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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

Case No. IPR2016-00685
Patent No. 9,095,348

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,095,348**

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I. INTRODUCTION

Minerva Surgical, Inc., (“Petitioner”) hereby requests *inter partes* review of United States Patent No. 9,095,348 to Truckai *et al.* (hereinafter “the ’348 patent,” Ex. 1001) that issued on August 4, 2015, and is currently assigned to Hologic, Inc. (“Patent Owner”). This petition demonstrates that there is a reasonable likelihood that claims 1-15 of the ’348 patent are unpatentable over the cited prior art. Claims 1-15 of the ’348 patent should be found unpatentable and canceled.

The ’348 patent claims recite a uterine ablation surgical device construction, including: (1) an elongate body; (2) an expandable applicator head; and (3) a handle mechanism to actuate the expandable head. Ex. 1002 ¶ 14. This construction, however, was a basic design already utilized for an endometrial surgical device that must pass the device’s distal portion through a narrow cervical canal for subsequent expansion in the uterus for treatment.

In fact, as explained by Petitioner’s expert, an elongate device with an expandable distal portion and proximal actuating mechanism was an archetypical design for many

minimally invasive

surgical tools

(including

electrosurgical

devices) dating back at

least to the 1930s, as

evidenced by this

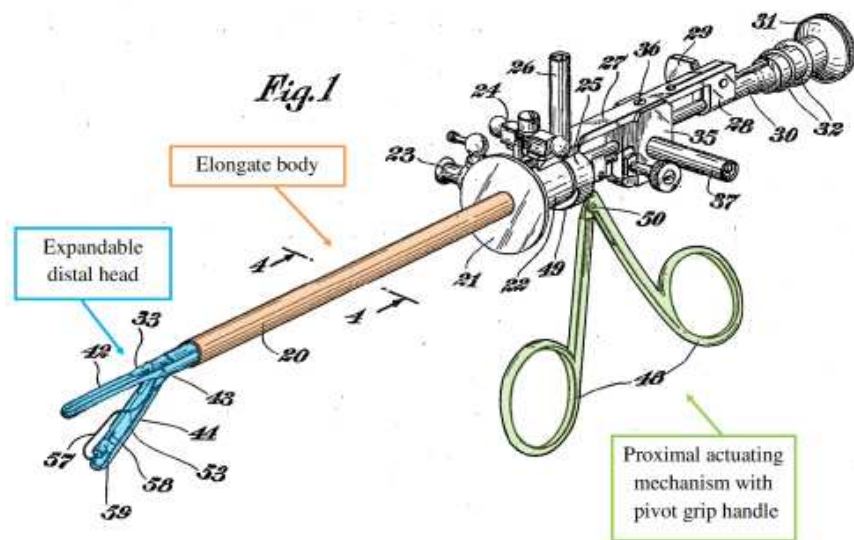
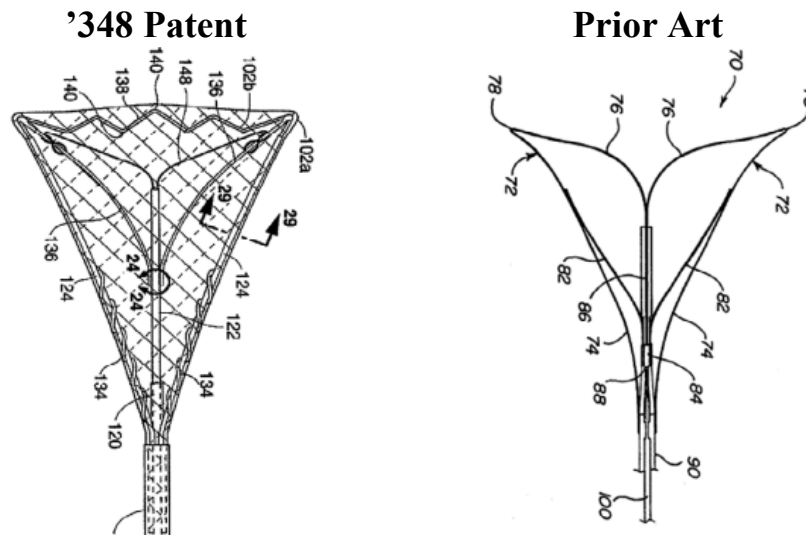


figure (annotated by Petitioner’s expert) from U.S. Patent No. 2,004,559 (entitled “Method and Instrument for Electrosurgical Treatment of Tissue”). Ex. 1002 ¶ 14; Ex. 1016 at FIG. 1 (annotated version shown).

As to the particular design choices recited in the ’348 patent claim for the expandable head (e.g., deflecting mechanism, flexures) and handle mechanism (e.g., pivot grip handle), those configurations were already well-known and readily found in similar prior art devices. Ex. 1002 ¶ 14. For example, the ’348 patent claims a structure for its expandable head “deflecting mechanism” that is indistinguishable from what was already known in the prior art at the time:



Ex. 1001 at FIG. 23; Ex. 1006 at FIG. 7; *see also* Ex. 1001 at claim 1.

Thus, as explained in further detail below, the uterine ablation devices claimed in the ’348 patent represent a conventional surgical device design, and merely incorporate design features that were already commonly employed in the same manner in similar minimally-invasive surgical devices for manipulating and ablating tissue. Ex. 1002 ¶ 14.

A. Brief Overview of the '348 Patent

The '348 patent relates to devices for ablation or coagulation of tissues in the interior linings of the uterus - a procedure known as endometrial ablation. Ex. 1001 at 1:19-21. Consistent with previously known endometrial ablation techniques, the ablation approach described in the '348 specification involves applying energy to the lining of the uterus to destroy the endometrial tissue in order to reduce menstrual flow. Ex. 1002 ¶¶ 11-13.

Claim 1 of the '348 patent is representative of the claims at issue and recites the following (*see also* Ex. 1002 ¶ 15):

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.

The “Second Exemplary Embodiment” is most directly relevant to the claims. *See* Ex. 1001 at 11:50-18:67; Ex. 1002 ¶ 16. Figure 21 depicts this embodiment, and is annotated here to highlight the applicator head, elongate member, and

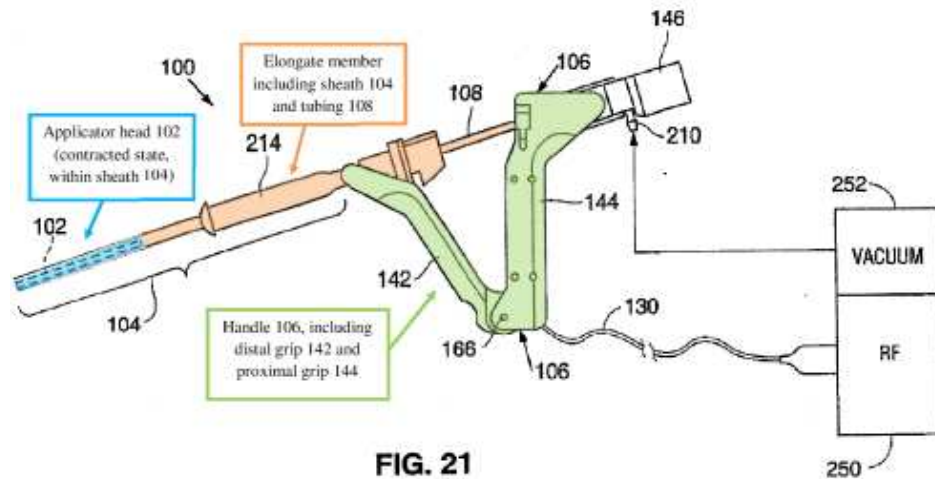
handle recited in the claims.

Ex. 1002 ¶¶ 16-

17. As the specification

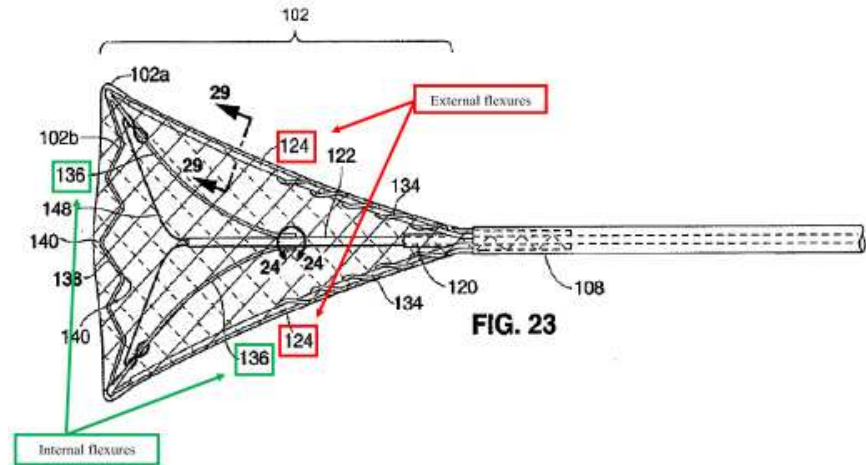
explains, the

handle is used to expand the applicator head once it has been inserted into the uterus, enabling ablation treatment. Ex. 1001 at 11:61-67 (“[T]he applicator head is slidably disposed within the sheath (FIG. 21) during insertion of the device into the uterine cavity, and the handle 106 is subsequently manipulated to cause the applicator head 102 to extend from the distal end of the sheath 104 (FIG. 22) and



to expand into contact with body tissue.”); *see also* Ex. 1002 ¶ 17.

The applicator head is depicted in its expanded state in Figure 23, which also depicts the deflecting mechanism recited in the claims, including the claimed internal and external flexures, as noted here.



Ex. 1002 ¶¶ 18-21; Ex.

1001 at 13:12-13 (“Flexures 124 extend from the tubing 108”), 13:56-58

(“[I]nternal flexures 136 extend laterally and longitudinally from the exterior

surface of hypotube 122”). The specification states that the deflecting mechanism

expands into a triangular shape to conform to the uterus dimensions. Ex. 1001 at

14:21-24 (“The deflecting mechanism formed by the flexures 124, 136, and ribbon

138 forms the array into the substantially triangular shape shown in FIG. 23, which

is particularly adaptable to most uterine shapes.”); *see also* Ex. 1001 13:61-67, Ex.

1002 ¶ 21. The specification also discusses the “external hypotube 120” and an

“internal hypotube 122 [that] is slidably and co-axially disposed within hypotube

120,” both seen in Figure 23, corresponding to the outer and inner sleeves recited

in the claims. Ex. 1001 at 13:9-12; *see also* Ex. 1002 ¶ 19.

