

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
MITCHELL G. WEATHERLY, *Administrative Patent Judges*.

PETRAVICK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Post-grant Review
35 U.S.C. § 328(a) and C.F.R. § 42.73

I. INTRODUCTION

A. Background

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.”). Petitioner relies on a Declaration of Dr. John Anthony Pearce (Ex. 1002) and a Declaration of Csaba Truckai (Ex. 1014) to support its analysis in the Petition.

We instituted post-grant review (Paper 9, “Inst. Dec.”) of the ’989 patent on the following grounds:

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

Hologic, Inc. (“Patent Owner”) filed a Patent Owner’s Response. Paper 13 (“PO Resp.”). Patent Owner relies on a Declaration of Dr. Warren Grundfest (Ex. 2005) to support its arguments in the Patent Owner’s Response.

Petitioner filed a Reply to the Patent Owner’s Response (Paper 18, “Pet. Reply”).

Patent Owner filed a Motion to Exclude Evidence. Paper 24 (“Mot.”). Petitioner filed an Opposition to the Motion to Exclude (Paper 29, “Opp. to Mot.”), and Patent Owner filed a Reply (Paper 30, “Reply to Mot.”).

Patent Owner and Petitioner filed briefing as to the impact of the Board’s decision in *Ex parte Truckai*, Appeal No. 2016-008146 (PTAB, Oct. 18, 2017). Papers 22, 26.

An oral hearing was held on January 24, 2018. A transcript of the hearing is included in the record. Paper 35 (“Tr.”).

After consideration of the parties’ arguments and evidence, and for the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–19 of the ’989 patent are unpatentable for failure to satisfy the written description requirement.

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.

The named inventor of the ’989 patent is Csaba Truckai. Ex. 1001, (72). Patent Owner acquired the ’989 patent when it acquired Cytac Corporation, which previously acquired the ’989 patent along with Novacept, Inc., a company co-founded by Mr. Truckai. See PO Resp. 17; Ex. 1001, (73) (listing Cytac Surgical Products as assignee). Mr. Truckai is also a founder of Petitioner, Minerva Surgical, Inc., and a named inventor on a number of patents and pending patent applications related to ablations devices. See PO Resp. 17–18; Papers 27, 28, 34.

In particular, Mr. Truckai is a named inventor in U.S. Patent Application No. 13/267,258, which was the subject of *Ex parte Truckai*. See Ex. 3001. The claims at issue in *Ex parte Truckai* were rejected over U.S. Patent Application No. 2002/0022870 (“the ’870 publication”), which also names Mr. Truckai as an inventor. *Id.* The ’870 publication is a publication of Patent Application No. 09/103,072, to which the ’989 patent claims priority. Ex. 1001, (60).

According to Patent Owner, “[the ’870 publication] and the ‘989 patent share a common specification; all passages and figures discussed by the Board [in *Ex parte Truckai*] thus have *identical* counterparts in the ‘989 patent.” Paper 22, 1–2; *see also* Paper 26, 2 (Petitioner stating, “the ‘989 and [the ’870 publication] do share a common specification”). A panel of the Board in *Ex parte Truckai* made certain findings of fact concerning the disclosure of the ’870 publication.¹ *See* Ex. 3001. Patent Owner contends that these findings of fact are “dispositive of Minerva’s core contention” here. Paper 22, 3. Petitioner disagrees because the decision in *Ex parte Truckai* is not precedential, the issue in *Ex parte Truckai* is fundamentally different than the issues here, and the record here is more fully developed than the record in *Ex parte Truckai*. Paper 26.

The issue in *Ex parte Truckai* is whether the ’870 publication anticipated the pending claims of U.S. Patent Application No. 13/267,258. The claims in that application differ from the claims here. *See e.g.*, Ex. 1001, 19:13–37; Ex. 3001, 2. Here, the issues concern written description support for and enablement of the invention claimed in the ’989 patent. Further, as acknowledged by the panel in *Ex parte Truckai*, the record here contains evidence not considered in *Ex parte Truckai*. *See* Ex. 3002, 4–5 (“we do not consider [in *Ex parte Truckai*] the evidence presented in the PGR petition”). For example, the record here contains testimony of Dr. Pearce and Dr. Grundfest. In *Ex parte Truckai*, Dr. Pearce’s testimony was not considered and Dr. Grundfest’s testimony was not of record. Given this, we do not consider the decision in *Ex parte Truckai* to dispose of any issues

¹ The decision in *Ex parte Truckai* is on appeal to the U.S. Court of Appeals for the Federal Circuit.

in this proceeding and will base the decision here on the issues and evidence in the record before us.

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 the body cavity.” *Id.* at Abstract.

Because the issues before us concern written description and enablement, an overview of the different embodiments disclosed in the '989 patent is helpful. The '989 patent discloses two types of exemplary embodiments. *Id.* at 4:55–57. The first type of embodiment also includes a number of alternative embodiments. *E.g., see id.* at 8:54–9:14. The challenged claims recite elements directed to the second type of embodiment. We first turn to a discussion of the second embodiment.

Second Embodiment

Figure 23 of the '989 patent is reproduced below. We have added labels and coloring to some of the elements recited by the challenged claims.

