1, reproduced below, is illustrative of the '989 patent.

> 1. A method for performing endometrial ablation comprising:
>
> transcervically positioning a distal portion of an ablation device into a uterus, the distal portion comprising an energy applicator, the energy applicator comprising a tissue contacting surface and an expandable-contractible carrying member, the expandable-contractible carrying member including first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve

and the first and second inner flexures being coupled to an inner sleeve, the inner sleeve being slidably and coaxially disposed within the outer sleeve;

actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus, the handle comprising a proximal grip and a distal grip pivotally attached to one another at a pivot point, and wherein actuating the handle includes moving the proximal grip and the distal grip closer together while translating the inner sleeve relative to the proximal grip;

actuating an inflation source to further expand the energy applicator in the uterus; and

delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Ground	Claims
§ 112(a) for failure to satisfy the written description requirement	1–19
§ 112(a) for lack of enablement	1–19

Petitioner proffers a Declaration of Dr. John Anthony Pearce (Ex. 1002) and a Declaration of Csaba Truckai (Ex. 1014), the named inventor of the ’989 patent, to support its analysis in the Petition.

II. ANALYSIS

A. Claim Interpretation

In a post-grant review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.200(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard in the similar context of *inter partes* review). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as they would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner proposes that the broadest reasonable construction of "flexure" is "a component capable of being bent or curved." Pet. 12–13. Patent Owner contends that it is unnecessary to construe the term "flexures" for the purposes of this decision. Prelim. Resp. 13.

For the purposes of this Decision, we determine that no explicit construction is needed to resolve the issues before us. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quotation omitted).

B. Post-Grant Review Eligibility

Petitioner has the burden of demonstrating eligibility for post-grant review. *See Mylan Pharms. Inc. v. Yeda Res. & Dev. Co.*, Case PGR2016-00010, slip op. at 10 (PTAB Aug. 15, 2016) (Paper 9). As required by 37

C.F.R. § 42.204(a), Petitioner certifies that Petitioner is not barred or estopped from requesting post-grant review of the '989 patent on the grounds identified in the Petition. Pet. 10.

The post-grant review provisions set forth in Section 6(d) of the AIA[3] apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) ("The amendments made by subsection (d) . . . shall apply only to patents described in section 3(n)(1)."). The first-inventor-to-file provisions apply to any application for a patent, and to any patent issuing thereon, that contains or contained at any time a claim to a claimed invention that has an effective filing date on or after March 16, 2013. *See* AIA § 3(n)(1). Section 3(n)(1) of the AIA provides that the effective filing date is:

> (A) if subparagraph (b) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or
>
> (B) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c).

35 U.S.C. § 100(i)(1).

The '989 patent issued on February 2, 2016 from U.S. Application No. 14/635,957 ("the '957 application"), which was filed on March 2, 2015. March 2, 2015 is after March 16, 2013. Thus, based on the filing date of U.S. Application No. 14/635,957 the '989 patent would be eligible for post-grant review.

The '989 patent, however, claims priority to parent applications filed prior to March 16, 2013, as follows:

> This application is a continuation of U.S. application Ser. No.14/278,741 filed May 15, 2014, now U.S. Pat. No. 8,998,898, which is a continuation of pending U.S. application Ser. No. 13/962,178 filed Aug. 8, 2013, which is a continuation of U.S. application Ser. No.12/581,506 filed Oct. 19, 2009, now U.S. Pat. No. 8,506,563, which is a continuation of U.S. application Ser. No. 10/959,771 filed Oct. 6, 2004, now U.S. Pat. No. 7,604,633, which is a divisional of U.S. application Ser. No. 09/103,072 filed Jun. 23, 1998, now U.S. Pat. No. 6,813,520, which claims the benefit of U.S. provisional application 60/084,791 filed May 8, 1998.

Ex. 1001, 1:6–16. Thus, based on the filing date of the applications to which the '989 patent claims priority, the '989 patent would not be eligible for post-grant review.

Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365, is premised on disclosure of the claimed invention in the manner provided by § 112(a) (other than the requirement to disclose the best mode)." *See* 35 U.S.C. §§ 119(e)(1), 120. Section 112(a) provides that

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skill in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .

35 U.S.C. § 112(a).

Petitioner contends that "[t]he '989 patent in not entitled to priority any earlier than its actual filing date, despite on its face claiming priority to a chain of applications dating back to 1998" and, thus, the claims of the '989 patent have an effective filing date after March 16, 2013 and are eligible for post-grant review. Pet. 13. According to Petitioner, the parent applications do not provide the required written description support. *See id.* at 16–51. Patent Owner disagrees that the '989 patent is eligible for post-grant review.

