

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

Case IPR2016-00685
Patent 9,095,348 B2

Before WILLIAM V. SAINDON, RICHARD E. RICE, and
NEIL T. POWELL, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Minerva Surgical, Inc. (“Petitioner”) filed a Petition (Paper 3, “Pet.”) requesting an *inter partes* review of claims 1–15 (“the challenged claims”) of U.S. Patent No. 9,095,348 B2 (Ex. 1001, “the ’348 Patent”). Petitioner

supported the Petition with a Declaration from John Anthony Pearce, Ph.D. (Ex. 1002). Hologic, Inc. (“Patent Owner”) filed a Preliminary Response (Paper 7, “Prelim. Resp.”).

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we do not institute *inter partes* review.

B. Related Proceedings

We are informed that Petitioner is named as a defendant in a federal district court case involving the ’348 Patent (Case No. 1:15-cv-01031-SLR pending in the U.S. District Court for the District of Delaware). Pet. 14. We also are informed that Petitioner has filed a second Petition for *inter partes* review of the ’348 Patent (IPR2016-00680). *Id.*

C. The ’348 Patent

The ’348 Patent, titled “Moisture Transport System for Contact Electrocoagulation,” issued from an application filed August 8, 2013, and claims priority to May 8, 1998. Ex. 1001, at (54), (21), (22), (60), 1:6–13. The ’348 Patent relates to an apparatus for ablating the interior linings of body organs such as the uterus. *Id.* at 1:19–21. Ablation of the interior lining of a body organ, the ’348 Patent explains, “involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins for hemostasis.” *Id.* at 1:26–28. Ablation may be performed, for example, to treat chronic bleeding of the endometrial layer of the uterus.

Id. at 1:28–30. The '348 Patent states that conventional methods of effecting ablation include “application of RF energy [i.e., radio frequency energy] to the tissue to be ablated.” *Id.* at 1:31–35. Problems addressed by the '348 Patent include the need for a device that eliminates steam and liquid buildup at the ablation site and that allows control of the depth of ablation in the treated tissue. *Id.* at 1:48–2:30.

Figure 21 of the '348 Patent, which is reproduced below, illustrates ablation device 100:

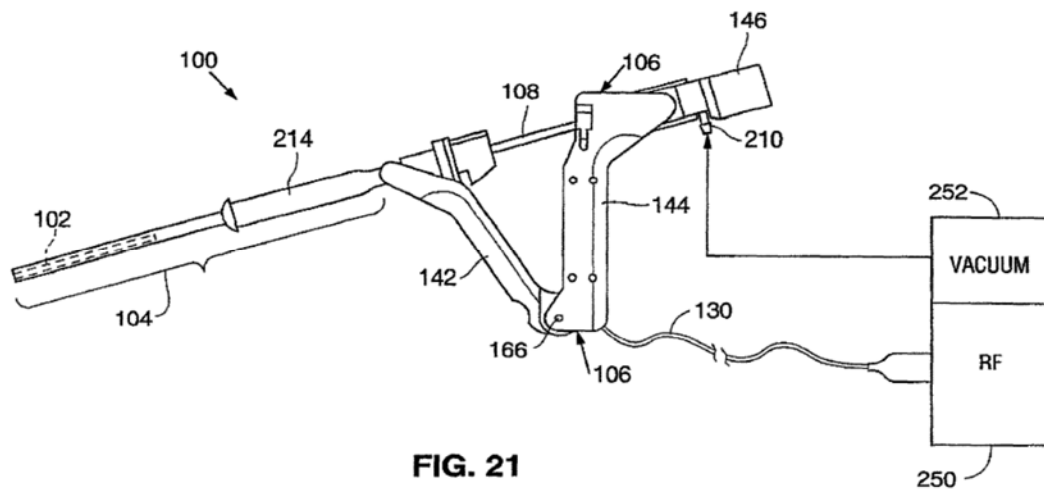


Figure 21 is a side elevation view of ablation device 100 showing sheath 104, tubing 108, handle 106, and RF applicator head 102 slidably disposed within sheath 104. *Id.* at 11:59–62, 12:2–5. After insertion of the device into the uterine cavity, manipulation of handle 106 causes the applicator head to extend from the distal end of the sheath and to expand into contact with body tissue. *Id.* at 11:63–12:5. The ablation device can be used to measure the width of the uterus, and gauge 146 displays the measured width. *Id.* at 14:33–36. The measured width is entered into RF generator system 250 and used to calculate the ablation power. *Id.* at 18:37–

39. Vacuum source 252 is connected to inner hypotube 122 (discussed below) via suction port 210. *Id.* at 18:40–41.

As illustrated in Figure 23 of the '348 Patent, which is reproduced below, applicator head 102 extends from the distal end of tubing 108. *Id.* at 12:2–5.

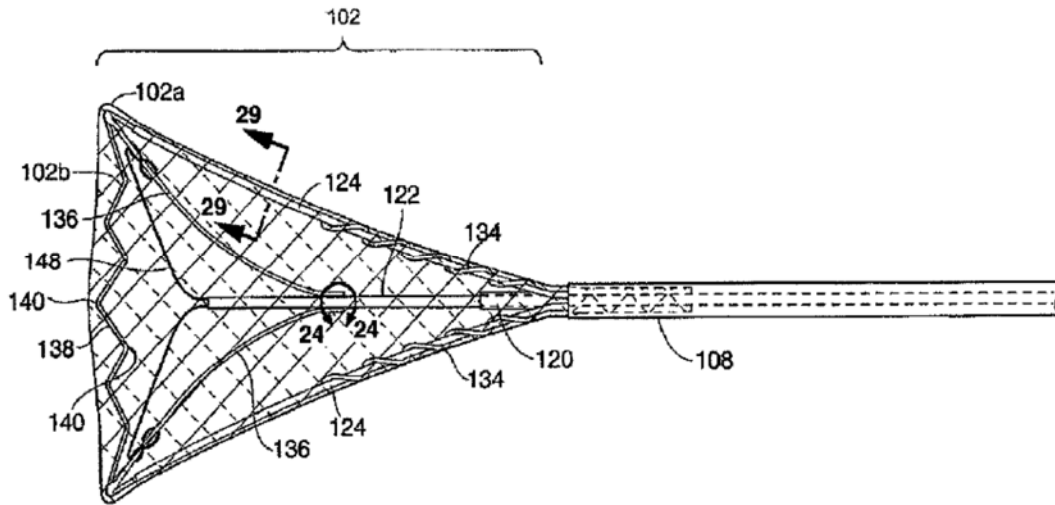


Figure 23 illustrates applicator head 102 in the expanded or deployed state.¹ *See id.* at Fig. 23. Applicator head 102 includes: external electrode array 102a, which is formed of a stretchable metallized fabric mesh; an internal deflecting mechanism 102b, which is used to expand and tension the electrode array for positioning into contact with uterine tissue; and non-conductive suturing threads 148, which extend from hypotube 122 for use in measuring the width of the uterus. *Id.* at 12:5–12, 14:33–39.