The other independent claim of the ’348 patent, claim 11, recites substantively similar requirements as claim 1. Ex. 1002 ¶ 22. Other requirements

recited in the dependent claims relate to minor variations or common features of

electrosurgical devices and other types of minimally invasive surgical tools. *Id.* For example, claims 4-6 present further limitations regarding the arrangement and interoperation of the handle grips, inner and outer sleeve, and (in the case of claim 5) an introducer sheath used to cover the device components during insertion into the body, while claims 8 and 9 are directed to a “locking mechanism” used to limit the expansion of the applicator head or movement of the handle grips. *Id.*

As discussed in more detail below, the field of electrosurgical devices saw many developments in the years leading up to the ’348 patent, several of which were directed to improving the safety, effectiveness, and ease of use of such devices. *Id.* ¶ 23. The expandable applicator head containing electrodes, pivot grip handle for effecting expansion of the head, deflecting mechanism containing internal and external flexures, and dimension indicator mechanism claimed by the ’348 patent were all well known to those in this field. *Id.*

B. Brief Overview of the Prosecution History

Application No. 13/962,178 was filed on August 8, 2013 and issued on August 4, 2015 as U.S. Patent No. 9,095,348. The ’348 patent on its face identifies a chain of related U.S. Applications extending back to Provisional Application No. 60/084,791, filed on May 8, 1998.

The Patent Owner originally made a priority claim to Application No. 08/632,516, filed April 12, 1996, which issued as U.S. Patent No. 5,769,880 (“the ’880 patent”). Ex. 1004 at 1136. However, during *ex parte* prosecution of the ’348 patent, Patent Owner amended the specification to delete the reference to the ’880 patent and disclaimed the April 12, 1996 priority date. *Id.* at 142, 146; *see also id.*

at 88 (acknowledging deletion of the priority claim). The '880 patent qualifies as § 102(e) prior art against the '348 patent and differs in content primarily with respect to addition of the pivot grip handle embodiment.

The prosecution involved a single Office Action, in response to which the Patent Owner amended what would become claim 1 by adding the pivot grip handle requirement. *Id.* at 52. While the pivot grip handle requirement was thus relied on as a key distinction over the prior art during prosecution, this element was a conventional feature found in minimally invasive surgical devices at the time and was disclosed by multiple references predating the '348 patent.¹

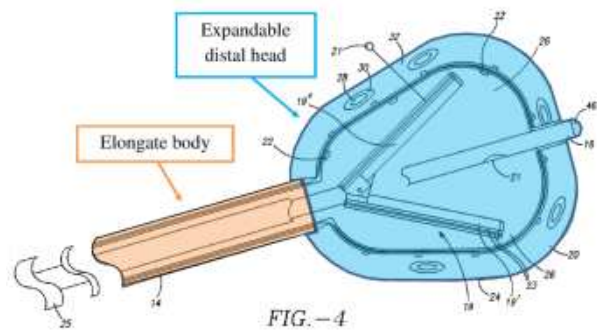
As discussed in further detail below, the pivot grip handle required by the claims of the '348 patent was a known design employed in elongate, minimally invasive surgical devices at that time. Ex. 1002 ¶¶ 14, 36, 39. One such example is found in U.S. Patent No. 5,620,459 to Lichtman (“Lichtman,” submitted as Ex. 1008). As another example, U.S. Patent No. 5,353,784 to Nady-Mohamed (“Nady-Mohamed,” submitted as Ex. 1009), describes an expandable device useful for gripping or manipulating a uterus or other similar tissues, which employs a pivot grip handle as recited in the '348 patent claims. *See also* Ex. 1016 at FIG. 1 (1930s device with a pivot grip handle); Ex. 1002 ¶ 14.

¹ During prosecution, the Examiner asserted that the “indicator mechanism” recited in the '348 patent claims was reflected in the prior art such that it did not provide a point of novelty or nonobviousness. The Patent Owner did not contest that assertion. *See* Ex. 1004 at 90-95, 57-58, 7.

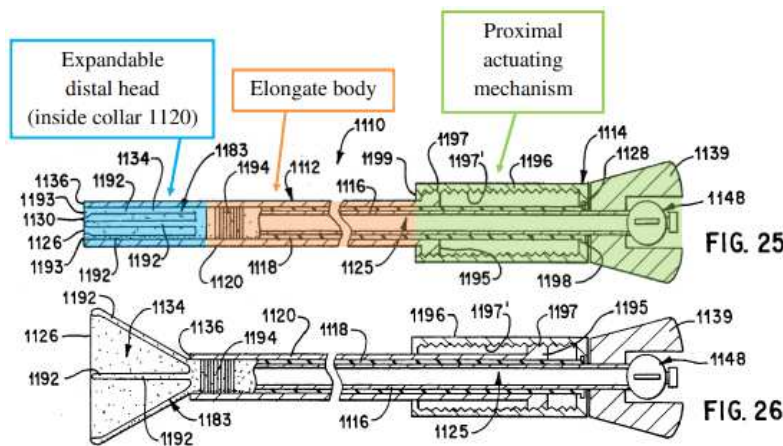
C. Knowledge in the Relevant Field and Brief Overview of the Art

As explained in detail in the corresponding Declaration of John Anthony Pearce, Ph.D. (Ex. 1002) and addressed in further detail below (Section VII), the involved claims would not have been considered new or non-obvious to a person of ordinary skill in the art at the relevant time. Ex. 1002 ¶¶ 14, 30. Both the archetypical design and the specific elements of the device recited in the '348 patent claims, such as an expandable applicator head including a flexible deflecting mechanism, a pivot grip handle, and a dimension indicator, were conventional aspects of minimally invasive surgical devices at the time. *Id.*

Endometrial ablation as a medical procedure was well-known prior to the '348 patent, and there were likewise numerous known devices in the mid- to late-1990s that employed an applicator head that collapsed for insertion into the body and then could be expanded once in the uterine cavity for ablation treatment. *Id.* ¶¶ 31-34. For example, U.S. Patent No. 5,358,496 to Edwards ("Edwards," Ex. 1005) describes an elongate surgical device with an expandable distal applicator head for ablation of uterine tissue and a proximal actuating mechanism. Ex. 1005 at 1:21-24, FIG. 2. Edwards' expandable applicator head is "configured to be positioned in a uterine cavity in a non-deployed state, receive an expansion media and extend to a deployed state." *Id.* at 2:53-56, FIG. 4 (annotated here); *see also* Ex. 1002 ¶¶ 31, 33.



Another example of an elongate endometrial ablation device with an expandable distal RF energy applicator head is seen in U.S. Patent No. 5,514,091 to Yoon (“Yoon,” submitted as Ex. 1007). Yoon discloses an “expandable multifunctional instrument for performing various diverse operative procedures,” including “uterine ablation.” Ex. 1007 at Abstract, 20:34-38; *see also id.* at FIG. 13. As seen in the annotated figures shown here, Yoon discloses an ablation device that comprises the typical structure of an expandable applicator head, an



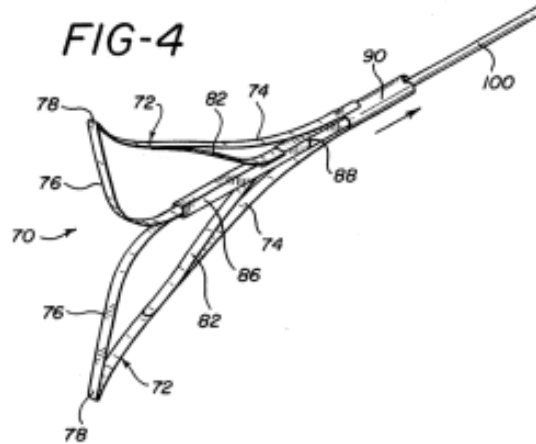
elongate body, and a distal actuating mechanism (*i.e.*, a handle). *Id.* at FIGS 25 (head collapsed), 26 (head expanded); Ex. 1002 ¶ 32. The device described in Yoon “can be made of an

electrically conductive material or can include electrically conductive fibers or an electrically conductive spine for electrical coagulation or cauterization of tissue depending on procedural use.” *Id.* at 6:40-44; *see also* Ex. 1002 ¶ 32. Yoon discloses that its applicator head may have “a predetermined triangular or conical configuration in the expanded position advantageous for uterine use.” Ex. 1007 at 26:43-48, 26:65-27:2, FIG. 26; *see also* Ex. 1002 ¶ 34.

In addition, a triangular assembly of flexible support components actuated using telescoping tubes or sleeves was also well known in the medical device art prior to the ’348 patent. Ex. 1002 ¶ 35. For example, U.S. Patent No. 5,358,496 to

Ortiz *et al.* (“Ortiz,” submitted as Ex. 1006) discloses “an improved tissue manipulator which is adapted for insertion through an endoscopic device into a body cavity to manipulate internal body tissue therein.” Ex. 1006 at 2:32-35; *see also* 2:42-47. The expandable platform of Ortiz is formed from “a plurality of flexible, interconnected strips which

provide a pair of fingers 72” comprising an “outer strip 74,” “inner strip 76,” and flexible strut “82.” *See id.* at 4:52-66. The flexible strips are connected to an “actuator tube 90” and “a shaft or push rod 100 inside of

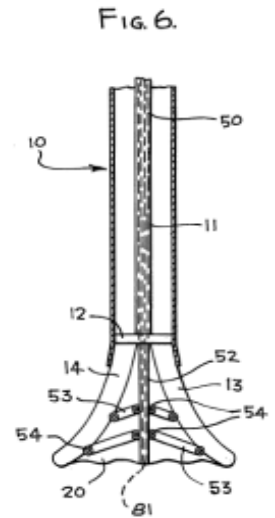
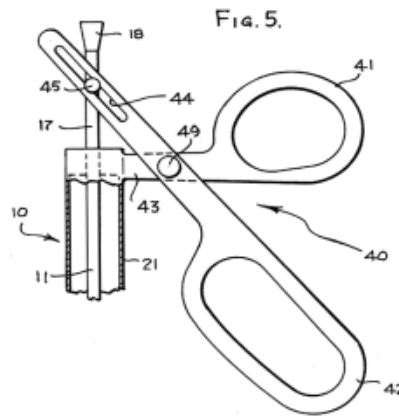


the actuator tube 90.” *Id.* Ortiz explains that “when actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.” *Id.* at 5:28-31, FIG. 4 (shown here); *see also* Ex. 1002 ¶ 35.

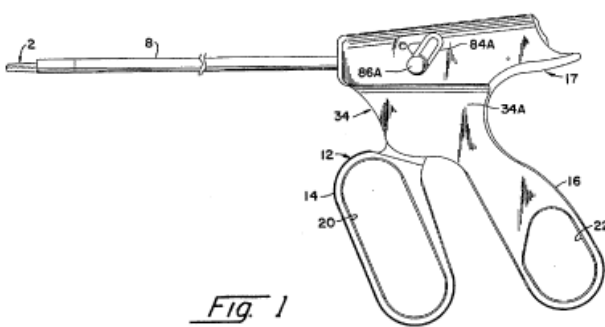
Another example of a minimally invasive surgical device that utilized flexible supports for an expandable distal head is seen in Nady-Mohamed. Nady-Mohamed discloses “an expandable device useful for gripping or manipulating a uterus or other similar organ within the body through engagement of the walls of the lumen of the organ, without engaging the outer surface of the same.” Ex. 1009 at 2:38-43; *see also id.* at FIGS. 5 (shown here – illustrating a *pivot grip handle*) and 6 (shown here – illustrating an *expandable head with flexures*); Ex. 1002 ¶ 37.