PO Resp. 13–29. Patent Owner argues that the claims of the '989 patent are entitled to its earliest claimed priority date, May 8, 1998, which is prior to March 16, 2013. *Id.* at 13–15.

The issue, thus, before us is whether the effective filing date of the '989 patent is the filing date of the '957 application, March 2, 2015, or the filing date of U.S. provisional application 60/084,791, May 8, 1998. To determine the effective filing date of the claims of the '989 patent, we must determine whether the specifications of the parent applications contain the required written description of the invention.

Written Description and the '506 Application

The test for written description is an objective inquiry into the four corners of the specification from the perspective of a POSA. Using this test, the invention must be described in a manner sufficient to demonstrate that the inventor actually invented the claimed invention. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). "One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Written description is a question of fact judged as of the relevant filing date. *Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006).

An *ipsis verbis* disclosure, however, is not necessary to satisfy the written description requirement. *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The disclosure need only reasonably convey to a POSA that the inventor had possession of the subject matter in question, even if every nuance of the claims is not explicitly described in the specification. *Id.; see Ariad*, 598 F.3d at 1351.

Both Petitioner and Patent Owner acknowledge that the specifications of the '957 application, from which the '989 patent issued, and each parent application are substantially the same and the applications only differ in their originally filed claims. Pet. 16, 38–49; Prelim. Resp. 6, n. 1, 15. For the purposes of our decision, the specification of U.S. Application No. 12/581,506 ("the '506 application"), filed Oct. 19, 2009, is exemplary of the specifications of the parent applications.[1]

Petitioner contends that the claims of the '989 patent require both a mechanical expansion means and an inflation expansion means. Pet. 15–16. For example, independent claim 1 requires "first and second inner flexures" that are components of an "expandable-contractible carrying member." Ex. 1001, claim 1. According to Petitioner, these are elements of a mechanical expansion means. Pet. 15. Claim 1 also requires "actuating an inflation source to further expand the energy applicator in the uterus," and Petitioner argues that this describes elements of an inflation expansion means. Pet. 15 (quoting Ex. 1001, claim 1). Independent claim 14 recites similar elements.

Petitioner argues that "the identical disclosures of the '989 patent and the parent '506 application do not describe an endometrial ablation device, or method of using such a device, with an applicator head containing ***both*** a mechanical expansion means and an inflation means." Pet. 16 (emphasis original). According to Petitioner, the '506 patent describes mechanical expansion and inflation as mutually exclusive alternatives. *Id.* at 16–30.

[1] Both Petitioner and Patent Owner use the specification of the '506 application as exemplary of the specification of all of the parent applications. *See* Pet. 16, Prelim. Resp. 6, n. 1.

Petitioner, further, argues that the mechanical expansion means and an inflation means are incompatible. *Id.* at 30–38.

Patent Owner disagrees. Prelim. Resp. 18–29. Patent Owner does not dispute that the independent claims require both a mechanical expansion means and an inflation expansion means. Patent Owner disputes that the '506 application disclose the mechanical expansion and the inflation expansion means as mutually exclusive alternatives and that they are incompatible expansion means. *Id.* at 17. According to Patent Owner, the '506 application discloses an ablation device that uses both a mechanical expansion means (i.e., spring members or flexures) and an inflation expansion means (i.e., a balloon) to expand an energy applicator. *Id.* at 6–11, 18–20.

The '506 application discloses two exemplary embodiments. Ex. 1008, 9:17–18. The '506 application only explicitly discloses an inflation expansion means (e.g., balloon 52) with respect to the first embodiment. *See id.* at 19:5–8. In this regard, the '506 application states:

> Because during use it is most desirable for the electrodes 14 on the surface of the electrode carrying means 12 to be held in contact with the interior surface of the organ to be ablated, the electrode carrying means 12 may be provide to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body.
>
> For example, referring to Fig. 11, alternative spring members 1 5a, 19a may be attached to the shaft 10 and biased such that, when in a resting state, the spring members are positioned in the fully resting condition shown in Fig. 11. Such spring members would spring to the resting condition upon withdrawal of the sheath 32 from the RF applicator head 2.
>
> Alternatively, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in

> Fig. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52. After insertion of the apparatus into the organ and following retraction of the sheath 32, the balloons 52 would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port 38 using an apparatus similar to the suction/insufflation apparatus 40.