The deployment structure for deflecting mechanism 102b includes external hypotube 120, which extends from tubing 108, and internal hypotube 122, which is slidably and co-axially disposed within

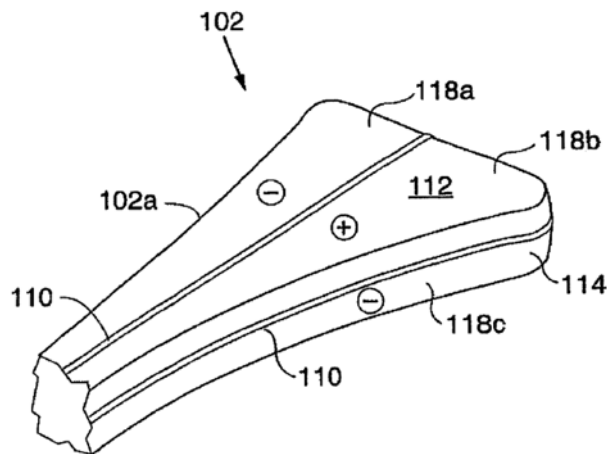
¹ The '348 Patent states that, for clarity, sheath 104 is not shown in Figure 23. *Id.* at 12:2–3.

hypotube 120. *Id.* at 13:8–12. Outer flexures 124 extend laterally and longitudinally from tubing 108 on opposite sides of external hypotube 120. *Id.* at 13:12–13. Internal flexures 136 extend laterally and longitudinally from the exterior surface of internal hypotube 122. *Id.* at 13:56–58. Each internal flexure 136 is connected at its distal end to one of the outer flexures 124, and a transverse ribbon 138 extends between the distal portions of the internal flexures 136. *Id.* at 13:58–61. As described in the '348 Patent,

during use distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head. This action results in relative rearward motion of the hypotube 120 and relative forward motion of the hypotube 122. The relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102a.

Id. at 14:25–31.

Deflecting mechanism 102b and its deployment structure are enclosed within electrode array 102a. *Id.* at 13:8–9. Figure 25A of the '348 Patent is a perspective view of electrode array 102a in the deployed or expanded state. *Id.* at 3:52–53, 12:53–55. Figure 25A is reproduced below.



As shown in Figure 25A, insulating regions 110 are formed on the applicator head to divide the mesh into electrodes 118a–118d. *Id.* at 12:59–13:7. As power is supplied to the electrodes, the tissue is heated, releasing moisture. *Id.* at 18:44–47. Moisture is withdrawn from the uterine cavity through internal hypotube 122, which is connected to vacuum source 252. *Id.* at 18:47–49. Apertures formed in outer flexures 124 facilitate moisture withdrawal by preventing trapping of moisture between the flexures and the lateral walls of the uterus. *Id.* at 18:49–52.

Handle 106 comprises distal and proximal grip sections 142, 144, which are pivotally attached to one another at a pivot pin. *Id.* at 16:13–16, Figs. 21–22. Proximal grip section 144 is coupled to hypotube 122 via yoke 168, overload spring 170, and spring stop 172. *Id.* at 16:17–19, 17:38–40, Figs. 34, 37A, 37B. Distal grip section 142 is coupled to external hypotube 120 via male and female couplers 174, 176. *Id.* at 16:20–22, Figs. 32A, 32B, 34. Figure 34 of the '348 Patent is reproduced below.

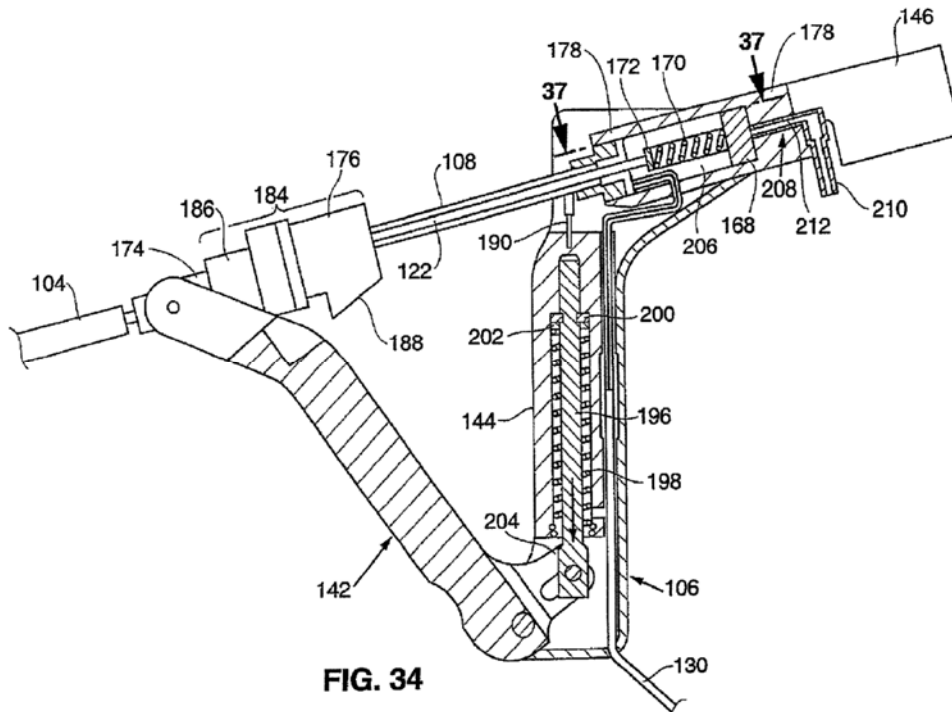


Figure 34 is a side elevation view of handle 106 as depicted in Figure 21 (reproduced above). *Id.* at 4:19–21.

As the distal and proximal grips are moved towards one another, sheath 104 is withdrawn from array 102a until female coupler 176 contacts and bears against frame member 178. *Id.* at 17:54–59, Fig. 37A, 37B. “Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120.” *Id.* at 17:59–61. “An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122.” *Id.* at 17:61–63, Figs. 37A, 37B. “The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array.” *Id.* at 17:63–66.