The device includes flexible arms 13, 14 having a retracted configuration for

insertion into the uterus and an expanded configuration whereby “[u]pon full deployment the arms and membrane will firmly engage the walls of the lumen.” Ex. 1009 at 5:65-6:2, FIG. 6; *see also* Ex. 1002 ¶¶ 38-39.



Additionally, prior art elongate devices with an expandable member included a proximal actuating mechanism. The pivot grip handle required by the claims of the '348 patent was a well-known actuation member design for elongate, minimally invasive surgical devices at that time. Ex. 1002 ¶¶ 14, 36. One such example is found in Lichtman, which discloses “surgical instruments for manipulating tissue and . . . instruments



such as graspers and forceps for facilitating freedom of the hands of the surgeon and also for conducting electrosurgery.” Ex. 1008 at 1:8-12. Lichtman discloses a pivot handle mechanism coupled to a pair of

telescoping tubes for opening or closing a distal jaw assembly. *See* Ex. 1008 at FIG. 1 (shown here); *see also* Ex. 1002 ¶ 36.

Nady-Mohamed also teaches a pivot grip handle to actuate its expandable

head. As seen in FIG. 5 above, the device includes a handle comprising “a scissors-like mechanism 40 having scissor arms 41 and 42 which are pivotally attached near their mid points,” such that “[w]hen the finger rings of the scissor arms 41 and 42 are brought together, . . . plunger 11 [is] moved toward the distal end of the tube.” *Id.* at 4:58-62, 4:66-5:3, FIG. 5; *see also* Ex. 1002 ¶¶ 38-39.

Finally, as acknowledged during *ex parte* prosecution of the '348 patent, devices for indicating the dimensions of a uterus were also known prior to the '348 patent. *See* Ex. 1004 at 90-95, 57-58, 7; *see also* Ex. 1002 ¶¶ 40-41. Indeed, the '348 patent acknowledges conventional, prior art indicator mechanisms as falling within the scope of the purported invention. *See* Ex. 1001 at 14:60-63 (describing “using a conventional sound or other means” to determine a uterine dimension); *see also id.* at 15:56-62. As an example, Chinese Patent Publication No. CN 1060594A to Jing *et al.* (“Jing,” submitted as Ex. 1010; a certified English translation of Jing is submitted as Ex. 1011) discloses sensors deployed from an elongate sleeve such that its “apparatus may measure a transverse dimension and a longitudinal dimension of the uterine cavity and automatically display the measured data.” *Id.* at Abstract, 5:9-13; *see also* Ex. 1002 ¶¶ 40-41.

Other aspects and features as claimed by the '348 patent, such as an introducer sheath and a locking mechanism, were also known before the '348 patent. *See, e.g.,* Ex. 1006 at 4:48-51 (discussing “sheath 96”); Ex. 1008 at 9:30-32 (discussing “locking means”); *see also* Ex. 1002 ¶ 42. For these reasons, and as described in greater detail below and in Dr. Pearce’s declaration, the devices for treating a uterus as recited in claims 1-15 were already described in the prior art as

of the presumed priority date for the '348 patent. Ex. 1002 ¶ 43.

D. Brief Overview of the Level of Skill in the Art

Petitioner's technical expert, Dr. John Anthony Pearce, is the Temple Foundation Professor of Electrical Engineering at the University of Texas at Austin. Ex. 1002 ¶ 1. Dr. Pearce has worked in the field of electrosurgery and biomedical instrumentation since the early 1970s and is therefore familiar with the knowledge and level of ordinary skill prior to the '348 patent. *Id.* ¶¶ 1-7; *see also* Ex. 1003. As Dr. Pearce explains, a person of ordinary skill in the relevant field prior to May 8, 1998 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.

A person of ordinary skill in the relevant field would have been aware of developments in the field of electrosurgical devices and would have been working with trends from the mid- to late-1990s, including 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, such as those described above in Section I.C. *Id.* ¶¶ 48-49.

II. GROUNDS FOR STANDING

Petitioner certifies that, under 37 C.F.R. § 42.104(a), the '348 patent is available for *inter partes* review, and Petitioner is not barred or estopped from requesting *inter partes* review of the '348 patent on the grounds identified.

III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)): Minerva Surgical, Inc. and Hermes Innovations, LLC are the real parties-in-interest.

Related Matters (37 C.F.R. § 42.8(b)(2)): Patent Owner has asserted the '348 patent against Petitioner in United States District Court for the District of Delaware, Case No. 1:15-cv-01031-SLR (attached as Ex. 1012). Petitioner is concurrently filing a second petition for *inter partes* review of the '348 patent based on separate, non-redundant grounds.

Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)): Lead Counsel: Michael T. Rosato (Reg. No. 52,182); Back-Up Counsel: Matthew A. Argenti (Reg. No. 61,836), Steven W. Parmelee (Reg. No. 31,990)

Service Information – 37 C.F.R. § 42.8(b)(4). Petitioners hereby consent to electronic service. Email: mrosato@wsgr.com; margenti@wsgr.com; sparmelee@wsgr.com; Post: WILSON SONSINI GOODRICH & ROSATI, 701 5th Ave, Suite 5100, Seattle, WA 98104-7036; Tel.: 206-883-2529; Fax: 206-883-2699

IV. STATEMENT OF THE PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED

Petitioners request review of claims 1-15 of the '348 patent under 35 U.S.C. § 311 and AIA § 6. The specific grounds for relief are as follows:

- Ground 1: Claims 1-15 are obvious 35 U.S.C. § 103 over Edwards, Ortiz, Lichtman, and Jing.

V. CLAIM CONSTRUCTION

A claim subject to *inter partes* review receives the broadest reasonable

construction in light of the specification of the patent in which it appears. *See* 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC.*, 793 F.3d 1268, 1275-1280 (Fed. Cir. 2015), *cert. granted*, *Cuozzo Speed Techs., LLC v. Lee*, 2016 U.S. LEXIS 632 (U.S. Jan. 15, 2016) (No. 15-446). For the purposes of this review, claim terms are to be given their broadest reasonable interpretation, consistent with how they would be understood by one of ordinary skill in the art. A few terms that warrant discussion are identified and discussed below.

“frame”: Independent claim 1 requires that the inner sleeve is translated relative to a “frame” in order to expand the applicator head. The claim recites that the frame forms part of the handle, but does not otherwise require any particular structure or configuration for the frame. Ex. 1002 ¶ 51.

The specification does not provide an express definition for the term “frame.” Although “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.” *See, e.g.*, Ex. 1001 at 4:28-36, 17:37-53, FIG. 34; Ex. 1002 ¶ 52.

Dr. Pearce explains that a person of skill in the art would understand the broadest reasonable interpretation of the term “frame,” in view of the surrounding claim language and the specification of the ’348 patent, to refer to a structure mounted on or connected to a handle grip, that surrounds or encloses another component. Ex. 1002 ¶ 53. This is consistent with the plain and ordinary meaning of the word “frame” as a structure that surrounds or encloses something. Ex. 1013

at 4 (“an enclosing structure or case”); Ex. 1014 at 3 (“an arrangement of structural parts that gives form or support”). Accordingly, the term “frame” should be construed to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve).

“flexure”: Independent claims 1 and 11 require flexures that are disposed within the applicator head, and specifically recite “external flexures” and “internal flexures” coupled to the outer and inner sleeves, respectively. Ex. 1002 ¶ 54.

The ’348 patent does not specifically define “flexures,” but does describe that they “are preferably an insulated spring material such as heat treated 17-77 PH stainless steel,” Ex. 1001 at 13:65-67. Figure 30 depicts “flexures 124” and “internal flexures 136,” consistent with the “external flexures” and “internal flexures” recited in the claims, respectively. *Id.* at 13:56-14:31; Ex. 1002 ¶ 55. The specification explains that “[t]he deflecting mechanism formed by the flexures 124, 136, and ribbon 138 forms the array into the substantially triangular shape shown in FIG. 23,” and “relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array.” *See* Ex. 1001 at 14:21-31; *see also* Ex. 1002 ¶ 55.

As Dr. Pearce explains, a person of skill in the art would understand the term “flexure” to refer to a component designed to be bent or curved. Ex. 1002 ¶ 56. This is consistent with both its use in the specification to describe elements that deflect, or change direction from a straight path, to form the deflecting mechanism, as well as the plain and ordinary meaning of the term. Ex. 1013 at 3 (“a bent part”). The term “flexure,” therefore, should be construed to include a component

designed to be bent or curved.

VI. STATEMENT OF NON-REDUNDANCY

Petitioner is concurrently filing a separate petition for *inter partes* review of the '348 patent based on different prior art. Each ground raised in the two petitions is meaningfully distinct. The ground in this petition relies on Edwards, a U.S. Patent qualifying as prior art under 35 U.S.C. § 102(e). The grounds in the concurrently-filed petition rely on Yoon, a U.S. Patent qualifying as prior art under 35 U.S.C. § 102(b). In addition to their separate and distinct disclosures, should the Patent Owner attempt to disqualify Edwards as prior art (*e.g.*, swear behind), the availability of Yoon would likely render such an attempt moot considering the latter reference predates the '348 patent by some two years.

VII. DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY

A. [Ground 1] Claims 1-15 are Obvious under 35 U.S.C. § 103 over Edwards, Ortiz, Lichtman, and Jing

Edwards, filed February 4, 1998, is qualified as a prior art printed publication under 35 U.S.C. § 102(e). Ortiz, issued October 25, 1994, Lichtman, issued April 15, 1997, and Jing, published April 29, 1992, are each qualified as a prior art printed publication under 35 U.S.C. § 102(b). As described in further detail below, claims 1-15 of the '348 patent would have been obvious to one of ordinary skill in the art in view of Edwards, Ortiz, Lichtman, and Jing. Ex. 1002 ¶¶ 59-164.

Edwards² describes an endometrial ablation device including an elongated design, a distal applicator head including a frame for mechanical expansion within the uterus, and a proximal handle to facilitate manipulation and operation by a physician. Ex. 1001 at 2:53-56, 5:10-20, 6:57-61, 7:19-22; *see also* Ex. 1002 ¶¶ 31, 33. Edwards also discloses ultrasound imaging of uterine morphology to determine the parameters of the ablation treatment. Ex. 1005 at 6:23-54; *see also* Ex. 1002 ¶ 70. Thus, Edwards discloses each of the main elements of the ablation device described in the '348 patent assembled in a manner consistent with similar minimally invasive surgical devices at the relevant time. *See, e.g.*, Ex. 1002 ¶ 14; Section I.C, *supra*.

Edwards describes numerous exemplary applicator head designs and expressly states that other known designs for an expandable applicator head can also be used in its ablation device. *See* Ex. 1005 at 4:57-62, 6:4-8; *see also* Ex. 1002 ¶ 62. Ortiz³ describes a known design for an expandable applicator head used to manipulate tissues in a minimally invasive surgical procedure. Ex. 1002 ¶ 35. In particular, Ortiz discloses an expandable frame including interconnected

² While a number of patents to which Edwards is a continuation-in-part were disclosed during *ex parte* prosecution in an IDS along with over 300 other references, Edwards itself was never disclosed. Ex. 1004 at 167-168.