Id. at 18:20–19:18. As can be seen from the above, the '506 application describes using balloons 52 as an alternative to spring members 15, 19 or spring members 15(a), 19(a). Petitioner's declarant Dr. Pearce testifies that a POSA would have understood from the specification of '989 patent, which is the same as the specification of the '506 application, that a POSA would have understood that the inflation expansion means is an alternative to the mechanical expansion means. *See* Ex. 1002 ¶¶ 45–51.

Patent Owner points to the use of the phrase "additional components inside it that add structural integrity" in the passage above (Ex. 1008, 18:22–25) to argue that the '506 application discloses an ablation device that has a combination of spring member 15, 19 and balloons 52. Prelim. Resp. 8–9, 18–19. Patent Owner's argument, however, is unpersuasive. At this stage of the post-grant review, Patent Owner proffers no evidence to show that a POSA would have understood from the use of the phrase "additional components" that balloons 52 would be used in addition to spring member 15 and 19, particularly, in light of the '506 application's use of the word "alternately" or "alternative" when describing balloons 52 and spring member 15(a), 19(a), respectively. Ex. 1008, 18:26–19:8; *see* Pet. 21–24.

Further, the ablation devices depicted in Figures 7, 11, and 20 also indicate that balloons 52 are alternatives to spring members 15, 19 or spring

members 15(a), 19(a). Figures 7, 11, and 20 are reproduced side-by-side below.

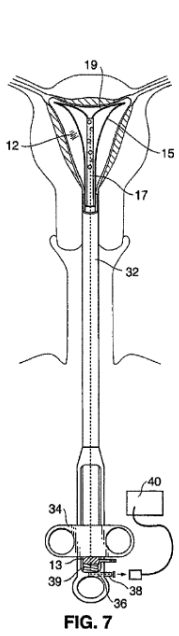

FIG. 7

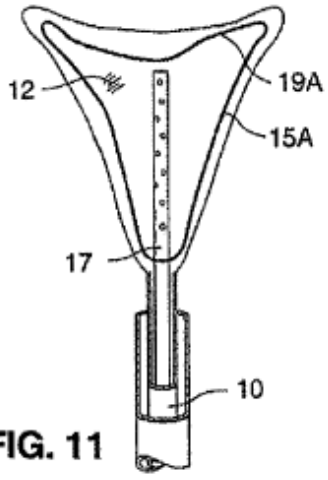

FIG. 11

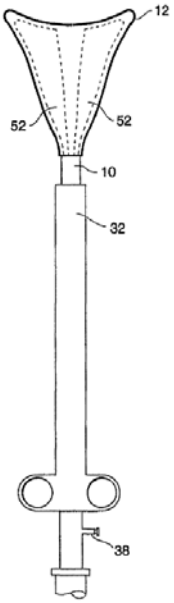

FIG. 20

Figures 7, 11, and 20 each depict configurations of the first embodiment of the ablation device. *See id.* at 18:20–19:18. Figure 1 depicts an ablation device showing expansion of the RF applicator head, using spring member 15 and 19. *Id.* at 5:15–18, 17:8–11. Figure 11 depicts an ablation device "which utilizes an alternative spring member configuration for the RF applicator head." *Id.* at 6:6–8, 18:26–19:4. Figure 20 depicts an ablation device "in which the electrode carrying means include inflatable balloons." *Id.* at 6:26–7:3, 19:5–12. As can be seen from the above, none of the figures reproduced above depict the use of spring members 15, 19 or spring members 15(a), 19(a) in combination with balloons 52. Nor do any other figures of the '506 application depict such a combination.

Patent Owner argues that Figure 20 depicts the combination of mechanical expansion means and inflation expansion means because the ablation device of Figure 20 shows the same finger cutouts shown in Figure

7. Prelim. Resp. 19–20. According to Patent Owner, because the '506 patent describes that the finger cutouts are used to mechanically expand the energy applicator, "the inclusion of finger cutouts in Fig. 20 means that the mechanical spring member components 15 and 19 are used to expand the applicator." *Id.* at 20. Patent Owner's argument is unpersuasive. At this stage of the post-grant review, Patent Owner proffers no evidence to show that a POSA would have understood that the inclusion of finger cutouts in Figure 20 means spring members 15, 19 are used in combination with balloons 52 in the ablation device depicted in Figure 20. For example, the '506 patent also describes using handle 34, having finger cutouts 37, to retract sheath 32 from the electrode carrying means 12 after insertion. Ex. 1008, 16:5–20. In Figure 20, finger cutout 37 may be used to retract sheath 32 and not to mechanically expand the energy applicator.