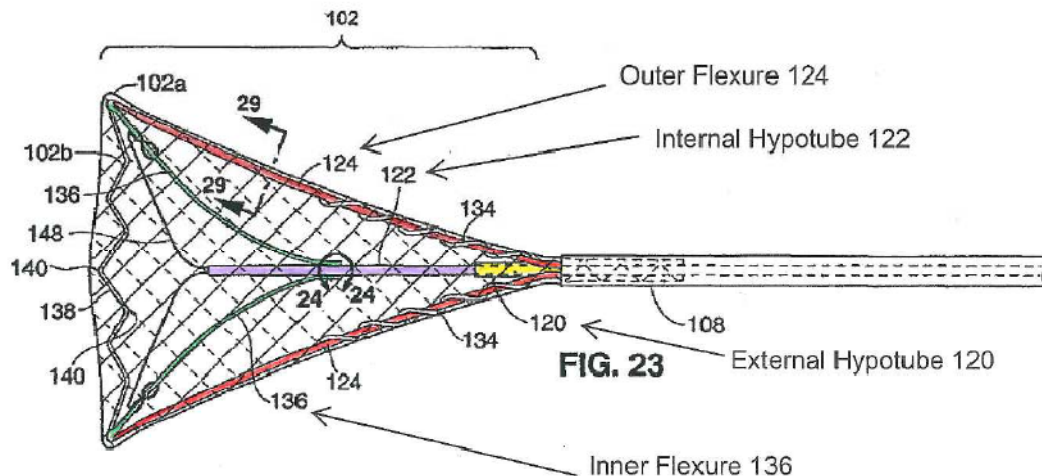


Figure 23 depicts the applicator head of the ablation device of the second embodiment. *Id.* at 3:55–56. Applicator head 102 has a stretchable metallized fabric mesh electrode array 102a and an internal deflecting mechanism 102b, which expands the array. *Id.* at 12:12–18. Internal deflecting mechanism 102b includes outer flexures 124 (colored red) and internal flexures 136 (colored green). *Id.* at 13:14–18, 13:62–63. Internal hypotube 122 (colored purple) is able to slide within external hypotube 120 (colored yellow). *Id.* at 13:15–18. “Flexures 124 extend from the tubing 108 on opposite sides of external hypotube 120.” *Id.* at 13:18–19. “[I]nternal flexures 136 extend laterally and longitudinally from the exterior surface of hypotube 122. Each internal flexure 136 is connected at its distal end to one of the flexures 124” *Id.* at 13:62–65.

Figure 22 of the '989 patent is reproduced below.

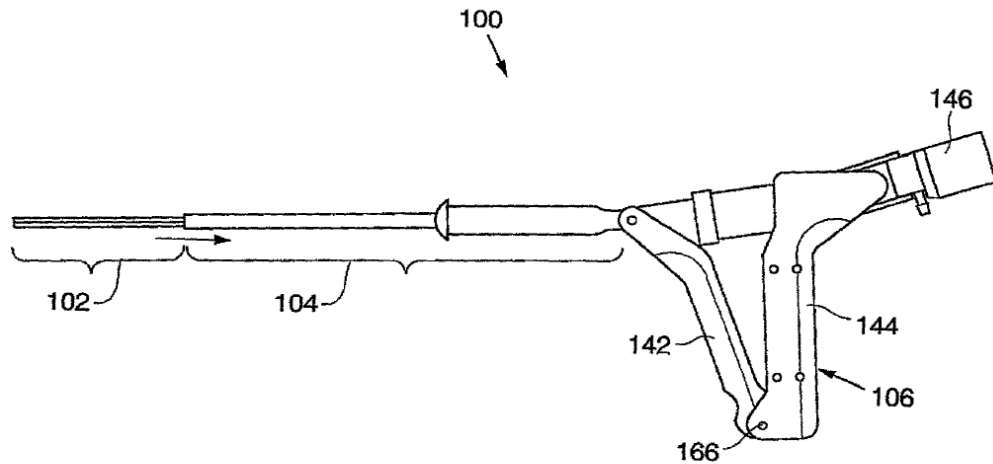


FIG. 22

Figure 22 depicts a side view of the ablation device of the second embodiment, showing the array in a deployed state. *Id.* at 3:53–54. The ablation device has handle 106 formed of distal grip 142 and proximal grip 144 connected by pivot point 166. *Id.* at 14:29–32, 16:14–20. Squeezing distal grip 142 and proximal grip 144 together deploys the applicator head 102, including rearward motion of hypotube 120 and forward motion of hypotube 122. *Id.* at 14:29–34, 16:21–31. “The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.” *Id.* at 14:34–36.

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.

First Embodiment

A first embodiment is depicted in Figures 1–10 and alternatives embodiments of the first embodiment are depicted in Figures 11 and 20. See *id.* at 2:51–3:44. Figure 7 of the '989 patent is reproduced below.

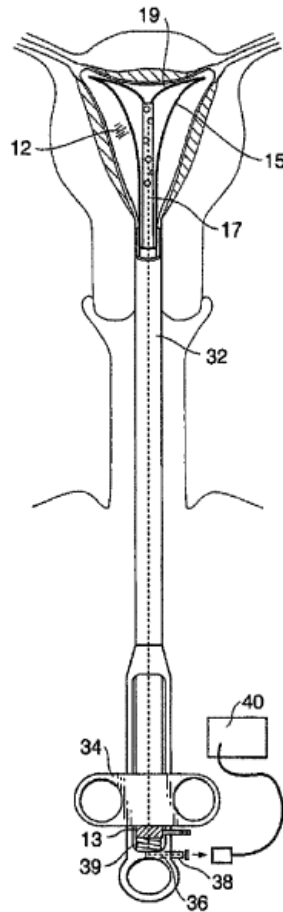


FIG. 7

Figure 7 depicts the ablation device of the first embodiment in an expanded state. See *id.* at 3:3–6. The ablation device includes an RF applicator head 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 expansion of electrode carrying means 12. *See id.* at 7:55–8:20, Figs. 6–7. Sheath 32 is retracted by manipulating handle 34. *Id.* at 7:55–56. Manipulating handle 34 causes shaft 10 to slide proximally or distally, causing the retraction or expansion of electrode carrying means 12. *See id.* at 7:55–8:25, 9:53–62, 11:48–52.