³ While Ortiz was included in a Notice of References Cited during *ex parte* prosecution, this reference was never applied against the claims in an Office Action. Ex. 1004 at 98.

flexures and actuated by two coaxially slidable sleeves. Ex. 1006 at 2:42-27, 4:52-66, 5:28-31; *see also* Ex. 1002 ¶ 35. One of ordinary skill would have recognized Ortiz's configuration as well matched to the anatomical aspects of the uterine cavity and well suited for use as an expansion mechanism in an endometrial ablation device as disclosed in Edwards. Ex. 1002 ¶¶ 63-64. Such a configuration would allow improved contact with the uterine wall during ablation and would have simplified the design disclosed in Edwards, for example, by reducing the need for fluid expansion components. *Id.* ¶ 64.

Edwards does not expressly identify a pivot grip handle as its proximally-placed actuating mechanism, but the pivot grip design in this regard was well known in the surgical device art since at least the 1930s. *See* Ex. 1016 at FIG. 1; Ex. 1002 ¶ 14. Such a design is exemplified in the minimally invasive surgical devices described in Lichtman. Ex. 1002 ¶ 65. In particular, Lichtman discloses an electrosurgical instrument utilizing a pair of pivotally-coupled handle grips to actuate the opening and closing of distal applicator jaws. *See* Ex. 1008 at 1:8-12, 3:41-51, 6:19-22; *see also* Ex. 1002 ¶ 36. Lichtman further discloses an adjustable locking mechanism to limit movement of the pivot grip handle and applicator head. *See* Ex. 1008 at 9:30-32; *see also* Ex. 1002 ¶¶ 36, 42. A pivot grip handle as disclosed in Lichtman enables one-handed operation of the instrument, and would benefit the operation of an ablation device as in Edwards by allowing one-handed deployment of the applicator head. Ex. 1002 ¶ 67.

Regarding an "indicator mechanism" as recited in the '348 patent claims, Edwards discloses the use of ultrasound imaging to map the interior of the uterus

and determine ablation parameters. Ex. 1005 at 6:24-54; *see also* Ex. 1002 ¶ 70. Edwards does not teach the ultrasound element located on the device sleeve. Use of an indicator mechanism, including placement in an elongate device inserted into the uterus, was well known in the art, as illustrated in Jing. Ex. 1002 ¶¶ 40-41. Jing discloses a device for measuring uterine dimensions using two contacts deployed from a hollow sleeve and outputting the measurement data to a controller. Ex. 1011 at Title, Abstract, 3:5-7, 5:9-13; *see also* Ex. 1002 ¶¶ 40-41. Utilizing a uterine measurement device as disclosed in Jing would have allowed for low cost morphology-based determination of treatment parameters. Ex. 1002 ¶ 70.

The discussion below further illustrates that each and every element of claims 1-15 of the '348 patent would have been obvious to one of ordinary skill in the art in view of Edwards, Ortiz, Lichtman, and Jing. The particular citations listed are intended to be illustrative, not exhaustive. More detailed discussion of rationale to combine is set forth below. *See* Section VII.A.iv, *infra*.

i. Independent Claim 1

Assuming that the **claim 1 preamble** is limiting, this language is disclosed by the combination of Edwards, Ortiz, Lichtman and Jing.

'348 Patent	Edwards, Ortiz, Lichtman, and Jing
1. A device for treating a uterus comprising:	<p>Edwards discloses: “This invention 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 method and apparatus to create selective cell necrosis of target sites of the uterus.” 1:21-24.</p> <p>Jing discloses: “The present invention relates to a medical apparatus, particularly to a computer-controlled measurement apparatus for measuring the morphology of a woman’s uterine cavity and obtaining data</p>

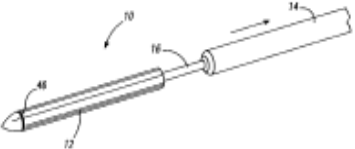
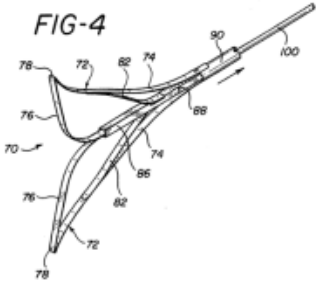
	<p>thereof.” 3:5-7. Ortiz discloses: “The present invention relates to a tissue manipulator adapted for manipulating tissue in a human body and, more particularly, to an endoscopic tissue manipulator which is insertable through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity.” 1:8-12. Lichtman discloses: “During surgical operations, it is often necessary for the surgeon to be able to manipulate blood vessels, ligaments or other tissue precisely, particularly when the surgeon is relatively remote from the surgical site, as is the case in performing endoscopic procedures. 1:34-38. <i>See also</i> Ex. 1002 ¶¶ 72-74.</p>
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Edwards and Jing each disclose a device for treating a uterus. Ex. 1002 ¶ 72. For example, Edwards discloses an “apparatus to controllably create cell necrosis of at least a portion of the uterus, and more particularly to a method and apparatus to create selective cell necrosis of target sites of the uterus.” Ex. 1005 at 1:21-24. Likewise, Jing discloses that “ a computer-controlled measurement apparatus for measuring the morphology of a woman’s uterine cavity and obtaining data thereof.” Ex. 1011 at 3:5-7; *see also* Ex. 1002 ¶ 72.

While Ortiz and Lichtman do not expressly disclose a device for treating a uterus, these references do disclose minimally invasive surgical devices for treating internal body tissues. Ex. 1002 ¶ 73. For example, Ortiz discloses “an endoscopic tissue manipulator which is insertable through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity.” Ex. 1006 at 1:8-12. Similarly, Lichtman discloses devices for manipulating tissues “particularly when the surgeon is relatively remote from the surgical site, as is the case in performing endoscopic procedures.” Ex. 1008 at 1:34-38; *see also* Ex. 1002 ¶ 73.

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing teaches or suggests “a device for treating a uterus.” Ex. 1002 ¶ 74.

This combination also discloses **limitation 1.1**:

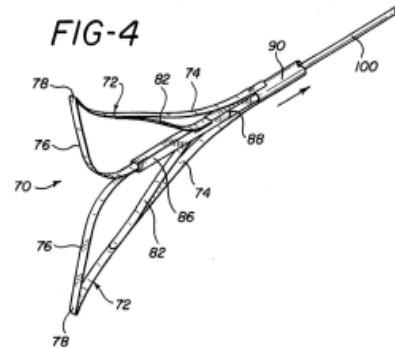
'348 Patent	Edwards, Ortiz, Lichtman, and Jing
<p>[1.1] an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;</p>	<p>Edwards discloses: “One embodiment of cell necrosis apparatus 10 of the invention is illustrated in FIGS. 1(a), 1(b) and 1(c) and includes a porous membrane and/or an expandable member 12 that is introduced into a desired body organ or lumen through an introducer sleeve 14 which can be attached to a handpiece (handle) 15 (FIG. 2).” 4:52-57; <i>see also</i> 5:4-9, 5:19-21, FIGS. 1B, 2.</p>  <p>Ortiz discloses: “The endoscopic tissue manipulator 50 . . . includes a proximal handle assembly 60 and a distal platform 70 . . . A finger operated actuator or slide 80 is connected to an elongated actuator tube 90 which is slidable relative to handle assembly 60 for expanding the platform 70 into the desired configuration.” 4:30-51. “The outer strip 74 is attached, e.g., by spot welding, to the distal end of the actuator tube 90. Also, the inner strip 76 is attached, e.g., by spot welding, to the distal end of a shaft or push rod 100 inside of the actuator tube 90.” 4:59-63. “Referring to FIG. 4, 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.” 5:28-31. <i>See also</i> FIGS. 1, 2, 4.</p>  <p>Lichtman discloses: “Outer shaft 8, which coaxially surrounds and is free to slide axially relative to inner tube 10, is rigidly joined to a gear rack tube or sleeve 36, e.g., by a press fit, a cement, welding or a pin.” 6:31-34. <i>See also</i> Ex. 1002 ¶¶ 75-83.</p>

As disclosed in both Edwards and Ortiz, elongate sleeves slidable relative to one another were a well-known configuration for actuating components of minimally invasive surgical devices at the time. Edwards, for example, discloses an elongate member having a proximal portion and a distal portion. For example, figures 1B and 2 illustrate an elongate “cell necrosis apparatus 10” with an “expandable member 12 that is introduced into a desired body organ through an introducer sleeve 14 attached to a handpiece (handle)15.” Ex. 1005 at 4:52-57. The expandable member 12 and handle 15 are the distal and proximal portions of the elongate member, respectively. Ex. 1002 ¶ 75.

Edwards further discloses that the expandable member 12 is slidably disposed within the introducer sleeve 14. For instance, the “[e]xpandable member 12 is introduced through introducer sleeve 14 in a folded, or non-distended configuration,” after which the “introducer sleeve 14 is withdrawn and can be retracted into handle 15.” Ex. 1005 at 5:4-5, 19-21; Ex. 1002 ¶ 76.

In mapping to the specific aspects of the claims, Edwards does not specifically describe an inner sleeve slidably and coaxially disposed within an outer sleeve. However, as Dr. Pearce explains, these aspects are fully disclosed by Ortiz. Ex. 1002 ¶ 77. Like Edwards, Ortiz discloses an elongate member having a proximal portion and a distal portion. *See, e.g.*, Ex. 1006 at 4:30-51, FIG. 2 (including “proximal handle assembly 60” and “distal platform 70 which is expandable, after insertion inside the body”); Ex. 1002 ¶ 78. Ortiz explains that this distal platform can be expanded into a “tulip-shaped configuration” as shown here in Figure 4. *See* Ex. 1006 at 4:40-42; *see also* Ex. 1002 ¶ 79.

Ortiz further discloses that the device includes an inner sleeve slidably and coaxially disposed within an outer sleeve. For example, Ortiz describes “an elongated actuator tube 90 which is slidable relative to the handle assembly 60 for expanding the platform 70 into the desired configuration.” *Id.* at 4:44-48. Dr. Pearce explains that the “elongated actuator tube



90” discloses an outer sleeve. Ex. 1002 ¶ 80. Ortiz further describes a “shaft or push rod 100” coaxially located “inside of the actuator tube 90.” Ex. 1006 at 4:59-63, FIG. 4. This shaft (element 100) teaches or suggests the inner sleeve recited in claim 1. Ex. 1002 ¶ 80. The two sleeves are slidable relative to each other, as the platform is expanded by moving the actuator tube relative to the shaft. Ex. 1006 at 5:28-31 (“[W]hen actuator tube 90 is . . . moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded”); *see also* Ex. 1002 ¶ 80.