Patent Owner directs our attention to the '506 application's statement that "naturally, aspects of the first and second exemplary embodiment and their methods of operation may be combined without departing from the scope of the present invention" (Ex. 1008, 25:24–26) to further support its argument. Prelim. Resp. 20–23. On this record, Patent Owner's argument is unpersuasive. Dr. Pearce testifies that, based on the wider disclosure of the '506 patent, a POSA would understand this statement to say that the different electrode arrays and handle styles described in the first and second embodiments are combinable with the other embodiments and not to say that the mechanical expansion means, like springs 15, 19 or flexures 136, are combinable with inflation expansion means, like balloons 52. Ex. 1002 ¶ 72. At this stage of post-grant review, Patent Owner proffers no evidence to sufficiently rebut Dr. Pearce's testimony.

In addition to arguing that the ’506 patent fails to describe an ablation device that uses a combination of a mechanical expansion means and an inflation expansion means, Petitioner contends that such expansion means are incompatible with each other. Pet. 30–38. The ’506 patent provides no disclosure of how springs 15, 19 or flexures 136 would be used with balloons 52 to expand electrode carrying means 12. *See* Pet. 35–36. Dr. Pearce testifies that the use of springs 15, 19 or flexures 136 with balloons 52 would be incompatible or result in an inoperable ablation device for a number of reasons. Ex. 1002 ¶¶ 96–112. For example, Dr. Pearce testifies that spring members 15, 19 and balloons 52 occupy the same physical space within the electrode carrying means 12 and there is no adequate description or guidance in the ’506 application as to how they could be combined without interfering with or preventing the operation of the other. Ex. 1002 ¶¶ 107–110. As another example, Dr. Pearce testifies that the ’506 patent describes electrode carrying means 12 of both the first and second embodiments as permeable. *Id.* According to Dr. Pearce, permeability is a critical feature of the invention. *Id.* at ¶¶ 98–104. For instance, the ’506 patent discloses suctioning moisture released as the tissue is heated through the permeable material into suction/insufflation tube 17. Ex. 1008, 18:5–9, 42:2–5. According to Dr. Pearce, balloons 52 would be formed of a non-permeable material in order for it to inflate and would block the suction disclosed in the ’506 patent. Ex. 1002 ¶ 111; Pet. 37–38.

Patent Owner argues that neither Petitioner nor Dr. Pearce sufficiently show that a POSA would have combined spring members 15, 19 and balloons 52 in the manner asserted by Dr. Pearce or that the combination allegedly suggested by the ’506 application is incompatible. Patent Owner’s

argument is unpersuasive. Dr. Pearce relies upon the disclosures of the '506 application to support his testimony. *E.g.*, *see* Ex. 1002 ¶ 102 (citing to Ex. 1008 and annotating Figure 6 of the '506 application). At this stage of post-grant review, Patent Owner proffers no evidence to sufficiently rebut Dr. Pearce's testimony.

Finally, Petitioner proffers a declaration of Mr. Casaba Truckai, the sole named inventor of the '989 patent, to support its argument. Pet. 49–51. Mr. Truckai testifies that the '989 patent claims an invention, one that has both a mechanical expansion means and an inflation expansion means, that is not described in the '506 application or any other parent application. *See generally* Ex. 1014. Patent Owner argues that Mr. Truckai's testimony should be given little or no weight, because Mr. Truckai's testimony is not based upon what a POSA would have understood from the disclosures of the '506 application but allegedly upon his own subjective recollections. Prelim. Resp. 27–29. Patent Owner's argument is unpersuasive. At this stage of post-grant review, Mr. Truckai has not been cross-examined, and Patent Owner's arguments concerning his testimony are unsupported. During trial, Patent Owner will have the opportunity to cross-examine Mr. Truckai.

Upon consideration of all of Petitioner's evidence and arguments, taking into account Patent Owner's evidence and arguments, and on this record, we determine the claims of the '989 patent are not entitled to priority to the filing date of the '506 application or any other parent application because at least the '506 application fails to satisfy the written description requirement under 35 U.S.C. 112(a). Thus, the effective filing date of the

claims of the ’989 patent is after March 16, 2013, and the ’989 patent is eligible for post-grant review.