Figure 10 of the '989 patent is reproduced below.

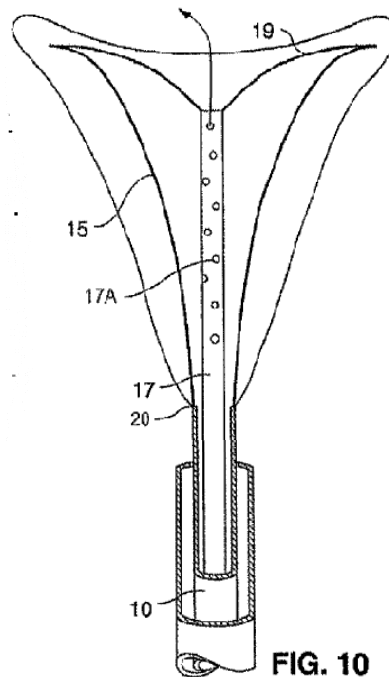


Figure 10 depicts the RF applicator head of the first embodiment. *See id.* at 3:16–20. “[P]assive spring member 15 [is] attached to the distal end of the shaft 10.” *Id.* at 5:5–6. “An arched active spring member 19 is connected between the distal ends of the passive spring members 15 and the distal end of the suction/insufflation tube 17.” *Id.* at 5:9–11. “The amount by which the springs 15, 19 are spread may be controlled by manipulating the handle 34 to slide the shaft 10 . . . proximally or distally. Such sliding movement of the shaft 10 causes forceps-like movement of the spring members 15, 19.” *Id.* at 8:21–25.

Figure 11 of the '989 patent is reproduced below.

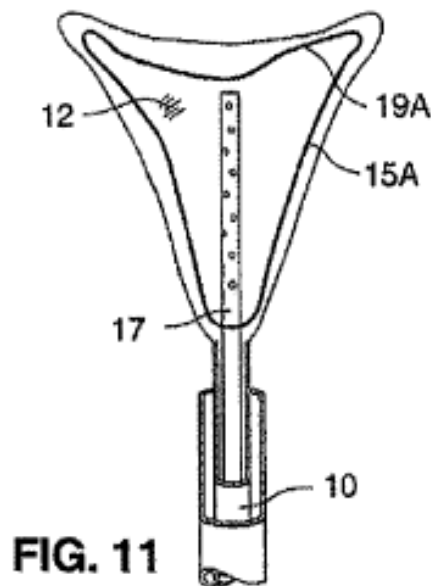


Figure “11 is a cross-section view of a distal portion of an RF ablation device similar to FIG. 1 which utilizes an alternative spring member configuration for the RF applicator head.” *Id.* at 3:21–23. Figure 11 depicts an ablation device having “alternative spring members 15a, 19a” attached to shaft 10. *Id.* at 8:60–63. Alternative spring members 15a, 19a have a resting state as shown in Figure 11 and “[s]uch spring members would

spring to the resting condition upon withdrawal of the sheath 32 from the RF applicator head 2.” *Id.* at 8:63–65.

Figure 20 of the '989 patent is reproduced below.

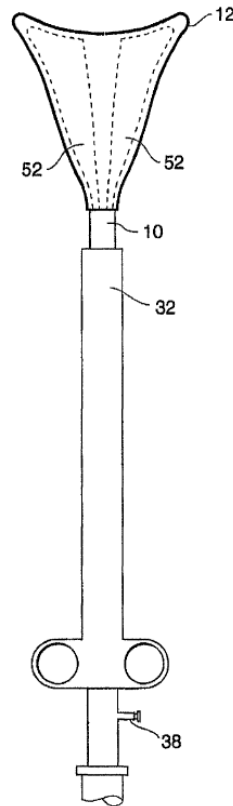


FIG. 20

Figure “20 is a side elevation view, similar to the view of FIG. 2, showing an ablation device according to the present invention in which the electrode carrying means includes inflatable balloons.” *Id.* at 3:45–48. The '989 patent states:

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 balloon 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 8:66–9:2.

D. Illustrative Claims

Claims 1 and 14 of the '989 patent are independent. Claims 2–13 depend from claim 1. Claims 15–19 depend from claim 14. Claims 1 and 5, reproduced below, are illustrative of the challenged claims.

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.

5. A method as in claim 1, wherein the expandable-contractible carrying member comprises a balloon.

E. Nomenclature

In the record, the parties refer to “mechanical expansion” and “inflation expansion.” *E.g. see*, Pet. 15; PO Resp. 2. For consistency, we also refer to mechanical expansion and inflation expansion. Our reference to mechanical expansion, however, is to the specific mechanical expansion recited by claims 1 and 14. Claims 1 and 14 recite limitations directed to a specific mechanical expansion of the carrying member. In this regard, claim 1 recites

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 . . .

and

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.