To the extent that shaft 100 in Ortiz is not expressly disclosed as being a hollow sleeve, Dr. Pearce explains that a person of ordinary skill would have understood this to be a design variation readily found in the art. Ex. 1002 ¶ 81. For example, Lichtman discloses hollow outer and inner sleeves in the form of outer shaft 8 and inner tube 10, respectively. *See, e.g.*, Ex. 1008 at 6:31-34. As is discussed below with respect to limitation 1.3, it would have been obvious to combine the teachings of Ortiz and Lichtman such that the Lichtman pivot handle was used to expand and contract the Ortiz deflection mechanism. Ex. 1002 ¶ 81.

One of ordinary skill in the art would have incorporated an expansion mechanism as in Ortiz into an ablation device as disclosed by Edwards, because Edwards teaches that different expansion designs can be used and because Ortiz’s design is well-suited to conform to the uterine shape. Ex. 1002 ¶¶ 61-64, 82. In addition, 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 ¶¶ 64, 82; *see also* section VII.A.iv, *infra*.

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing teaches or suggests “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.” Ex. 1002 ¶ 83.

This combination also discloses **limitation 1.2**:

'348 Patent	Edwards, Ortiz, Lichtman, and Jing
[1.2] 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	<p>Edwards discloses:</p> <p>“The apparatus includes an expandable member configured to be positioned in a uterine cavity in a non-deployed state, receive an expansion media and extend to a deployed state.” 2:53-61; <i>see also</i> FIGS. 1B, 1C.</p> <p>“Expandable member 12 is introduced through introducer sleeve 14 in a folded or non-distended configuration. Introducer sleeve . . . is small enough to be introduced into the cervix under local anesthesia.” 5:4-9.</p> <p>“[C]ell necrosis apparatus 10 is first introduced into the uterus under local anaesthesia. Introducer sleeve 10 is then withdrawn, and expandable member 12 is expanded.” 6:2-8.</p> <p>“[C]ell necrosis apparatus conforms lightly with the interior of</p>

<p>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;</p>	<p>the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20. Conforming member 20 is fitted into the entire uterus and expandable member 12 does not have to be moved about the uterus to complete the treatment.” 7:38-44; <i>see also</i> 6:34-38, FIG. 4.</p> <p>“A variety of electromagnetic energy sources can be coupled to the porous membrane [forming the exterior of the expandable member], including, (i) an RF source coupled to an RF electrode” 5:28-30; <i>see also</i> 2:60-61, 5:46-48, 6:34-38, 7:19-36.</p> <p>“[T]he entire endometrium can be treated and selectively ablated.” 6:55-57.</p> <p><i>See also</i> Ex. 1002 ¶¶ 84-90.</p>
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Edwards on its own fully discloses the recited elements of limitation 1.2. Ex. 1002 ¶ 84. Edwards discloses an “expandable member” serving as the applicator head recited in this limitation. Ex. 1005 at 2:53-61 (describing an “expandable member configured to be positioned in a uterine cavity in a [contracted] non-deployed state”). A comparison of the contracted and expanded states can be seen in Figures 1B (contracted) and 1C (expanded). *Id.* at FIGS. 1B, 1C; Ex. 1002 ¶ 85. When in the contracted state, the applicator head in Edwards is configured for transcervical insertion. Ex. 1005 at 4-9 (stating that the “folded or non-distended configuration” of the applicator head “is small enough to be introduced into the cervix under local anesthesia”); *see also* Ex. 1002 ¶ 86.

Edwards also teaches that the applicator head conforms to the shape of the uterus when in the expanded state. Ex. 1002 ¶ 86. In the expanded state after insertion into the uterus, “[c]ell necrosis apparatus 10 automatically conforms to the interior of the uterus.” Ex. 1005 at 6:34-38; *see also* 7:38-44 (stating that the

device “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”); Ex. 1002 ¶ 86.

Edwards discloses that its applicator head includes electrodes for ablating endometrial lining tissue of the uterus. *See, e.g.*, Ex. 1005 at 2:60-61 (“[a]n energy delivery device is coupled to the expandable member”), 5:28-30 (electromagnetic energy sources can be coupled to the porous membrane, including, (i) an RF source coupled to an RF electrode”), 5:46-48 (“the energy delivery device is one or more RF electrodes”), 6:55-57 (“the entire endometrium can be treated and selectively ablated”); *see also* Ex. 1002 ¶¶ 88-89. Edwards also explains that these electrodes may be integrated into the structure used to expand and contract the applicator head, describing “one or more energy delivery devices 23 [that] can be coupled to frame 19 and advanced into a selected tissue site.” *Id.* at 7:19-36; Ex. 1002 ¶ 88.

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing discloses the “applicator head” recited in limitation 1.2. Ex. 1002 ¶ 90.

This combination also discloses **limitation 1.3**:

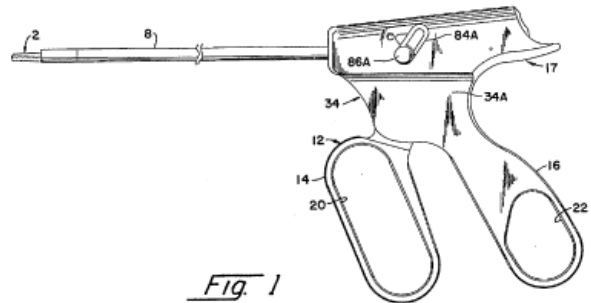
'348 Patent	Edwards, Ortiz, Lichtman, and Jing
[1.3] a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a	<p>Edwards discloses: “FIG. 2 is a perspective view of a handle associated with the cell necrosis apparatus of the invention.” 3:27-28; <i>see also</i> 5:10-20, FIG. 2.</p> <p>Ortiz discloses: “[T]he tissue manipulator comprises a handle, a support shaft extending from the handle, an expandable frame mounted at the distal end of the support shaft, and a means for expanding the frame.” 2:48-53; <i>see also</i> 6:21-28, FIG. 6.</p> <p>Lichtman discloses: “. . . an improved surgical instrument that is essentially</p>

<p>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;</p>	<p>characterized by first and second shafts disposed in axial telescoping relation with one another, a jaw assembly or head at the distal (front) end of the first shaft, with the proximal (rear) end of the first shaft being affixed to a novel handle mechanism that is also coupled to the second shaft, so that manipulation of the handle mechanism by the surgeon will cause the second shaft to reciprocate axially relative to the first shaft, thereby resulting in opening and closing of the jaw assembly.” 3:41-51; <i>see also</i> 6:13-18, FIG. 1.</p> <p>“Handle assembly 12 includes a stationary handle member 16 and a movable handle member 14 that is rotatable with respect to stationary handle member 16 about a pivot pin or rod 18 (FIG. 9).” 6:19-24, FIG. 9.</p> <p>“Outer shaft 8, which coaxially surrounds and is free to slide axially relative to inner tube 10, is rigidly joined to a gear rack tube or sleeve 36.” 6:31-34.</p> <p>“Movable handle member 14 is provided with a curved set of gear teeth 38 which engage gear rack teeth 40 (FIG. 9) of gear rack tube 36 . . . outer tubular shaft 8 moves axially toward or away from stationary handle member 16 as gear rack tube 36 is forced to reciprocate by rotation of movable handle member 14 relative to stationary handle member 16.” 7:47-60; <i>see also</i> 1:66-2:6, 3:41-66.</p> <p>“Consequently, when the handle 14A is pivoted forwardly (clockwise) on the axis of pivot pin 18, as viewed in FIG. 20, the gear rack tube 36 will move forwardly in chamber 42 to effect closing of jaw piece 2.” 14:63-67, FIG. 20.</p> <p><i>See also</i> Ex. 1002 ¶¶ 91-101.</p>
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Each of Edwards and Ortiz disclose that their devices include a handle coupled to the proximal portion of the elongate member. Ex. 1002 ¶ 91. For example, Figure 2 of Edwards provides “a perspective view of a handle associated with the cell necrosis apparatus of the invention.” Ex. 1005 at 3:27-28; *see also id.* at 5:10-20 (describing handle as “provid[ing] physical control” and receiv[ing] the introducer sleeve when it is withdrawn from the applicator head”); Ex. 1002 ¶ 91. Likewise, in Ortiz “the tissue manipulator comprises a handle, a support shaft

extending from the handle, an expandable frame mounted at the distal end of the support shaft, and a means for expanding the frame.” Ex. 1006 at 2:48-53; *see also id.* at 6:21-28 (describing “grip” portion of handle); Ex. 1002 ¶ 92.

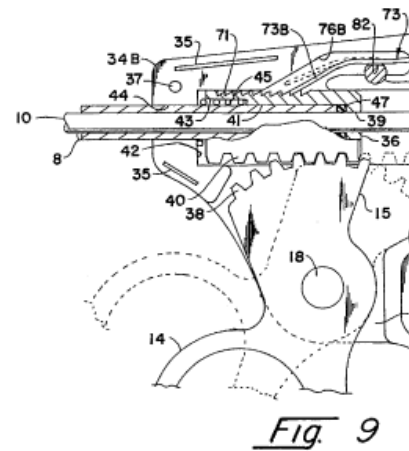
While each of Edwards and Ortiz discloses a handle, neither expressly discusses two handle grips pivotally attached to each other as required by this claim limitation. As Dr. Pearce explains, however, such a handle design was well-known in the prior art and is described at the time, as illustrated in Lichtman. Ex. 1002 ¶¶ 14, 93; *see also* Section I.C.



Lichtman discloses a device including an elongate member having inner and outer sleeves (“first and second shafts”), an applicator head (“a jaw assembly or head”) coupled to the distal end of the elongate member, and a handle coupled to the proximal end of the elongate member for expanding the applicator head (a “handle mechanism” that results in “opening and closing of the jaw assembly”). Ex. 1008 at 3:41-51; Ex. 1002 ¶ 94. For example, Figure 1 of Lichtman, shown here, illustrates a device with an elongate member (outer hollow shaft 8 enclosing inner shaft 10), distal applicator head (jaw piece 2), and proximal handle (handle assembly 12). *See also* Ex. 1006 at 6:13-18; Ex. 1002 ¶ 95.

Lichtman discloses that “[h]andle assembly 12 includes a stationary handle member 16 and a movable handle member 14 that is rotatable with respect to stationary handle member 16 about a pivot pin or rod 18 (FIG. 9).” Ex. 1006 at

19-24; FIG. 9. Thus, the stationary handle member 16 and movable handle member 14 disclose proximal and distal grips pivotally attached to each other at a pivot point. Ex. 1002 ¶ 96. As for the claimed “frame,” Lichtman describes that “[o]uter shaft 8, which coaxially surrounds and is free to slide axially relative to inner tube 10, is rigidly joined to a gear



rack tube or sleeve 36.” Ex. 1006 at 6:31-34; FIG. 9 (shown here). As Dr. Pearce explains, and as discussed in further detail with respect to limitation 1.4, the gear rack tube 36 teaches or suggests the claimed frame. Ex. 1002 ¶ 97.