D. Illustrative Claims

Claims 1 and 11 are independent. Claims 2–10 and 12 depend, directly or indirectly, from claim 1; claims 13–15 depend directly from claim 11. Claims 1 and 11 are illustrative of the claimed subject matter, and are reproduced below:

1. A device for treating a uterus comprising:
 - an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;
 - an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

Id. at 19:9–42.

11. A device for treating a uterus comprising:
an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

a handle coupled to the proximal portion;

an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;

a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and

second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state;

an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and

wherein when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.

Id. at 20:17–47.

E. The Asserted References

Petitioner relies upon the following references (Pet. 14):

Reference	Patent No./Pub. No.	Date	Exhibit No.
Edwards	US 6,024,743	Feb. 15, 2000	Ex. 1005
Ortiz	US 5,358,496	Oct. 25, 1994	Ex. 1006
Lichtman	US 5,620,459	Apr. 15, 1997	Ex. 1008
Jing	CN 1060594A	Published Apr. 29, 1992	Exs. 1010, 1011 (translation)

F. The Asserted Grounds

Petitioner challenges claims 1–15 of the '348 Patent on the following grounds (Pet. 14):

References	Basis	Claim(s) Challenged
Edwards, Ortiz, Lichtman, and Jing	§ 103(a)	1–15

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a) for instituting review.

A. Level of Skill in the Art

Dr. Pearce testifies that a person of ordinary skill in the art 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 ¶ 47. Patent Owner does not provide evidence or argument on the level of ordinary skill. Prelim. Resp. 10 n.3. We adopt Dr. Pearce's definition for purposes of this Decision.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language.

See SuperGuide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes express constructions for two claim terms, “frame” and “flexure.” Pet. 15–17. Patent Owner does not propose an express construction for any claim term. Prelim. Resp. 8–9.

I. “frame”

Claim 1 recites “a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a *frame*” (emphasis added). Petitioner proposes to construe “frame” “to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve).” Pet. 16. Petitioner asserts that “[a]lthough ‘frame’ is not specifically defined, the specification does describe a ‘frame member 178’ mounted on the proximal grip section and enclosing various components of the handle and expansion mechanism including the ‘yoke 168,’ ‘spring stop 172,’ ‘compression spring 170,’ and ‘hypotube 122.’” *Id.* at 15 (citing Ex. 1001, 4:28–36, 17:37–53, Fig. 34; Ex. 1002 ¶ 52). Petitioner also asserts that this construction “is consistent with the plain and ordinary meaning of the word ‘frame’ as a structure that surrounds or encloses something.” *Id.* at 15–16 (citing Ex. 1013, 4; Ex. 1014, 3).

On this record, we agree that the Specification uses “frame” in accordance with its ordinary meaning. *See, e.g.*, Ex. 1001, 17:37–49 (referring to “frame member 178” and “the frame”); Ex. 1013, 4; Ex. 1014, 3. We do not agree with Petitioner’s proposed claim construction, however,

because it encompasses only one (apparently, the narrower) of the two dictionary definitions of “frame” cited in the Petition. *See* Pet. 15–16 (citing Ex. 1013, 4 (“an enclosing structure or case”); Ex. 1014, 3 (“an arrangement of structural parts that gives form or support”)). Petitioner has not explained sufficiently why the broadest reasonable claim construction should not encompass both of the dictionary definitions.

We determine that the broadest reasonable interpretation consistent with the Specification of “frame” encompasses: an arrangement of structural parts that gives form or support; and a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve).

2. *flexures*

Claim 1 recites “a deflecting mechanism including *flexures* disposed within the applicator head” (emphasis added”). Petitioner argues that the term “flexure” “should be construed to include a component designed to be bent or curved.” *Id.* at 16–17. Petitioner asserts that its proposed claim construction is consistent with the use of “flexure” in the Specification and the term’s ordinary meaning. *Id.* at 16 (citing Ex. 1001, 13:65–67, 13:56–14:31, Figs. 23, 30; Ex. 1002 ¶¶ 54–56; Ex. 1013, 3).

We do not agree with Petitioner’s proposed claim construction because it is not consistent with the Specification’s description of flexures 124, 136 as strips that are capable of being bent or curved. *See, e.g.*, Ex. 1001, 4:1–9, 13:8–14:31, Figs. 23, 28–30. Figures 23 and 28, for example, depict flexures 124 as strips that have been bent or curved as the result of relative motion between hypotubes 120 and 122. *Id.* at 13:8–15, 14:29–30, Figs. 23, 28. Indeed, Petitioner’s declarant, Dr. Pearce, testifies

that “a person of skill in the art would understand the term ‘flexure’ to refer to a component capable of being bent or curved.” Ex. 1002 ¶ 56.

On this record, we determine that the broadest reasonable interpretation consistent with the Specification of “flexures” is strips that are capable of being bent or curved. We note that a distinction with Petitioner’s proposed construction is that “designed to be bent,” for example, could mean a structure that has been bent but is no longer bendable or a structure that is bendable. “Capable of being bent,” on the other hand, means that the structure is further bendable.

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (“POSA”) to which the subject matter pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. The question of obviousness is resolved on the basis

of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In this case, Petitioner challenges claims 1–15 as unpatentable for obviousness over Edwards, Ortiz, Lichtman, and Jing. Pet. 14. For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

1. Overview of Asserted References

a. Edwards

Edwards “relates generally to a method and apparatus to controllably create cell necrosis of at least a portion of the uterus, and more particularly to a [a] method and apparatus to create selective cell necrosis of target sites of the uterus.” Ex. 1005, 1:21–24. Cell necrosis apparatus 10 includes expandable member 12, which is introduced into the uterus through introducer sleeve 14 “in a folded, or non-distended configuration.” *Id.* at 5:4–5, 6:1–4. Following introduction, sleeve 14 is withdrawn, and expandable member 12 is expanded. *Id.* at 6:4–5. Figure 1B of Edwards is reproduced below.