Independent claim 14 recites similar limitations. Ex. 1001, 20:15–38. The claimed mechanical expansion of the carrying member corresponds to mechanical expansion described in the second embodiment of the ’989 patent. The second embodiment of the ’989 patent is the only embodiment described as having inner and outer flexures connected to inner and outer sleeves, in which the inner sleeve translates by actuating a proximal grip pivotally attached to the distal grip. *See generally* Ex. 1001.

Similarly, our reference to inflation expansion is specifically to the inflation expansion recited by the claims. Claim 1 recites “actuating an inflation source to *further expand* the energy applicator in the uterus.” *Id.* at 19:34–35 (emphasis added). Claim 14 recites a similar limitation. *Id.* at 20:39–40. As claimed, the inflation expansion is *further* expansion of the energy applicator. Both Petitioner and Patent Owner point to Figure 20 of the ’989 patent as depicting inflation of the applicator using balloons. *E.g.* see, Pet. 1; PO Resp. 9–10. Dependent claim 5 recites, “wherein the expandable-contractible carrying member comprises a balloon.” Ex. 1001, 19:44–45.

We keep this nomenclature in mind in our analysis below concerning written description and enablement because our analysis focuses on the invention as claimed.

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 a broadest reasonable construction of “flexure.” Pet. 12–13. Patent Owner contends that it is unnecessary to construe the term “flexures” for the purposes of resolving the grounds at issue here. PO Resp. 22. We agree and determine that no explicit construction of any claim term 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.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. Level of Ordinary Skill in the Art

Petitioner and Patent Owner dispute the level of ordinary skill in the art. *See* Pet. 9–10, PO Resp. 23–27, Pet. Reply. 1–3. Petitioner contends that Dr. Pearce’s testimony is based on the understanding of a person of skill in the art (“POSA”) at the time of filing of the ’989 patent. Pet. 9–10 (citing Ex. 1002); Pet. Reply 1–3. Dr. Pearce 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

and

[a] person skilled in the relevant field would have been aware of developments in the field of electrosurgical devices and would have been working with trends toward increasing the effectiveness, safety, and ease of operation of such devices. Such a person would also have been familiar with known techniques for minimally invasive surgery.

Ex. 1002 ¶¶ 34, 35.

Patent Owner argues that Dr. Pearce’s testimony concerning the skill in the art is “erroneous at least to the extent that it does not explicitly require any experience with uterine surgical devices, procedures and anatomy, as well as other types of minimally invasive surgical devices that employ expandable inflation-based and mechanical-based components.” PO Resp. 23. Patent Owner argues that the level of ordinary skill must reflect this because the claims are limited to endometrial ablation and because of unique considerations related to the design and implementation of surgical tools for transcervical uterine procedures. *Id.* at 23–25. Patent Owner states that a POSA “must have training in the anatomy and physiology of the uterus, and cannot glean applicable analogous experience merely from working with other internal organs, or from generic knowledge of basic surgical procedures and principles.” *Id.* at 25. Patent Owner relies upon the testimony of Dr. Grundfest for support and argues that a POSA must also have experience with “other types of minimally invasive surgical devices that employ expandable inflation-based and mechanical-based components.” *See* PO Resp. 23 (citing Ex. 2005 ¶¶ 47–54).

Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.

Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007) (quoting *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)).

We are not persuaded that Dr. Pearce’s testimony concerning the level of skill in the art is erroneous to the extent it does not explicitly require experience related to devices used for uterine surgical procedures or surgical devices that employ expandable inflation-based and mechanical-based components. Patent Owner’s argument and Dr. Grundfest’s testimony is inconsistent with the ’989 patent, which does not disclose an ablation device or method of using an ablation device that solves problems unique to endometrial ablation or unique to surgical devices that employ expandable inflation-based and mechanical-based components. The ’989 patent does not limit the art to be “the field of minimally invasive surgical and uterine devices” (Ex. 2005 ¶ 60). The ’989 patent states: “The present invention relates generally to the field of apparatuses and methods for ablating or coagulating the interior surfaces of body organs. Specifically, it relates to an apparatus and method for ablating the interior linings of body organs such as the uterus and gallbladder.” Ex. 1001, 1:20–24; *see also id.* at 2:36–38 (“The present invention is an apparatus and method of ablation and/or coagulating tissue, such as that of the uterus or other organ”).

Patent Owner argues that because of prior art problems unique to endometrial ablation, such as visualizing the surgical site, providing the appropriate amount of heat, and the variability in size and shape of the uterus, the level of ordinary skill in the art must include experience with uterine devices. PO Resp. 24–25. The ’989 patent also discloses similar prior art problems, as well as others, but does not describe them as unique to endometrial ablation as opposed to general ablation of other organs. *See* Ex. 1001, 1:28–2:32, 5:49–51. The invention of the ’989 is also not a solution to alleged prior art problems that are unique for use in endometrial

ablations. The '989 patent discloses that its ablation device may be used to ablate other organs as well as the uterus. For example, the '989 patent discloses that its electrode carrying means 12 may have a shape that approximates “the shape of the body organ,” such as a uterus, or “a shape which is generally tubular and thus is not specific to any particular organ shape.” *Id.* at 5:49–56, 9:14–24. A general shape “is useful for bleeding control during laparoscopic surgery (FIG. 14), tissue ablation in the prostate gland (FIG. 17), and also intrauterine ablation (FIGS. 15 and 16).” *Id.* at 9:18–24. Further, Dr. Grundfest’s cross-examination testimony indicates that an ablation device may be designed for a more general use rather than specifically for just use in the uterus. *See* Ex. 1020, 19:11–20:22, 27:56–29:6 (testimony describing designing ablation devices for a variety of uses); *see also id.* at 31:14–19 (“as one accumulates understanding of mechanical devices and of energy imparting devices one doesn’t just have blinders on, you learn to develop expertise in one field and then apply it in the next field”). We, thus, are not persuaded by Patent Owner that the level of ordinary skill in the art requires experience related to devices used for uterine surgical procedures.