Lichtman also teaches that the proximal and distal grips are operably coupled to the applicator head in order to actuate expansion of the applicator head. For instance, as explained in Lichtman, “manipulation of the handle mechanism by the surgeon will cause the second shaft to reciprocate axially relative to the first shaft, thereby resulting in opening and closing of the jaw assembly.” Ex. 1006 at 3:41-66; *see also* 7:47-60 (describing “gear teeth” of movable handle member 14 that “engage gear rack teeth 40 (FIG. 9) of gear rack tube 36” to cause axial movement of shaft 8); 1:66-2:6 (describing opening and closing of jaws based on axial movement of inner shaft relative to outer shaft); Ex. 1002 ¶ 98.

Lichtman discloses a “reversing gear mechanism” whereby movement of the proximal and distal grips closer together causes the applicator head to transition from the contracted to the expanded state. Ex. 1006 at 14:63-67 (“[W]hen the handle 14A is pivoted forwardly (clockwise) on the axis of pivot pin 18, as viewed

in FIG. 20, the gear rack tube 36 will move forwardly in chamber 42 to effect closing of jaw piece 2.”), FIG. 20. Pivoting of the handle 14A in the opposite direction towards the handle member 16 results in proximal movement of the gear rack tube 36 and outer shaft 8, thus opening the jaw piece 2. Ex. 1002 ¶ 99.

One of ordinary skill in the art would reasonably have included a pivot grip handle as a proximally-located mechanism for actuating a distal expandable applicator head in an ablation device, as such a design was known for decades prior to the ’348 patent and would provide greater ease of operation, for example, allowing a physician to operate the handle with one hand instead of two. Ex. 1002 ¶¶ 65, 67, 100; *see also* Section VII.A.iv, *infra*. Moreover, Lichtman, Edwards, and Ortiz all similarly disclose endoscopic surgical devices including expandable elements for interacting with tissue, Lichtman and Edwards are similarly directed to electrosurgical instruments, and Lichtman and Ortiz operate according to nearly identical mechanical operating principles. *See, e.g.*, Ex. 1005 at 5:28-30; Ex. 1006 at 5:28-31; Ex. 1008 at 2:53-67, 3:37-39, 5:62-6:2; Ex. 1002 ¶¶ 65-66, 100.

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing teaches or suggests the “handle” recited in limitation 1.3. *Id.* ¶ 101.

This combination also discloses **limitation 1.4**:

'348 Patent	Edwards, Ortiz, Lichtman, and Jing
[1.4] a deflecting mechanism including flexures disposed within the	Edwards discloses: “[E]xpandable member 12 is expanded, either mechanically, with the introduction of a fluid or gaseous expanding medium, such as [an] electrolytic solution, or a combination of both.” 6:4-8. “A frame 19 can be included in expandable member 12 and in one embodiment is used to assist opening expandable member 12 to

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

[the] deployed position. Frame 19 can include one or more arms 19' that can be coupled together.” 7:19-22, FIG. 4.

Ortiz discloses:

“ . . . the platform 70 consists of a plurality of flexible, interconnected strips which provide a pair of fingers 72 adapted to expand bilaterally

outward . . . Each of the fingers 72 comprises an elongated, flat metal strap which is folded or bent back upon itself to provide an outer strip 74 and inner strip 76 which meet at a distal finger tip 78. The outer strip is

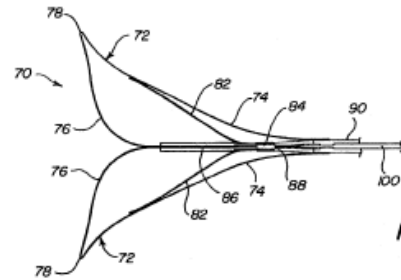


FIG-7

attached, e.g., by spot welding, to the distal end of a shaft or push rod 100 inside of the actuator tube 90. Each finger 78 includes a flexible strut 82 with its distal end secured to an intermediate portion of the outer strip adjacent to the finger tip 78. Each strut 82 has its proximal end attached to a connector sleeve 84 (FIG. 7) which is slidably mounted on the inner strips 76 of the fingers 72 . . . The connector sleeve 84 and guide tube 86 slidably receive the inner strips 76 of the fingers 72.” 4:48-5:10, FIGS. 3, 7.

“The outer strip 74 is attached, e.g., by spot welding, to the distal end of the actuator tube 90.” 5:59-60.

“A finger operated actuator or slide 80 is connected to an elongated actuator tube 90 which is slidable relative to handle assembly 60 for expanding the platform 70 into the desired configuration.” 4:43-48.

“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).” 8:10-19; *see also* 4:48-51, FIG. 9.

Lichtman discloses:

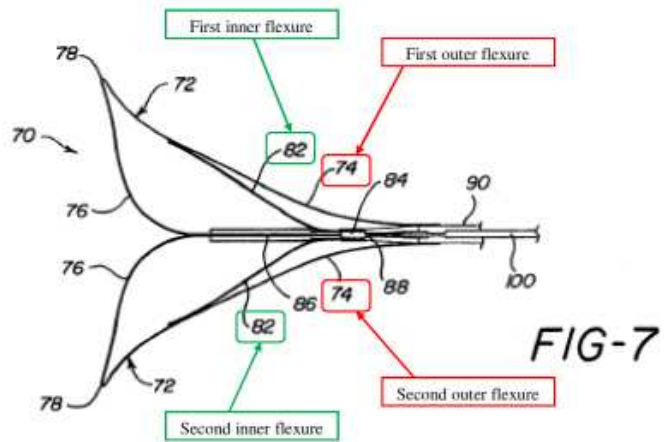
“Movable handle member 14 is provided with a curved set of gear teeth 38 which engage gear rack teeth 40 (FIG. 9) of gear rack tube 36 . . . outer tubular shaft 8 moves axially toward or away from stationary handle member 16 as gear rack tube 36 is forced to reciprocate by rotation of movable handle member 14 relative to stationary handle member 16.” 7:47-60

See also Ex. 1002 ¶¶ 102-109.

The combination of Edwards, Ortiz, Lichtman, and Jing teaches the precise features of the applicator head as set forth in limitation 1.4. For example, Edwards discloses that its applicator head (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.” Ex. 1005 at 6:4-8. As seen in Figure 4 of Edwards, “[a] frame 19 can be included in expandable member 12 and in one embodiment is used to assist opening expandable member 12 to tie [sic] deployed position. Frame 19 can include one or more arms 19’ that can be coupled together.” *Id.* at 7:19-22; *see also* Ex. 1002 ¶ 102.

While Edwards teaches a mechanical frame used to assist in expanding its applicator head, it

does not specifically teach a deflecting mechanism with internal and external flexures coupled to inner and outer sleeves as claimed. However, Dr. Pearce explains that these aspects are fully disclosed by Ortiz. Ex. 1002 ¶ 103. For example, Ortiz discloses an expandable platform including “a plurality of flexible, interconnected strips” (i.e., flexures) coupled to inner and outer sleeves as recited in the limitation. *See* Ex. 1006 at 4:52-5:10. As can be seen in Figure 7 (annotated above), Ortiz discloses first and second outer flexures, each referred to as “outer strip 74,” and first and second inner flexures, each referred to as “flexible strut 82.” *See id.*; Ex. 1002 ¶ 103. The actuator tube 90 and shaft 100 disclose as the claimed



inner and outer sleeves, respectively, as previously discussed with respect to limitation 1.1. Ex. 1002 ¶ 103.

The flexures and sleeves in Ortiz are arranged and connected as recited in this limitation. For example, the outer flexures in Ortiz are coupled to the outer sleeve. Ex. 1006 at 5:59-60 (“The outer strip 74 is attached, e.g., by spot welding, to the distal end of the actuator tube 90”). Likewise, the inner flexures are coupled to the inner sleeve (shaft 100). *Id.* at 4:65-68 (“Each strut 82 has its proximal end attached to a connector sleeve 84 (FIG. 7) which is slidably mounted on the inner strips 76 of the fingers 72”), 4:61-63 (“[T]he inner strip 76 is attached, e.g., by spot welding, to the distal end of a shaft or push rod 100 inside of the actuator tube 90”). Dr. Pearce explains that a person of ordinary skill in the art would understand that the struts 82 are coupled to the shaft 100 serving as the inner sleeve by virtue of being mounted on the inner strips 76, which are in turn attached to the shaft 100. Ex. 1002 ¶ 104.

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. Ex. 1002 ¶ 105. For example, Ortiz describes “an elongated actuator tube 90 which is slidable relative to handle assembly 60 for expanding the platform 70 into the desired configuration.” Ex. 1006 at 4:43-48. 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.

Moreover, Ortiz also discloses that its deflecting mechanism includes a transverse ribbon. Ex. 1002 ¶ 106; Ex. 1006 at 4:55-59 and Figure 7.

Although Ortiz teaches all of the aspects of this limitation, the term “frame” as recited in this limitation refers to an element of the handle previously recited in the limitation 1.3. As described above with respect to limitation 1.3, the gear rack tube 36 of Lichtman teaches or suggests as the claimed frame. Ex. 1002 ¶ 107. As Dr. Pearce explains, a person of ordinary skill at the time would have understood that a pivot grip handle as in Lichtman could reasonably be used to actuate the deflecting mechanism of Ortiz including inner and outer sleeves. Ex. 1002 ¶ 108. In such a combination, the inner and outer sleeves of Ortiz would be coupled to the proximal grip, distal grip, and frame (gear rack tube 36) of Lichtman, similar to the arrangement of the outer shaft 8 and inner tube 10 shown in Figure 20 of Lichtman. *Id.* The deflecting mechanism of Ortiz, when combined with the handle mechanism of Lichtman, would be configured such that “translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state.” *Id.*; *see also* Section I.C.

One of ordinary skill in the art would reasonably have modified an endometrial ablation device such as disclosed by Edwards to incorporate the mechanical expansion elements taught by Ortiz, including a deflecting mechanism. *Id.* ¶¶ 61, 108. Edwards expressly states that alternative designs for the expandable head may be utilized (*see* Ex. 1005 at 4:57-62), and Ortiz’s deflecting mechanism with flexures would have been a reasonable design choice enabling improved contact with the uterine wall. Ex. 1002 ¶¶ 62, 108. Moreover, Dr. Pearce explains

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. Ex. 1002 ¶¶ 63-64, 108; *see also* Section VII.A.iv, *infra*.

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing teaches or suggests the “deflecting mechanism” recited in limitation 1.4. *Id.* ¶ 109.