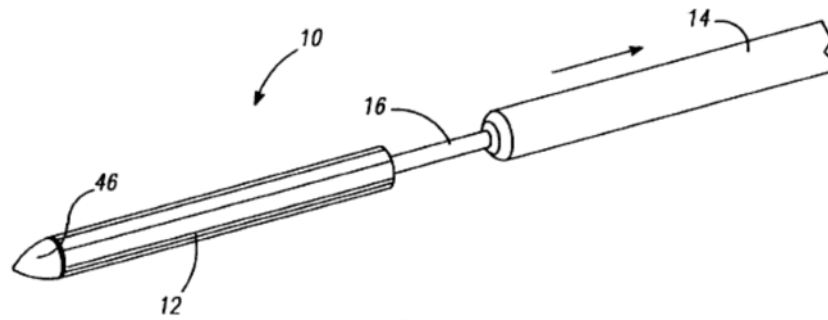


FIG. - 1B

Figure 1B is a perspective view of cell necrosis apparatus 10 in a non-deployed position as introducer sleeve 14 is withdrawn. *Id.* at 3:22–24.

Expandable member 12 can be expanded “either mechanically, with the introduction of a fluid or gaseous expanding medium, such as [an] electrolytic solution, or a combination of both.” *Id.* at 6:4–8. Figure 1C is reproduced below.

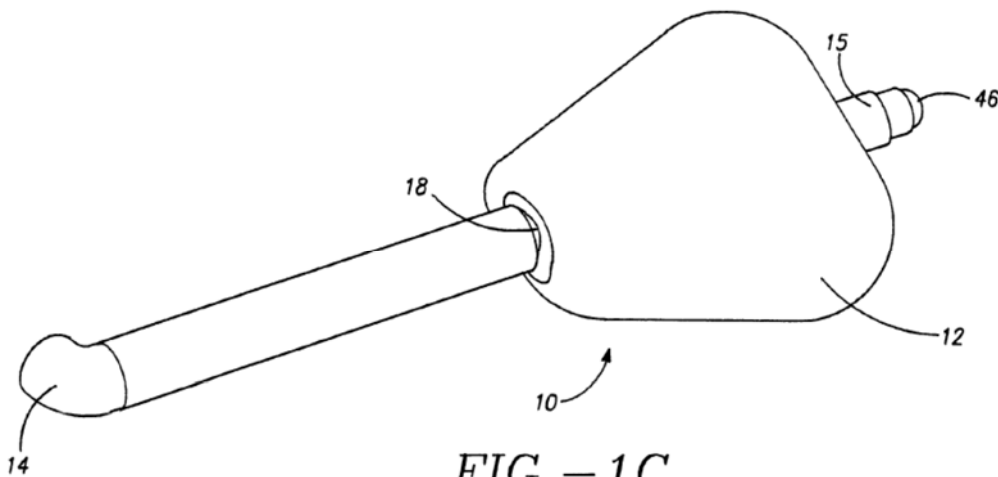


FIG. - 1C

Figure 1C is a perspective view of cell necrosis apparatus 10 in a deployed position showing expandable member 12 expanded. *Id.* at 3:25–26.

“Electrolytic solution is introduced into expandable member 12, causing it to become distended and be self-retained in the uterus.” *Id.* at 6:10–12. In the treatment phase, “[c]ell necrosis apparatus 10 automatically conforms to the

interior of the uterus.” *Id.* at 6:33–34. Edwards teaches using ultrasound to create a map of the interior of the uterus:

The amount of cell necrosis can vary. However, it is desirable to ablate about 2 to 3 mm, with approximately 1 mm of the myometrium. Ultrasound can be used to create a map of the interior of the uterus. This information is input to a controller. Individual electrodes are multiplexed and volumetrically controlled. If desired, the area of cell necrosis can be substantially the same for each cell necrosis event.

Id. at 6:48–54.

Figure 4 of Edwards is reproduced below.

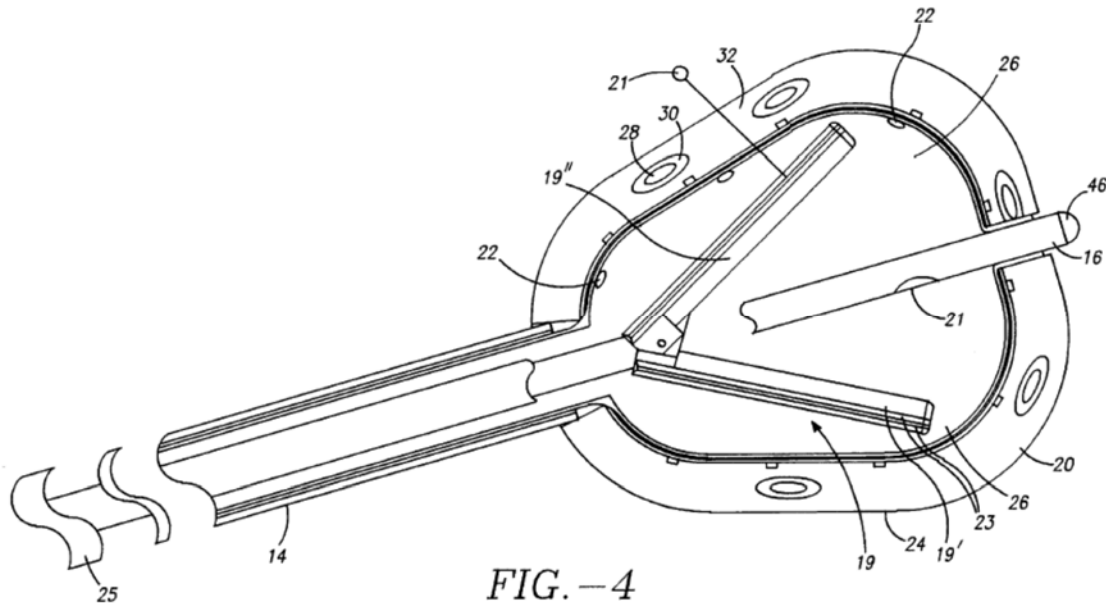
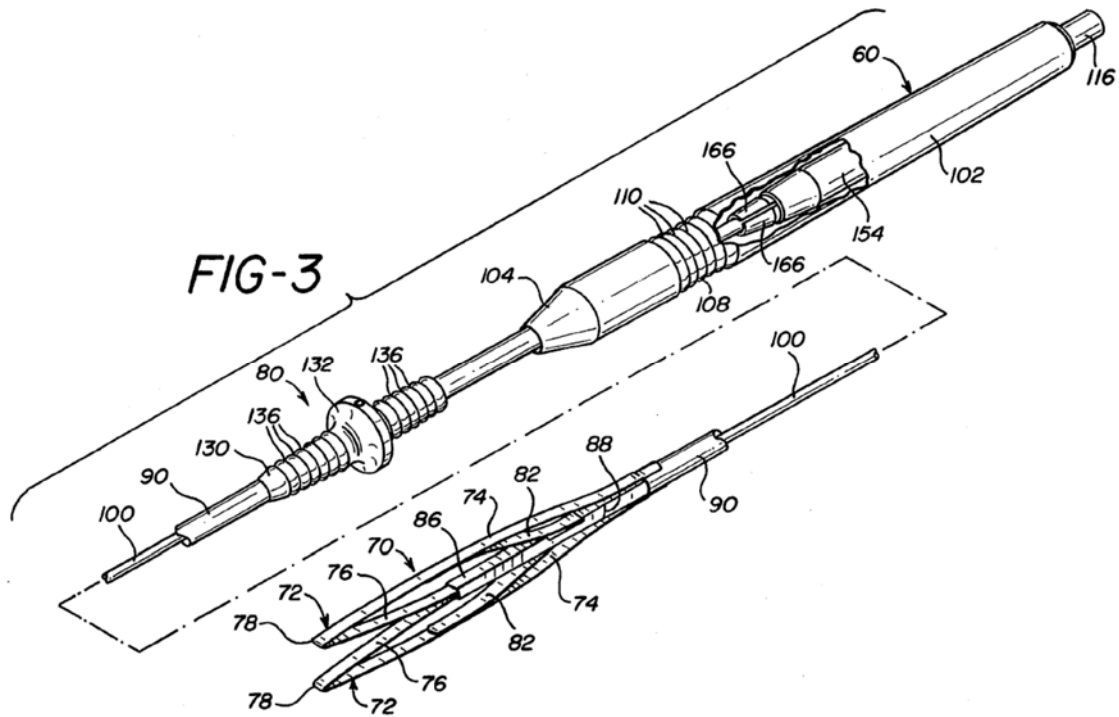