For similar reasons, we are not persuaded by Patent Owner that the level of ordinary skill in the art requires experience with minimally invasive surgical devices that employ both expandable inflation-based and mechanical-based components that are asserted through the cervical os. *See* PO Resp. 24. The '989 patent mentions no problems with asserting an ablation device through the cervical os or that its invention solves any such problem. As can be seen from our summary above, the '989 patent discloses multiple embodiments of its ablation device, including some that use

mechanical-base components and some that use inflation-based components. *See e.g.*, Ex. 1001, Figs. 6, 7, 10, 11, 20, 23.

We are not persuaded that Dr. Pearce's testimony concerning the level of skill in the art is erroneous to the extent it does not explicitly require experience related to devices used for uterine surgical procedures or surgical devices that employ expandable inflation-based and mechanical-based components. Based on the evidence and arguments of record, we are persuaded that, as Dr. Pearce testifies, a POSA would have education or practical experience 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.

C. Weight of Dr. Pearce's Testimony

Patent Owner contends that we should give Dr. Pearce's testimony little or no weight because:

Nothing in Dr. Pearce's declaration (Ex. 1002) or curriculum vitae (Ex. 1003) reflects specific knowledge, training or experience in (i) the *design* of surgical tools for any purpose, much less for uterine or other types of minimally invasive surgery; (ii) the anatomy and physiology of the uterus; or (iii) any experience whatsoever with the design of mechanical or balloon-based expansion mechanisms in a surgical setting.

PO Resp. 13–14. Petitioner disagrees. Pet. Reply. 3–6.

Patent Owner's argument is unpersuasive. Dr. Pearce has sufficient expertise in the design of surgical tools, including the design of mechanical or balloon-based expansion mechanisms to testify as to what a POSA would have understood from the '989 patent and its parent applications. As

Petitioner points out, “Dr. Pearce is one of the preeminent experts in electrosurgery and ablation techniques.” Pet. Reply 4 (citing Ex. 1002 ¶¶ 1–7); *see also* Ex. 1020 34:11–35:1, 82:12–25 (Dr. Grundfest testifying that Dr. Pearce “clearly has developed a very good reputation as an expert on electrosurgical safety” and is “well known for his capabilities in electrosurgical delivery”). Dr. Pearce holds multiple engineering degrees, conducts research related to “tissue fusion, coagulation and cutting processes with electrosurgery,” and serves as an instructor in surgery and biometry and electrical and biomedical engineering. Ex. 1002 ¶¶ 1–4; Ex. 1003. He has experience related to minimally invasive surgery. Ex. 2003, 13:20–14:19, 32:20–22:4. He is an author of numerous publications related to the topics of tissue tearing and coagulation, electrosurgery, and biomedical instrumentations. Ex. 1002 ¶ 7; Ex. 1003.

We are not persuaded by Patent Owner that Dr. Pearce requires specific knowledge, training or experience with the anatomy or physiology of the uterus to competently testify before us. Patent Owner bases its argument upon its narrow definition of the level of ordinary skill in the art. *See* PO Resp. 13–16, 23–27. As discussed above, the level of ordinary skill in the art is not so narrow as to require experience with the anatomy or physiology of the uterus. In any event, Dr. Pearce does have some knowledge of endometrial ablation devices. *See* Ex. 2021, 72:10–21, 25:1–27.

Based on the evidence and arguments of record, we are persuaded that Dr. Pearce is qualified to testify as to what a POSA would have understood from the ’989 patent and its parent applications and not persuaded that Dr. Pearce’s testimony should be given little or no weight.

D. 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 it 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 Leahy-Smith America Invents Act (“AIA”) 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 defined in section 100(i) of title 35, United States Code, which states:

(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. The '989 patent states:

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 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 skilled 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 is 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. 66–67. 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.*

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.

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; PO Resp. 67. For the purposes of our decision, the specification of U.S. Application No. 12/581,506 (Ex. 1008, “the '506 application”), filed Oct. 19, 2009, is exemplary of the specifications of the parent applications.

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.

Petitioner contends that the claims of the ’989 patent require both mechanical expansion and inflation expansion. Pet. 15–16. 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.” *Id.* at 16 (emphasis original). According to Petitioner, the ’506 application describes mechanical expansion and inflation expansion as mutually exclusive alternatives. *Id.* at 16–30. Further, Petitioner argues that the ’506 application does not disclose that the inflation expansion *further* expands the energy applicator. Pet. Reply 11.

Patent Owner does not dispute that the independent claims require both mechanical expansion and inflation expansion and contends that the

'506 application discloses a device that uses both mechanical expansion and inflation expansion. PO Resp. 27–35, 66.