This combination also discloses **limitation 1.5**:

'348 Patent	Edwards, Ortiz, Lichtman, and Jing
[1.5] an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus	<p>Edwards discloses: “In the treatment phase, the cell necrosis of the uterus can be conducted under feedback control. . . . Feedback can be included and is achieved by . . . (iii) ultrasound The feedback mechanism permits the turning on and off of different electrodes of the flexible circuit in a desired ablative pattern. . . . Ultrasound can be used to create a map of the interior of the uterus.” 6:23-54.</p> <p>Jing discloses: “[A] medical apparatus comprising a measurement device and a controller, wherein the measurement device comprises a probing handle and a probing rod, and the controller employs a computer control system. The apparatus may measure a transverse dimension and a longitudinal dimension of the uterine cavity.” Abstract. “The probing rod comprises a longitudinal dimension measuring rod, a dovetail-type transverse dimension measuring rod, and a measurement sleeve.” 3:25-28; <i>see also</i> 4:26-30, 5:7-14. “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 extend [<i>sic</i>] to the transverse dimension being measured.” 5:9-13; <i>see also</i> FIGS. 1, 2. <i>See also</i> Ex. 1002 ¶¶ 110-113.</p>

Edwards discloses the use of ultrasound to “create a map of the interior” of the uterus and to provide “feedback” that can be used to control the application of

energy during the ablation treatment. Ex. 1005 at 6:23-54. While Edwards does not disclose an indicator mechanism as specifically recited in the claim, this aspect is taught by Jing. Ex. 1002 ¶ 110.

Jing discloses an indicator mechanism configured to indicate a dimension of a uterus, for example describing “a medical apparatus . . . [that] may measure a transverse dimension and a longitudinal dimension of the uterine cavity.” Ex. 1011 at Abstract. The device described in Jing includes a “probing handle” and a “probing rod,” where the probing rod “comprises a longitudinal dimension measuring rod, a dovetail-type transverse dimension measuring rod, and a measurement sleeve.” *Id.* at 3:25-28. As reflected in Figures 1 and 2 of Jing, “dovetail-type contacts (22, 23)” used to measure the width of the uterus are housed within, and extend from, a “measurement sleeve (2)” of the rod. *Id.* at 4:26-30, 5:7-14, FIGS. 1, 2; Ex. 1002 ¶ 110.

Placement of indicator components, such as contacts 22, 23 of Jing, on an expandable applicator head of 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. Ex. 1002 ¶¶ 111-112. Such a placement would render those components operably coupled to the actuation mechanisms that deploy the applicator head (*e.g.*, slidable inner sleeve). *Id.* In one exemplary combination, the measurement components of the Jing apparatus (such as the transverse dimension measuring rod 3 and dovetail-type contacts 22, 23) would be integrated into the deflecting mechanism of Ortiz and the applicator head of Edwards so as to be mechanically expanded within the uterus by actuation of the

inner sleeve as taught by Ortiz (support shaft 100, *see* above discussion of limitation 1.1). In such a manner, the Jing indicator components would be considered to be “operably coupled to the inner sleeve.” Ex. 1002 ¶¶ 112-113.

As discussed above, 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; *see also* Section VII.A.iv, *infra*.

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing renders obvious claim 1. *Id.* ¶ 114.

ii. Independent Claim 11

As Dr. Pearce explains, independent claim 11 is rendered obvious by the combination of Edwards, Ortiz, Lichtman, and Jing for reasons similar to those discussed above for claim 1. Ex. 1002 ¶¶ 151-159. This claim contains requirements nearly identical to those in claim 1, and the few differences it presents, discussed below, are not significant.

Claim 11 differs from claim 1 in just three ways. First, instead of the “proximal grip,” “distal grip,” and other related elements found in limitation 1.3 of claim 1, claim 11 requires merely “a handle coupled to the proximal portion.” Because this limitation adds no requirements not found in claim 1, the analysis presented above with respect to that limitation also applies here. Ex. 1002 ¶ 154.

Second, where claim 1 requires that the deflecting mechanism is “configured so that translating the inner sleeve relative to the frame” causes the applicator head

to expand, claim 11 requires that the deflecting mechanism be “configured so that translating one of the inner and outer sleeves relative to the other” causes the head to expand. 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).” Ex. 1006 at 8:10-19; Ex. 1002 ¶ 155.

Third, claim 11 adds a requirement 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.” The combination of Edwards, Ortiz, Lichtman, and Jing discloses this limitation. Ex. 1002 ¶¶ 135-141. For example, Jing discloses that the measurements obtained by its probing rod are converted into electrical signals and sent to computer circuitry connected to the device. Ex. 1011 at 6:5-14 (“The measured lengths are proportionally converted to voltage signals. . . . Upon reception of the conversion completion signal, the CPU stores the data in the memory”); Ex. 1002 ¶ 135. Jing further discloses that the computer may be configured to send the measurement information to other components connected to the device, as the “computer control system” can include “an output port.” *See* Ex. 1011 at 4:2-5; Ex. 1002 ¶ 136.

Jing does not specifically describe whether the components receiving the dimension information would include a generator configured to deliver current to electrodes. However, these aspects of the limitation are disclosed by Edwards, which discloses delivery of RF energy to perform ablation. *See, e.g.*, Ex. 1005 at

11:34-35 (“a power supply 86 feeds energy into RF power generator(source) 68 and then to cell necrosis apparatus 10.”); Ex. 1002 ¶ 137.

Edwards further teaches the use of diagnostics and feedback control of the ablation device, including based on the use of ultrasound to “create a map of the interior of the uterus,” where the resulting information is then “input into a controller” and used to control the energy generated and sent to the electrodes. Ex 1005 at 6:50-55; *see also id.* at 6:23-46 (discussing “diagnostic phase” and “feedback” including ultrasound); Ex. 1002 ¶¶ 138-139. Therefore, Edwards teaches transmitting of uterine morphology data to a generator for delivering current to the electrodes. Ex. 1002 ¶ 139.

As discussed above with respect to claim 1, the addition of the dimension measuring components disclosed in Jing to the RF ablation device disclosed in Edwards would have been obvious. As Dr. Pearce explains, in such a combination, operably coupling the ablation device to the generator disclosed in Edwards would have sensibly been accomplished such that the device is configured to electronically transmit uterine morphology data to the generator. *Id.* ¶ 140. 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.*

As explained above, including discussion addressing claim 1, and further illustrated in the below claim chart, the combination of Edwards, Ortiz, Lichtman, and Jing renders obvious claim 11.

'348 Patent	Edwards, Ortiz, Lichtman, and Jing
11. A device for treating a uterus comprising:	Edwards at 1:21-24. Jing at 3:5-7. Ortiz at 1:8-12. Lichtman at 1:34-38. <i>See Ex. 1002 ¶ 151; see also discussion of claim 1 preamble.</i>
[11.1] 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;	Edwards at 4:52-57, 5:19-21, FIGS. 1B, 2. Ortiz at 4:30-51, 4:59-63, 5:28-31, FIGS. 1, 2, 4. Lichtman at 6:31-34. <i>See Ex. 1002 ¶ 152; see also discussion of claim 1, limitation 1.1.</i>
[11.2] a handle coupled to the proximal portion;	Edwards at 3:27-28, 5:10-20, FIG. 2. Ortiz at 2:48-53, 6:21-28, FIG. 6. Lichtman at 1:66-2:6, 3:41-66, 6:13-24, 6:31-34, 7:47-60, 14:63-67, FIGS. 1, 9, 20. <i>See Ex. 1002 ¶ 153; see also discussion of claim 1, limitation 1.3.</i>
[11.3] 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;	Edwards at 2:53-61, 5:4-9, 5:28-30, 5:46-48, 6:2-8, 6:34-38, 6:55-57, 7:19-44, FIGS. 1B, 1C, 4. <i>See Ex. 1002 ¶ 154; see also discussion of claim 1, limitation 1.2.</i>
[11.4] 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	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).” 8:10-19. Edwards at 6:4-8, 7:19-22, FIG. 4. Ortiz at 4:43-5:10, 5:59-60, FIGS. 3, 7, 9.

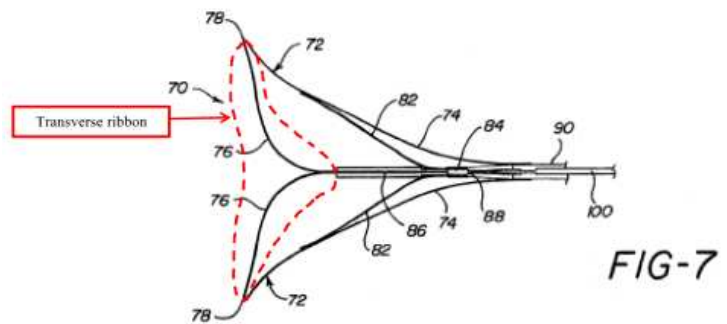
<p>second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state; and;</p>	<p>Lichtman at 7:47-60. <i>See</i> Ex. 1002 ¶¶ 155-156; <i>see also</i> discussion of claim 1, limitation 1.4.</p>
<p>[11.5] an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and</p>	<p>Edwards at 6:23-54. Jing at Abstract, 3:26-28, 5:9-13, FIGS. 1, 2. <i>See</i> Ex. 1002 ¶ 157; <i>see also</i> discussion of claim 1, limitation 1.5.</p>
<p>[11.6] 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.</p>	<p>Jing discloses: “Data of a transverse dimension and a longitudinal dimension of the uterine cavity are measured by the measurement device. The measured lengths are proportionally converted to voltage signals by the measurement conversion coils with different number of turns. . . . Upon reception of the conversion completion signal, the CPU stores the data in the memory and displays all of the data via the displays.” 6:5-14. “The controller may be a computer control system comprising a control data input circuit, . . . [and] an output port.” 4:2-5. Edwards discloses: “[A] power supply 86 feeds energy into RF power generator(source) 68 and then to cell necrosis apparatus 10.” 11:34-35; <i>see also</i> FIG. 13. “The diagnostic phase then begins. This is achieved through a variety of mechanisms, including but not limited to, . . . (iii) the use of ultrasound imaging to establish a base line for the tissue to be treated.” 6:23-46. “Thermal sensors 42, and sensors contained within RF energy source 68, measure voltage and current that is delivered to the endometrium. The output for these sensors is used by controller 78 to control the delivery of RF power.” 11:63-66. “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.” 6:50-54. <i>See also</i> Ex. 1002 ¶¶ 135-141, 158.</p>

Accordingly, the combination of Edwards, Ortiz, Lichtman, and Jing renders obvious claim 11. Ex. 1002 ¶ 159.

iii. Dependent Claims

Claim 2: Claim 2, which depends from claim 1, further requires “a transverse ribbon coupled to a distal end of the first and second external flexures, wherein the transverse ribbon is in a relaxed condition when the applicator head is in the expanded state.”

As discussed above with respect to claim 1, Ortiz discloses a transverse ribbon in its “inner strip 76,” comprising



“an elongated, flat metal strap.” See Ex. 1006 at 4:55-59; see also *id.* at FIG. 7 (annotated here); Ex. 1002 ¶ 115. As can be seen in this figure, the transverse ribbon (element 76) and the external flexures (elements 74) “meet at distal finger tip 78,” and therefore the ribbon is coupled to a distal end of the first and second external flexures as required by claim 2. See Ex. 1006 at 4:48-59; Ex. 1002 ¶ 116. When the Ortiz platform head is in an expanded state, as shown in Figure 7, the ribbon is not compressed toward itself as seen in, for example, the “tulip-shaped” configuration illustrated in Figure 9 of Ortiz. Ex. 1002 ¶ 117. Therefore, the transverse ribbon as taught by Ortiz is in a “relaxed condition” when the applicator head is expanded. *Id.* Accordingly, claim 2 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. *Id.* at ¶ 118.