Figure 4 is a cross-sectional view of an embodiment of cell necrosis apparatus 10 in which expandable member 12 is substantially surrounded by conforming member 20. *Id.* at 7:4–10. “Conforming member 20 receives electrolytic solution from expandable member 12 . . . through a plurality of apertures 22 formed in expandable member 12.” *Id.* at 7:10–13. Frame 19, with arms 19’, is used to assist in opening expandable member 12. *Id.* at

7:19–21. Edwards discloses that, “[i]n one embodiment, cell necrosis apparatus 10 conforms lightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20.” *Id.* at 7:37–40.

b. Ortiz

Ortiz relates to an endoscopic tissue manipulator that can be inserted through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity. Ex. 1006, 1:10–12. A preferred embodiment includes a proximal handle assembly and a distal expandable platform 70. *Id.* at 4:37–39. Figure 3 of Ortiz is reproduced below:



As shown in Figure 3, platform 70 consists of a plurality of flexible, interconnected strips adapted to expand laterally outward to form a pair of fingers 72. *Id.* at 4:52–55. Each of fingers 72 comprises outer strip 74 and inner strip 76. *Id.* at 4:55–58. Outer strip 74 is attached to the distal end of

actuator tube 90, and inner strip 76 is attached to the distal end of shaft or push rod 100 inside of actuator tube 90. *Id.* at 4:59–63. “[W]hen actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.” *Id.* at 5:28–31. “The outer strips 74 are pulled in the proximal direction by the actuator tube 90 and the guide tube 86 is moved proximally along the inner strips 76 by the struts 82.” *Id.* at 5:32–34.

Figure 7 of Ortiz is reproduced below.

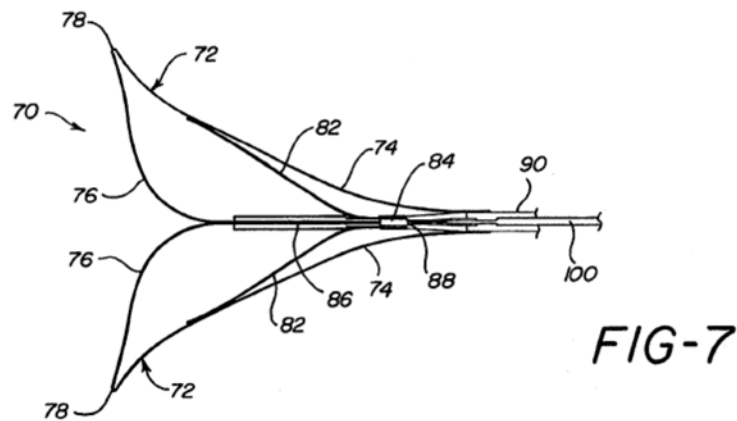


Figure 7 depicts a longitudinal cross section illustrating platform 70 in the tulip-shaped configuration. *Id.* at 3:29–30, 4:10–11. As shown in Figure 7, each of fingers 72 comprises flexible strut 82, having its distal end secured to outer strip 74 and its proximal end attached to connector sleeve 84, which is slidably mounted on inner strip 76. *Id.* at 4:63–5:1. Connector sleeve 84 is located within guide tube 86, which is slidably received in the distal end of actuator tube 90. *Id.* at 5:1–4. Struts 82 provide for shape control of platform 70 in its expanded configuration. *Id.* at 6:1–2. “The expanded platform 70 has a generally planar configuration which provides two flat tissue manipulating surfaces on its opposite sides.” *Id.* at 8:36–39.

c. Lichtman

Lichtman discloses handle mechanisms for surgical instruments employing movable jaws, and mechanisms for moving the jaws, typically involving coaxial telescoping elements. Ex. 1008, 5:19–21, 40–42. Figure 1 of Lichtman is reproduced below.

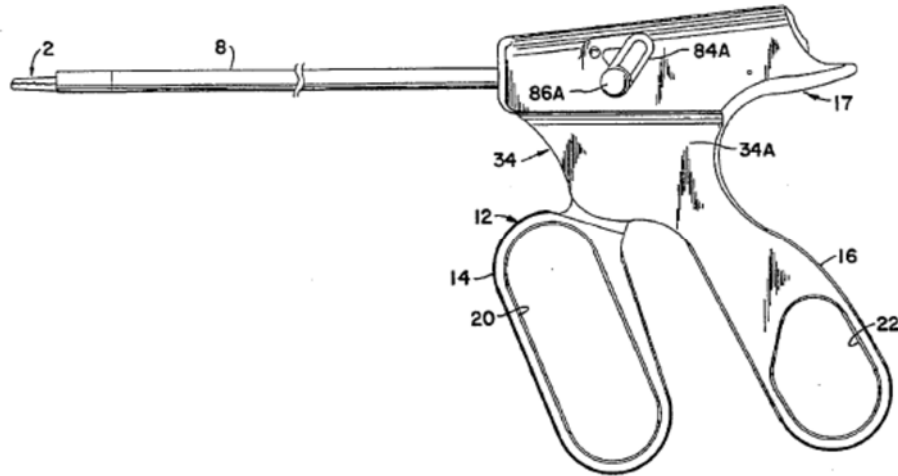


Figure 1 shows a side view of a preferred embodiment that includes unitary jaw piece 2, outer hollow shaft 8, and handle assembly 12 including stationary handle member 16 and movable handle member 14. *Id.* at 6:13–22.