C. Written Description and the Specification of the ’989 patent

Petitioner contends that 1–19 are unpatentable for failure to satisfy the written description requirement of 35 U.S.C. § 112(a). Pet. 51–64. As both Petitioner and Patent Owner acknowledge, the specification of the ’989 patent, the ’506 application, and the other parent applications are substantially the same. *See* Pet. 16, 38–49, Prelim. Resp. 6, n. 1, 15. Petitioner relies upon substantially the same arguments and evidence that it relied upon with respect to the ’506 application to argue that the ’989 patent fails to provide adequate written description for the claimed invention. *E.g.*, *see* Pet. 53 (“[a]s discussed above with respect to PGR eligibility and the effective filing date of the ’989 patent”). Likewise, Patent Owner relies upon substantially the same arguments and evidence that it relied upon with respect to the ’506 application to argue that the ’989 patent provides adequate written description for the claimed invention. *See* Prelim. Resp. 29–33.

For the same reasons as discussed above, we determine that Petitioner has demonstrated that it is more likely than not that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for failure to satisfy the written description requirement.

D. Enablement and the Specification of the ’989 patent

Under 35 U.S.C. § 112(a), enablement is separate and distinct from the written-description requirement. *Ariad*, 598 F.3d at 1344. “The test of

enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). "[A] patent specification complies with the statute even if a 'reasonable' amount of routine experimentation is required in order to practice a claimed invention." *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors, referred to as the *Wands* factors, include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claims.

Wands, 858 F.2d at 737.

Petitioner contends that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement. Pet. 64–66. Petitioner argues that the '989 patent does not enable a POSA to make or use an ablation device having both a mechanical expansion means and an inflation expansion means as required by the claims of the '989 patent. *Id.* at 64. According to Petitioner, the specification of the '989 patent does not provide sufficient guidance to allow a POSA to make such an ablation device and, the lack of guidance would require a POSA to use undue experimentation to make or use the invention. *Id.* Further, Petitioner argues that "[t]he difficulty for a [POSA] to achieve the claimed subject matter in view of the specification would be

compounded by the fact that the mechanical and inflation based expansion means . . . are incompatible with each other" and would require a complete redesign and a substantial amount of time and cost. *Id.* at 65. Petitioner contends that the '989 patent provides no working examples of ablation devices having both mechanical expansion means and inflation expansion means. *Id.* at 65–66. Petitioner relies upon the testimony of its declarant Dr. Pearce to support its arguments. *See* Ex. 1002 ¶¶ 145–152

Patent Owner argues that neither Petitioner nor its declarant Dr. Pearce has addressed meaningfully all of the *Wands* factors. Prelim. Resp. 34–42. For example, Patent Owner argues that Petitioner fails to address meaningfully the amount of direction or guidance provided in the specification or whether the specification provides any working examples. *Id.* at 37–38. As another example, Patent Owner argues that Petitioner fails to address the relative skill of those in the art. *Id.* at 38–39. Thus, Patent Owner contends that Petitioner has not shown sufficiently that the claims of the '989 patent are unpatentable for lack of enablement.

Patent Owner's argument is unpersuasive. Contrary to Patent Owner's argument, Petitioner addresses the *Wands* factors sufficiently to show that a POSA could not make or use the invention from the disclosures in the '989 patent coupled with information known in the art without undue experimentation. For example, Petitioner sufficiently addresses whether the specification provides direction or guidance or provides any working examples. *See* Pet. 64–65. According to Petitioner, the '989 patent provides no direction or guidance and no working examples because, for the same reasons as discussed above with respect to the written description requirement, the mechanical expansion means and the inflation expansion

means are incompatible with each other. *Id.* at 64–65. Petitioner relies upon the testimony of Dr. Pearce to support its argument. *E.g.*, *see* Ex. 1002 ¶¶ 147–148. Dr. Pearce also testifies that:

> a person skilled in the relevant field as of [March 2, 2015] would include someone who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices.

Ex. 1002 ¶ 34; *see* Pet. 9. At this stage of post-grant review, Patent Owner proffers no evidence to sufficiently rebut Dr. Pearce's testimony regarding lack of enablement.

Upon consideration of all of Petitioner's evidence and arguments, taking into account Patent Owner's evidence and arguments, and on this record, we determine that Petitioner has demonstrated that it is more likely than not that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

III. CONCLUSION

On this record, we determine that Petitioner demonstrates that it is more likely than not that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for failure to satisfy the written description requirement and claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

The Board has not yet made a final determination as to the patentability of any of the challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 324(a), post-grant review of the '989 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 324(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds of:

claims 1–19 being unpatentable under 35 U.S.C. § 112(a) for failure to satisfy the written description requirement, and

claims 1–19 being unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

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