The second embodiment of the '506 application discloses mechanical expansion, as required by the claims. *See* Ex. 1008, 41:1–42:4; *see also* Ex. 1001, 11:55–14:36. One alternative of the first embodiment of the '506 application discloses inflating balloons to expand an electrode carrying member. Ex. 1008, 23:5–12; *see also* Ex. 1001, 8:66–9:7. The '506 application does not explicitly disclose in detail an embodiment having both mechanical expansion and inflation expansion. *Generally* Ex. 1008; Ex. 1001; *see* Ex. 1002 ¶¶ 46–95 (testimony of Dr. Pearce). Similarly, the figures of the '506 application depict either mechanical expansion or balloon expansion, and no figure depicts an embodiment having both mechanical expansion and inflation expansion. *See Generally* Ex. 1008; Ex. 1020, 63:16–20 (cross-examination testimony of Dr. Grundfest).

The '506 application does make general statements concerning the combinability of the disclosed embodiments. Petitioner and Patent Owner dispute whether a POSA would have understood from the general statements that the inventor had possession of an embodiment that used both the mechanical expansion of the second embodiment and inflation expansion, such as by using balloons 52 of the one alternative of the first embodiment. First, with respect to the second embodiment, the '506 application 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.

Ex. 1008, 29:24–30:3; *see also* Ex. 1001, 11:59–64. Patent Owner argues that, based on this passage the ’506 application expressly contemplates combining the inflatable balloons of the alternative of the first embodiment with the mechanical expansion of the second exemplary embodiment. PO Resp. 28–31. Petitioner responds that, “[t]his generic statement is insufficient to convey written description of the specific combination recited in the claims” and argues that a generic statement “cannot possibly create a presumption that **all** aspects of both embodiments may be combined absent an express statement to the contrary.” Pet. Reply 11–13; *see also* Pet. 26–27.

Although this passage states that “aspects” of the first and second embodiments may be combined, it does not specify which aspects or how those aspects are combined. In particular, it does not explicitly state or suggest that balloons 52 of the alternative of the first embodiment may be combined with the second embodiment, in such a way that that balloons 52 provide a further inflation expansion to the mechanical expansion of the second embodiment. *See* Pet. Reply 11; *see also* Ex. 1002 ¶ 72 (testimony of Dr. Pearce). Dr. Grundfest testifies that a POSA would understand from this passage that aspects of the first and second embodiment may be combined, including combining expansion mechanisms. *See* Ex. 2005 ¶¶ 79–86. Dr. Grundfest’s testimony, however, does not address whether a POSA would know from this passage that the invention described in the ’989 patent included combining of balloons 52 of the first embodiment with the second embodiment in such a way that balloons 52 provide for further inflation expansion to the mechanical expansion. *See id.* We, thus, are persuaded by Petitioner that this passage does not provide sufficient written

description support for an embodiment having both mechanical expansion and inflation expansion, as required by the claims of the '989 patent.

With respect to the first embodiment, 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 15a, 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.

Structural integrity may also be added to the electrode carrying means through the application of suction to the proximal end 22a of the suction/inflation tube 17. Application of suction using the suction/insufflation device 40 would draw the organ tissue towards the electrode carrying means 12 and thus into better contact with the electrodes 14.

Ex. 1008, 22:20–23:18 (emphases added); *see also* Ex. 1001, 8:54–9:13.

Patent Owner argues that this passage provides a list of “approaches” for adding additional components to expand the electrode carrying means 12 of the first embodiment. PO Resp. 32–35. Patent Owner asserts that based

on this passage a POSA would know that the approaches could be combined in numerous ways and, therefore, a POSA would “not perceive a combination of combine[d] mechanical and balloon-based inflation to be mutually exclusive approaches to providing structural integrity to the applicator head within the uterus.” *Id.* at 34–35. In particular, Patent Owner argues that this passage “reasonably conveys the addition of inflation-based components to a mechanically expandable applicator head.” *Id.* at 32.

Petitioner responds that Patent Owner’s argument is “at odds with the plain language of the specification.” Pet. Reply 13. According to Petitioner, the use of the word “additional” in the passage above does not necessarily lead to the conclusion that the approaches can be combined, particularly when the approaches are described as alternatives in the ’989 patent. *Id.* at 13–15; *see also* Pet. 22–24.

Petitioner’s argument is persuasive. The statement in the first paragraph of the passage that additional components may be used to expand electrode carrying means 12 of the first embodiment does not necessarily lead to the conclusion that balloons 52, depicted in Fig. 20, may be added to spring members 15 and 19, depicted in Fig. 7. *See* Ex. 1002 ¶¶ 65–68. First, as Petitioner points out, the alleged list of approaches includes spring members 15a, 19a, which are alternatives for spring members 15, 19. Ex. 1008, 22:26; *see also* Ex. 1001, 8:60–65, Fig. 11; Pet. Reply 13–14. “FIG. 11 is a cross-section view of a distal portion of an RF ablation device similar to FIG. 1 which utilizes an *alternative spring member configuration* for the RF applicator head.” Ex. 1008, 10:6–8 (emphasis added); *see also* Ex. 1001, 3:21–23. Figure 11, reproduced above, does not depict the applicator head having both spring members 15, 19 and alternative spring

members 15a, 19a. *See* Ex. 1008, 53; *see also* Ex. 1001, Fig. 11. Thus, although alternative spring members 15a, 19a are described as additional components that may add structural integrity, the '989 patent explicitly describes them as alternatives to spring members 15, 19.