Figure 9 of Lichtman is reproduced below.

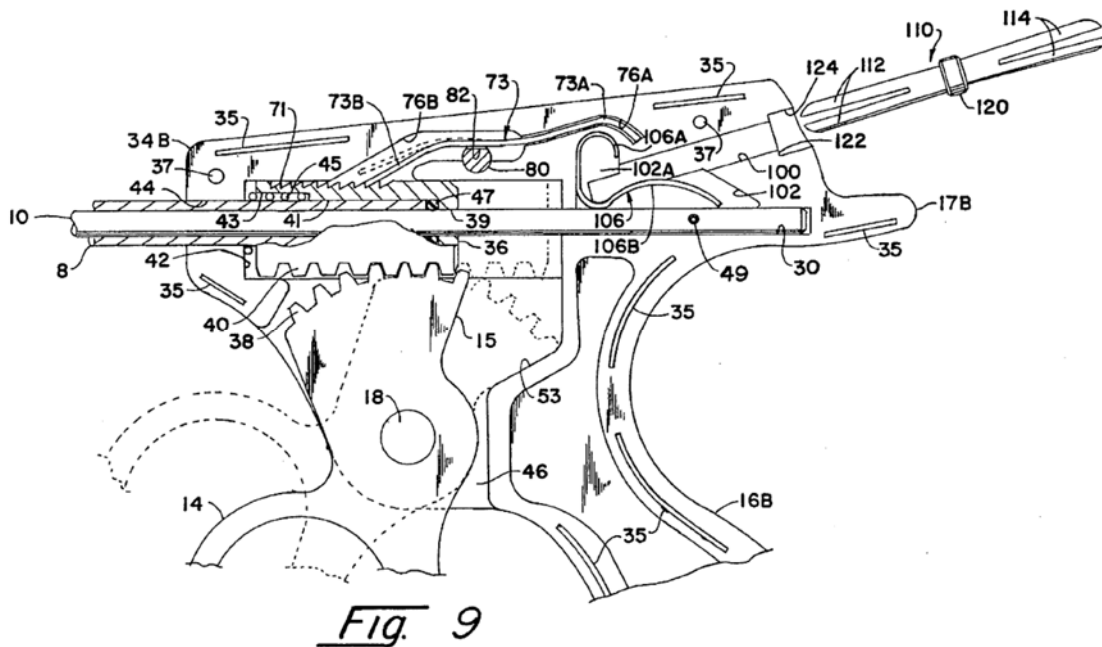


Figure 9 is a partially exploded view showing outer shaft 8, inner shaft 10, and movable handle member 14, which is rotatable about pivot pin 18. *Id.* at 4:40–43, 6:15–21. Outer shaft 8, which coaxially surrounds and is free to slide axially relative to inner tube 10, is rigidly joined to gear rack tube 36. *Id.* at 6:31–33.

d. Jing

Jing relates to a computer-controlled apparatus for measuring and displaying data of the morphology of a woman's uterine cavity. Ex. 1011, 3:5–7, 20–23, 4:25–30.² “An object of the present invention is to provide a computer-controlled measurement apparatus for measuring and displaying data of the morphology of the uterine cavity, thereby increasing the success rate of the IUD technique and facilitating the modification of IUDs.” *Id.* at 3:20–23. Figure 2 of Jing is reproduced below.

² We cite to the certified translation of Jing (Ex. 1011).

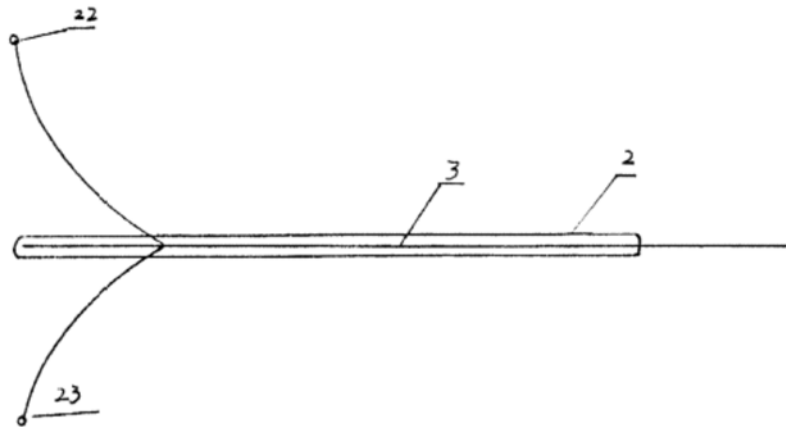


Figure 2 illustrates measuring rod 3 and dovetail-type contacts 22, 23. *Id.* at 5:9–13. Jing discloses:

When a transverse dimension of the uterine cavity is to be measured, the measurement push button may be pushed by hand, such that two dovetail-type contacts (22, 23) of the transverse dimension measuring rod protrude from through-holes (10) at two sides of the measurement sleeve and expand [sic] to the transverse dimension being measured.

Id.

2. *Petitioner's Contentions with Respect to Claims 1 and 11*

Petitioner argues that “Edwards on its own fully discloses” the “applicator head” limitation of claims 1 and 11. Pet. 26. While conceding that “Edwards does not specifically describe an inner sleeve slidably and coaxially disposed within an outer sleeve,” as required by the “elongate member” limitation of claims 1 and 11, Petitioner contends that “these aspects are fully disclosed by Ortiz.” *Id.* at 23 (citing Ex. 1002 ¶ 77). Petitioner asserts that “use of the mechanical expansion elements taught by Ortiz, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid or gaseous expansion media disclosed in Edwards because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination.” *Id.* at 25

(citing Ex. 1002 ¶¶ 64, 82); *see also id.* at 53 (arguing that “a skilled artisan would also have recognized that an endometrial ablation device as in Edwards would benefit from improved contact between the expandable applicator head and the uterine wall”) (citing Ex. 1002 ¶ 63).

With respect to the “deflecting mechanism” limitation requiring “external flexures being coupled to the outer sleeve” and “internal flexures being coupled to the inner sleeve,” Petitioner again relies on Ortiz. *Id.* at 33 (citing Ex. 1002 ¶ 103). Petitioner argues that Figure 7 of Ortiz discloses first and second outer flexures (“outer strip 74”) and first and second inner flexures (“flexible strut 82”). *Id.* (citing Ex. 1002 ¶ 103). Petitioner asserts that “Ortiz’s deflecting mechanism with flexures would have been a reasonable design choice enabling improved contact with the uterine wall.” *Id.* at 35 (citing Ex. 1002 ¶¶ 62, 108); *see also id.* at 53 (“It would have been apparent to the skilled artisan that the ‘plurality of flexible, interconnected strips’ and ‘flexible struts’ taught by Ortiz would be well matched to the shape of the uterus and well suited for use as an expansion device in an endometrial ablation device.”) (citing Ex. 1006 at 4:34–42, 52–55; Ex. 1002 ¶ 63). Petitioner also argues that “the combination of Edwards and Ortiz would have the added benefits of simplifying the device design by removing the need for fluid or gaseous expansion medium.” *Id.* at 36 (citing Ex. 1002 ¶¶ 63–64, 108).

Petitioner contends that “Ortiz also discloses that translation of the inner sleeve (shaft 100) relative to a frame causes an applicator head to

transition from a contracted to an expanded state,” as required by claim 1.³ *Id.* at 34 (citing Ex. 1002 ¶ 105). Petitioner argues:

Ortiz discloses that “[b]y pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7).” *Id.* at 8:10-19. Since the finger slide 80 is secured to the tube 90, the shaft 100 also moves relative to the finger slide 80. Ex. 1002 ¶ 105.

Id. at 34; *see also id.* at 51–52 (advancing similar arguments).⁴ Petitioner identifies Ortiz’s shaft 100 as corresponding to the “inner sleeve” and Lichtman’s gear rack tube 36 as corresponding to the “frame.” *Id.* at 34–35.

With respect to the requirement of claims 1 and 11 for an indicator mechanism configured to indicate a dimension of the uterus, Petitioner relies on Jing’s device for measuring a transverse dimension of the uterine cavity. *Id.* at 36–38. Petitioner contends that incorporating Jing’s measurement apparatus into the ablation device taught by Edwards would have allowed “measurement of a dimension of the uterus and thus the mapping expressly contemplated by Edwards.” *Id.* at 37 (citing Ex. 1002 ¶¶ 111–112).

³ We note that the claims 1 and 11 use different language to define the mechanism causing the applicator head to transition from a contracted state to an expanded state. Claim 1 recites “translating the inner sleeve relative to the frame,” while claim 11 recites “translating one of the inner and outer sleeves relative to the other.”

⁴ Petitioner similarly argues that Ortiz discloses “translating one of the inner and outer sleeves relative to the other,” as required by claim 11. *Id.* at 39 (“As Dr. Pearce explains, this limitation is disclosed by Ortiz, which teaches that ‘[b]y pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7).’”) (citing Ex. 1006 at 8:10–19; Ex. 1002 ¶ 155).

Petitioner further contends that “[a] person of ordinary skill would have had reason to apply Jing’s indicator mechanism to provide low cost dimension information.” *Id.* at 38 (citing Ex. 1002 ¶¶ 70, 112).

Claim 11 additionally requires “when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.” Petitioner concedes that “Jing does not specifically describe whether the components receiving the dimension information would include a generator configured to deliver current to electrodes.” *Id.* at 39. Petitioner contends that “these aspects of the limitation are disclosed by Edwards.” *Id.* (citing Ex. 1005, 11:34–35; Ex. 1002 ¶ 137). Petitioner argues that “addition of the dimension measuring components disclosed in Jing to the RF ablation device disclosed in Edwards would have been obvious” because “[a] person of ordinary skill in the art would have been motivated to combine Jing and Edwards in this manner in order to obtain automatic transmission of data useful for controlling the generator without requiring manual data entry, thus improving convenience.” *Id.* at 40 (citing Ex. 1002 ¶ 140).

3. *Patent Owner’s Responsive Contentions*

In response, Patent Owner argues, *inter alia*, that Petitioner has not explained sufficiently why a person of ordinary skill in the art would have combined the prior art teachings to arrive at the challenged claims as a whole. *See* Prelim. Resp. 3, 14, 57. Patent Owner asserts, for example, that Petitioner’s “arguments are legally insufficient, contrary to the teachings of the prior art references, and lack any articulated reasoning with rational underpinning.” *Id.* at 3.

More specifically, regarding Petitioner's asserted reasons for combining teachings of Edwards and Ortiz, Patent Owner argues that "Petitioner fails to explain how or why Ortiz's distal platform 70 improves contact with the uterine wall relative to Edwards's expandable member 12." *Id.* at 36–37. Patent Owner also challenges Petitioner's argument that "Ortiz's distal platform 70 would have 'simplif[ied] the device design by removing the need for fluid or gaseous expansion medium.'" *Id.* at 37 (citing Pet. 36). According to Patent Owner, Petitioner baselessly assumes that any combination of Ortiz with Edwards would involve a complete replacement of the fluid-actuated components of Edwards with the mechanical components of Ortiz. *Id.* Patent Owner asserts that, contrary to Petitioner's assumption, "Edwards describes the use of mechanical components to 'assist' in the expansion of the fluid-actuated components." *Id.* Patent Owner further asserts:

Moreover, even if the fluid-actuated components of Edwards were completely replaced by the mechanism of Ortiz, that would not simplify the device design. Ortiz's actuation mechanism requires multiple components (some fixed, some slidable), a specific handle mechanism, and a multitude of interconnected struts.

Id. at 37–38.

With respect to the limitation of claim 1 requiring a deflecting mechanism capable of "translating the inner sleeve relative to the frame," Patent Owner disputes Petitioner's contention that Ortiz's shaft 100 (the asserted "inner sleeve") is capable of translating relative to a frame. Patent Owner asserts:

Petitioner concedes that Ortiz describes movement of actuator tube 90 relative to fixed shaft 100. (Petition at 34; *see* Ortiz col. 5:28–38 ("[W]hen actuator tube 90 is retracted, *i.e.*, moved

proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.”.) Petitioner’s argument confirms that Ortiz contains an outer tube and frame that translates relative to a fixed inner shaft. This is different than the claimed requirement that the inner tube translates relative to a fixed frame.

Id. at 33–34.