Similarly, the '989 patent's description of the alternative of the first embodiment or approach having balloons 52 starts with “[a]lternatively, a pair of inflatable balloons 52 may be” Ex. 1008, 23:5; *see also* Ex. 1001, 8:66; Ex. 1002 ¶ 67. Further, the paragraph describing this approach goes on to say: “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” Ex. 1008, 23:8–11; *see also* Ex. 1001, 9:2–7. Notably, this sentence states that inflation occurs after retraction of the sheath 32 and not after expansion by spring members 15, 19.

Figure 20 depicts this alternative of the first embodiment or approach. Ex. 1008, 23:5–6; *see also* Ex. 1001 8:66–9:1. The '989 patent states: “FIG. 20 is a side elevation view, similar to the view of FIG. 2, showing an ablation device according to the present invention in which the electrode carrying means *includes* inflatable balloons.” Ex. 1008, 10:26–11:3 (emphasis added); *see also* Ex. 1001, 3:45–48. Patent Owner argues that a POSA “would understand the use of the verb ‘includes’ to indicate that balloons would be used together with other structure in the expanded applicator head, chief among it the mechanical expansion means described and depicted throughout the specification.” PO Resp. 33 (citing Ex. 2005 ¶ 109). To the contrary, however, Figure 20, reproduced above, depicts the electrode carrying means including only inflatable balloons and not

including both balloons and spring members 15, 19. Ex. 1008, 56; *see also* Ex. 1001, Fig. 20; Ex. 1020, 62:2–11. Neither spring members 15, 19 nor tube 17, to which they are attached, are depicted in Figure 20. Ex. 1008, 56; *see also* Ex. 1001, Fig. 20.

Upon consideration of Petitioner’s evidence² and arguments, taking into account Patent Owner’s evidence and arguments, 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.

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

Petitioner contends that claims 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

² Petitioner relies on testimony of the ’989 patent’s named inventor Csaba Truckai to support its argument concerning the lack of written description. Pet. 49–51 (citing Ex. 1014). Mr. Truckai testifies that he did not invent the method claims challenged. *See* Ex. 1014 ¶¶ 11–17. The test for written description, however, is an objective inquiry into the four corners of the specification from the perspective of a POSA. *Ariad Pharm., Inc* 598 F.3d at 1351; *see also Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984) (“Realistically, courts never have judged patentability by what the real inventor/applicant/patentee could or would do.”). As discussed in our analysis, the testimony of Dr. Pearce, certain testimony of Dr. Grundfest, and the disclosure of the ’989 patent establish lack of written description. We do not rely upon the testimony of Mr. Truckai.

the '989 patent and the '506 application are substantially the same and differ only in the originally filed claims. *See* Pet. 16, 38–49, PO Resp. 67.

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 Specification of the '989 patent provides adequate written description for the claimed invention. *See* PO. Resp. 27–35, 67. For the reasons discussed above, we determine that the Specification of the '989 patent fails to provide adequate written description for its claimed invention.

In addition, Patent Owner argues that the originally filed claim 1 of the '957 application, from which the '989 patent issued, provides written description support. PO Resp. 35–38.

Original claim 1 recites:

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;

actuating the carrying member to expand the energy applicator in the uterus;

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.

Ex. 1004, 50–51 (emphases added). Patent Owner argues that original claim 1 includes two expansion steps—a mechanical-based expansion and an inflation-based expansion. PO Resp. 36. Petitioner argues that original claim 1 is directed solely to the alternative of the first embodiment that uses balloons and does not recite the combination of the mechanical expansion of the second embodiment and the balloon expansion of the alternative of the first embodiment. Pet. 61–62; Pet. Reply 16–17.

We are persuaded by Petitioner’s argument and evidence that original claim 1 of the ’957 application fails to provide adequate written description for the claimed invention of the ’989 patent. As Dr. Pearce testifies, original claim 1 is directed solely to the alternative of the first embodiment, having balloons 52 and depicted in Fig. 20. See Ex. 1002 ¶¶ 115–120; Pet. 61–62. With regard to the alternative of the first embodiment, the ’989 patent states: “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” Ex. 1001, 9:2–7. The first actuating step of original claim 1 corresponds to the retraction of sheath, which would release the housing from around the balloon allowing it to expand to its natural size. See Ex. 1020, 66:6–69:9 (testimony of Dr. Grundfest). The second actuating step of original claim 1 corresponds to the inflation of the balloon. The dependent claims further confirm that original claim 1 is directed to the alternative first embodiment, having balloons 52. Original claim 6 recites, “wherein the expandable-contractible carrying member comprises a balloon.” Ex. 1004, 50. Original claim 10 recites, “actuating the carrying member includes eliminating compression of the

carrying member,” and original claim 11 recites, “eliminating compression releases the carrying member to its natural size.” Ex. 1004, 51.

For the reasons as discussed above, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for failure to satisfy the written description requirement.

F. Enablement and the Specification of the '989 patent

Petitioner contends that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement. Pet. 64–66; Pet. Reply 24–26. Patent Owner disagrees and argues that Petitioner fails to meet its burden in showing that the claims of the '989 patent are unpatentable for lack of enablement. PO Resp. 51–67, 58–66.

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 or absence 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 breadth of the claims.

Wands, 858 F.2d at 737.