With respect to the requirement of claims 1 and 11 for an indicator mechanism configured to indicate a dimension of the uterus, Patent Owner asserts that a person of ordinary skill in the art would not have combined Jing with Edwards. *Id.* at 41. Patent Owner argues, for example, that “Jing’s apparatus is not . . . a low cost replacement for Edwards’s ultrasound [as Petitioner contends], but rather an unnecessary additional structure that would only add to the manufacturing costs.” *Id.*

Patent Owner also disputes Petitioner’s arguments with respect to the additional limitation of claim 11 that “when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.” Patent Owner argues that “the width dimension provided by the Jing device is not relevant to Edwards’s operation.” *Id.* at 42 (citing Ex. 1005, 6:30–47); *see also id.* at 43 (“There is no evidence that the ‘map’ described in Edwards relates to a dimension of the uterus (*e.g.*, the width), as Petitioner asserts.”).

4. Analysis

Upon consideration of the Petition and the Preliminary Response, we agree with, and adopt, Patent Owner’s arguments, as summarized above, that the reasons advanced by Petitioner for combining elements of Edwards, Ortiz, Lichtman, and Jing to make the claimed invention are conclusory and

insufficient, and that the asserted combination does not teach or suggest all of the claimed features. We provide additional analysis below.

As discussed above, Petitioner relies on Edwards for the “applicator head” limitation of claims 1 and 11. *See* Pet. 26. Edwards’s applicator head includes expandable member 12, into which electrolytic solution is introduced for use in ablation treatment of the uterus. *See* Ex. 1005, 6:10–12, 6:33–41, 7:4–18.

Petitioner’s argument that using Ortiz’s mechanical expansion elements to expand Edwards’s applicator head would have simplified the device design by removing the need for a fluid or gaseous expansion medium is unpersuasive because it does not take into account that electrolytic solution is used in Edwards’s applicator head, not just for expansion, but also for ablation treatment. As such, Petitioner does not explain why using Ortiz’s mechanical expansion elements for expansion of Edwards’s applicator head, while continuing to use electrolytic solution in the applicator head for ablation treatment, would have resulted in any simplification or benefit. Dr. Pearce’s testimony that replacing the use of fluid or gaseous media with Ortiz’s mechanical expansion elements would have obviated potential safety issues, such as fluid leakage or contamination, similarly fails to account for the use of electrolytic solution in Edwards’s applicator head for ablation treatment and is, therefore, unpersuasive. *See* Ex. 1002 ¶ 64.

Dr. Pearce’s testimony that incorporating Ortiz’s expansion elements would have improved contact between Edwards’s applicator head and the uterine walls is also unpersuasive. *See* Ex. 1002 ¶ 63. In particular, Dr. Pearce does not explain sufficiently why replacing the two rigid arms

extending outward toward the walls of the uterus (as depicted in Figure 4 of Edwards) with the asserted flexures taught by Ortiz would have improved the ability of the device to conform to the shape of the uterus. *See id.* For example, Dr. Pearce’s testimony does not address or explain the disclosure in Edwards that “[c]ell necrosis apparatus 10 automatically conforms to the interior of the uterus.” *See* Ex. 1005, 6:33–41; *see also id.* at 7:37–40 (disclosing that, in one embodiment, “cell necrosis apparatus 10 conforms lightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20”).

We also are not persuaded by Petitioner’s argument that Ortiz teaches or suggests the requirement of claim 1 for a deflecting mechanism capable of “translating the inner sleeve relative to the frame.” *See* Pet. 34 (citing Ex. 1002 ¶105). Petitioner identifies Ortiz’s shaft 100 as corresponding to the “inner sleeve” and Lichtman’s gear rack tube 36 as corresponding to the “frame.” *Id.* at 34–35. As disclosed in Ortiz, however, shaft 100 does not move. For example, Ortiz discloses that “when actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.” Ex. 1006, 5:28–31, Fig. 4. Similarly, Ortiz discloses: “By pulling the finger slide 80 proximally, as shown in FIG. 6, the actuator tube 90 is retracted relative to the shaft 100 to expand the platform 70 into its tulip-shaped configuration (FIG. 7).” *Id.* at 8:10–14. Petitioner and Dr. Pearce have not explained sufficiently how Ortiz’s shaft 100, which does not move, is capable of translating relative to Lichtman’s gear rack tube 36 in the asserted combination.

Further, Petitioner has not provided a sufficient rationale for combining the teachings of Jing with those of Edwards, Ortiz, and Lichtman to teach or suggest either: (1) an indicator mechanism configured to indicate a dimension of the uterus, as required by claims 1 and 11; or (2) the additional limitation of claim 11 that “when the device is operably coupled to a generator to deliver current to the electrodes, the device is configured to electronically transmit the dimension of the uterus to the generator.” Petitioner argues that incorporating Jing’s device into an endometrial ablation device as described by Edwards “would allow measurement of a dimension of the uterus and thus the mapping expressly contemplated by Edwards.” Pet. 37 (citing Ex. 1002 ¶¶ 111–112). Petitioner also argues:

Edwards expressly discloses the use of ultrasound “to create a map of the interior of the uterus” that is used to determine the appropriate parameters of the ablation treatment. Ex. 1005 at 6:50–54. A person of ordinary skill would have had reason to apply Jing’s indicator mechanism to provide low cost dimension information. Ex. 1002 ¶¶ 70, 112.

Id. at 38. These arguments are conclusory, and the cited testimony from Dr. Pearce does not shed further light on why a skilled person would have combined the teachings of Jing and Edwards. *See* Ex. 1002 ¶¶ 70, 111–112. In particular, the record does not explain sufficiently why a person of ordinary skill in the art would have considered measurement of a dimension of the uterus (e.g., a transverse dimension), as taught by Jing, to constitute “the mapping expressly contemplated by Edwards,” as Petitioner argues.

For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to independent claims 1 and 11 as obvious over Edwards, Ortiz, Lichtman, and Jing. As Petitioner’s arguments and evidence with respect to dependent claims 2–10 and 12–15

do not remedy the deficiencies in the arguments and evidence with respect to the independent claims, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 2–10 and 12–15.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to: claims 1–15 as obvious over Edwards, Ortiz, Lichtman, and Jing.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner’s Petition for an *inter partes* review of claims 1–15 of the ’348 Patent is *denied*, and no *inter partes* review will be instituted pursuant to 35 U.S.C. § 314 as to any claim of the ’348 Patent on any of the grounds of unpatentability alleged by Petitioner in the Petition.

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