It is Petitioner's burden to show by a preponderance of the evidence that the claims of the '989 patent lack enablement. 35 U.S.C. § 326(e). Petitioner's evidence and argument does not sufficiently establish that the '989 patent fails to teach those in the art to make and use the claimed invention without undue experimentation. *See* PO Resp. 58–66. The Petition does not address the *Wands* factors sufficiently so as to show that undue experimentation is required to make or use the claimed invention. For example, neither the Petition nor Dr. Pearce sufficiently addresses the state of the prior art or the relative skill of those in the art. *See* Pet. 64–65; Ex. 1002 ¶¶ 145–152; PO Resp. 62. As Patent Owner argues, this is an “omission[] that [is] particularly fatal” to Petitioner's enablement argument, because Petitioner argues that mechanical expansion and inflation expansion are incompatible and cannot be combined. PO Resp. 62; *see* Pet. 30–38, 64. Dr. Grundfest, however, testifies that it was well known to combine mechanical and balloon-based expansion in surgical devices. Ex. 2005 ¶¶ 132–136; PO Resp. 56. During cross-examination, Dr. Pearce testified that he “thought about the state-of-the-art in minimally invasive surgery during the 1990s.” Ex. 2003 18:1–14. Dr. Pearce's testimony is conclusory and does not sufficiently address whether he considered whether it was well known to combine mechanical expansion and inflation expansion in surgical devices.

For another example, relying upon the testimony of Dr. Pearce, the Petition asserts that a redesign of the expansion design disclosed in the '989 patent “would take a substantial amount of time and cost to achieve.” Pet. 65 (citing Ex. 1002 ¶ 149). Likewise, Dr. Pearce testifies, “[s]uch a redesign would take a substantial amount of time and cost to achieve.” Ex. 1002 ¶ 149. Dr. Pearce, however, does not explain sufficiently why combining mechanical expansion and inflation expansion would require a substantial amount of time and cost. *See id.*

For these reasons, we determine that Petitioner has not met its burden of showing by a preponderance of evidence that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

III. MOTION TO EXCLUDE

Patent Owner moves to exclude the Declaration of John Anthony Pearce (Ex. 1002), the Declaration of Csaba Truckai (Ex. 1014), and Exhibits 1018, 1019, 1021, 1022, and 1023. Mot. 2.

A. Declaration of John Anthony Pearce (Ex. 1002)

Patent Owner requests that Exhibits 1002 (testimony of Dr. Pearce) be excluded under Federal Rule of Evidence (“FRE”) 702 because, according to Patent Owner, Dr. Pearce is not qualified. Mot. 3–6; Mot. Reply 1–3.

Patent Owner argues that Dr. Pearce is not qualified to testify because “his Declaration fails to recite any relevant training or experience in the design of surgical devices, the anatomy of the uterus, or the combination of mechanical and balloon-base expansion mechanisms in a surgical setting.” Mot. 4. Patent Owner also argues that Dr. Pearce’s opinions are not helpful to the Board because Dr. Pearce is not qualified to testify as to what a POSA

would understand and his opinions are not based upon sufficient facts or data. *Id.* at 4–5.

Petitioner disagrees and argues that Dr. Pearce is a qualified expert and, thus, his testimony is helpful to the Board. *Opp. to Mot.* 2–5.

Federal Rule of Evidence 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

We are not persuaded by Patent Owner that Dr. Pearce’s testimony should be excluded under FRE 702. Patent Owner’s arguments are based upon their definition of a POSA, which we did not adopt above. For the reasons discussed above, we determine that Dr. Pearce is qualified to testify as to the knowledge and understanding of a POSA.

Patent Owner also argues that Dr. Pearce’s testimony is unhelpful, for a number of reasons, such as being conclusory. *Mot.* 4–5. Patent Owner’s arguments go to the sufficiency of Dr. Pearce’s testimony, but not its admissibility. A motion to exclude is not the proper vehicle to challenge the sufficiency of the evidence to prove a particular fact. *See Office Patent Trial Practice Guide*, 77 Fed. Reg. at 48,767. Rather, it is within our discretion to

assign the appropriate weight to be accorded to evidence. *See, e.g., Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding Board has discretion to give more weight to one item of evidence over another “unless no reasonable trier of fact could have done so”); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) (“[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.”); *Velandier v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) (“In giving more weight to prior publications than to subsequent conclusory statements by experts, the Board acted well within [its] discretion.”)

Patent Owner’s motion to exclude Exhibit 1002, the testimony of Dr. Pearce is denied.

B. Declaration of Csaba Truckai (Ex. 1014) and Exhibits 1018, 1019, 1021, 1022, and 1023

We do not reply upon Exhibits 1014, 1018, 1019, 1021, 1022, and 1023 in our analysis above. Patent Owner’s Motion to Exclude Evidence as to these exhibits is dismissed as moot.

IV. CONCLUSION

We determine that Petitioner demonstrates by a preponderances of the evidence that the ’989 patent is eligible for post-grant review and that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for failure to satisfy the written description requirement. We also determine that Petitioner fails to demonstrate by a preponderance of the evidence that claims 1–19 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–19 of U.S. Patent No. 9,247,989
B2 are *unpatentable*; and

FURTHER ORDERED that Patent Owner’s Motion to Exclude
Evidence is *denied-in-part* and *dismissed-in-part*.

PETITIONER:

Michael Rosato
Matthew Argenti
Steven Parmelee
WILSON SONSINI GOODRICH & ROSATI
mrosato@wsgr.com
margenti@wsgr.com
sparmelee@wsgr.com

PATENT OWNER:

Jennifer A. Sklenar
Wallace Wu
ARNOLD & PORTER LLP
Jennifer.Sklenar@aporter.com
Wallace.Wu@aporter.com