Claims 3 and 13: Claims 3 and 13, which depend from claims 1 and 11, respectively, require that the “first internal flexure includes a plurality of longitudinally spaced apertures.”

Edwards discloses that the expandable member within its applicator head includes a plurality of apertures through which electrolytic solution passes, stating that “[c]onforming member 20 receives electrolytic solution from expandable member 12, heated or not heated, through a plurality of apertures 22 formed in expandable member 12, and passes it to conforming member 20.” Ex. 1005 at 7:10-14; *see also* FIG. 4; Ex. 1002 ¶ 119. In addition to the apertures in the expanding member itself, Edwards teaches the use of “fluid distribution ports” in the underlying “core lumen” structure supporting the applicator head. *See, e.g.*, Ex. 1005 at 9:16-28, 10:18-19; Ex. 1002 ¶ 120. Edwards, therefore, teaches use of apertures in both the exterior of the applicator head as well as the supporting structure for the applicator head. Ex. 1002 ¶ 120.

As discussed above with respect to claim 1, a person of ordinary skill would have reasonably integrated the Ortiz deflecting mechanism, including its internal and external flexures, into the expandable applicator head of the Edwards RF ablation device. *Id.* ¶ 121. Dr. Pearce testifies that in such a combination, it would additionally have been logical to include the plurality of fluid distributing apertures disclosed by Edwards in the Ortiz flexures in order to reduce resistance to fluid flow within the applicator head. *Id.* Given the long, narrow shape of the flexures taught by Ortiz, it would have been a readily apparent design choice for one of ordinary skill in the art to space the plurality of apertures longitudinally along the

length of the flexures. *Id.* Accordingly, claims 3 and 13 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. *Id.* ¶¶ 122, 162.

Claim 4: Claim 4 depends from claim 1 and further requires that “the proximal grip is coupled to the inner sleeve and the distal grip is coupled to the outer sleeve.”

As discussed above with respect to the limitation 1.3 of claim 1, Lichtman describes a device with a proximal grip (stationary handle member 16), a distal grip (movable handle member 14), and an outer hollow shaft 8 “which coaxially surrounds and is free to slide axially relative to inner tube 10.” Ex. 1008 at 6:31-34, FIGS. 1, 9; *see also* Ex. 1002 ¶ 123. Lichtman teaches that “inner shaft 10 is secured” to housing 34. Ex. 1008 at 7: 21-25. Since “[h]andle member 16 is formed integral with . . . housing 34,” Lichtman therefore discloses the proximal grip coupled to an inner sleeve. *See id.* at 23-24, FIG. 9; Ex. 1002 ¶ 123.

Additionally, Lichtman describes that the outer shaft 8 “is rigidly joined to a gear rack tube or sleeve 36” and the “[m]ovable handle member 14 [includes] gear teeth 38 which engage . . . gear rack tube 36.” *Id.* at 6:31-34; 7:47-49. Thus, Lichtman discloses the distal grip coupled to an outer sleeve. Ex. 1002 ¶ 123.

Moreover, it would have been obvious to couple the proximal and distal grips taught by Lichtman with the inner and outer sleeves disclosed by Ortiz, as discussed above with respect to the limitations 1.1 and 1.4 of claim 1. *Id.* ¶ 123. For example, the inner sleeve (support shaft 100) and outer sleeve (actuator tube 90) of Ortiz would be coupled to the proximal grip (handle member 16) and distal grip (handle member 14) of Lichtman, similar to the outer shaft 8 and inner tube 10

shown in Figure 9 of Lichtman. *Id.* Accordingly, claim 4 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. *Id.* ¶ 125.

Claim 5: Claim 5 depends from claim 1 and requires “an introducer sheath, wherein the inner sleeve and the outer sleeve are disposed within the introducer sheath when the applicator head is in the contracted state, and wherein the distal grip is coupled to the introducer sheath so that proximal movement of the distal grip causes the introducer sheath to move proximally relative to the applicator head.”

Edwards discloses an introducer sheath covering the contracted applicator head. *See* Ex. 1005 at 5:4-6 (“[Expandable member 12 is introduced through introducer sleeve 14 in a folded, or non-distended configuration.”], FIGS. 1A, 1B; Ex. 1002 ¶ 126. Ortiz also discloses an introducer sheath, teaching that “[a] sheath 96 is slidably mounted on the actuator tube 90 for covering the platform 70 prior to the insertion of the tissue manipulator 50 into the trocar tube or cannula.” Ex. 1006 at 4:48-51; *see also id.* at 7:54-8:2 (describing “protective sheath 96 covering the expandable platform” during insertion into the body, after which “platform 70 is moved distally out of the sheath 96”), FIG. 1 (sheath covering contracted platform), FIG. 2 (sheath retracted from platform); Ex. 1002 ¶ 127.

Dr. Pearce explains that in a combination of the expandable platform of Ortiz with the expandable applicator head of Edwards, the inner and outer sleeves would be disposed inside the introducer sheath when the applicator head is in the contracted state. Ex. 1002 ¶ 128. This configuration would be additionally obvious for being substantially similar to the working principle of the Ortiz

introducer sheath. *Id.* Therefore, the combination of Edwards and Ortiz discloses “an introducer sheath, wherein the inner sleeve and the outer sleeve are disposed within the introducer sheath when the applicator head is in the contracted state.”

Edwards further discloses that the introducer sheath is moved proximally relative to the applicator head when the device is deployed in the uterus. Ex. 1005 at 5:16-22 (“Following introduction [in the body], introducer sleeve 14 is withdrawn and can be retracted into handle 15”); *see also* Ex. 1002 ¶ 129. Dr. Pearce testifies that it in view of the combination of Edwards, Ortiz, and Lichtman it would have been readily apparent to a person of ordinary skill in the art that the introducer sheath could be coupled to the distal grip disclosed in Lichtman so that proximal movement of the distal grip causes the introducer sheath to move proximally. Ex. 1002 ¶ 130. One of ordinary skill in the art would have been motivated to couple the introducer sheath to the distal grip to enable the user to retract the introducer sheath with one hand (by squeezing the handles together) for greater ease of use. *Id.* Therefore, the combination of Edwards, Ortiz, and Lichtman discloses a device “wherein the distal grip is coupled to the introducer sheath so that proximal movement of the distal grip causes the introducer sheath to move proximally relative to the applicator head,” and claim 5 is rendered obvious by the combination of Edwards, Ortiz, Lichtman, and Jing. *Id.* ¶ 131.

Claim 6: Claim 6 depends from claim 5 and adds the requirement that “continued movement of the proximal grip and distal grip closer together causes relative movement between the inner sleeve and the outer sleeve.”

Lichtman discloses that its device can include a reversing gear mechanism such that “forward telescoping movement of the outer shaft 8 relative to the inner shaft 10 is achieved when the handles are moved away, rather than towards one another.” Ex. 1008 at 14:41-44; *see also id.* at 5:41-61, FIG. 20. Conversely, movement of the handles closer together would cause a reverse telescoping movement of the outer shaft 8 relative to the inner shaft 10. Ex. 1002 ¶ 132. Dr. Pearce explains that a person of ordinary skill in the art would consider this to be a “continued movement,” since the user can continue to move the handles closer together over a range of movement defined by the length of chamber 42 housing gear rack tube 36. *Id.* ¶ 132; *see also* Ex. 1008 at 7:30-34, FIGS. 9 and 20.

Moreover, as discussed above with respect to claim 4, it would have been obvious to couple the proximal and distal grips taught by Lichtman with the inner and outer sleeves disclosed by Ortiz. Ex. 1002 ¶ 133. In such a combination, the inner sleeve (support shaft 100) and outer sleeve (actuator tube 90) of Ortiz would be coupled to the proximal grip (handle member 16) and distal grip (handle member 14) of Lichtman in an arrangement similar to that of the outer shaft 8 and inner tube 10 shown in Figure 20 of Lichtman. *Id.* Therefore, as Dr. Pearce testifies, one of ordinary skill in the art would understand that the combination of Lichtman and Ortiz discloses a device “wherein continued movement of the proximal grip and distal grip closer together causes relative movement between the inner sleeve and the outer sleeve.” *Id.* Accordingly, claim 6 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. *Id.* ¶ 134.

Claim 7: Claim 7, which depends from claim 1, requires 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.” As discussed above with respect to limitation 11.6 of claim 11, this requirement is readily apparent in view of Jing and Edwards. *See* Ex. 1011 at 4:2-5, 6:5-14; Ex. 1005 at 6:23-46, 6:50-54, 11:34-35, 11:63-66, Fig. 13; *see also* Ex. 1002 at ¶¶ 135-141, 158. Accordingly, claim 7 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. Ex. 1002 at ¶ 141.

Claims 8, 9, and 14: Claims 8 and 14, which depend from claims 1 and 11, respectively, require “an adjustable locking mechanism configured to limit a degree of expansion of the applicator head.” Claim 9 depends from claim 1 and requires an adjustable locking mechanism limiting the distance a user may “move the proximal grip and the distal grip closer together.” Lichtman discloses these limitations.

With respect to claims 8 and 14, Lichtman discloses “a ratchet-type locking means for locking the two jaws against opening movement.” Ex. 1008 at 9:30-32. The ratchet-type locking means includes “a set of ratchet teeth 71 on sleeve 36” and a “pawl 73,” with the teeth 71 oriented to “intercept the pawl so as to obstruct rearward movement of gear rack tube 36.” *See id.* at 9:32-52, FIG 9. This inhibits rearward (proximal) movement of the outer shaft 8 relative to the outer shaft 10, thus preventing the jaws from being opened. *See id.* at 5:62-6:2, 7:47-65; Ex. 1002 ¶ 142. Therefore, Lichtman teaches a locking mechanism configured to limit the degree of expansion (opening) of the applicator head. Ex. 1002 ¶ 142.

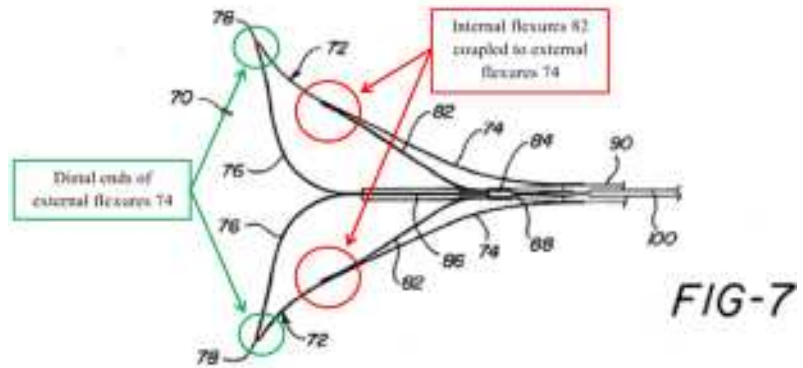
Furthermore, Lichtman explains that the locking mechanism is adjustable in that it can be selectively enabled by using levers 84A, 84B to bias the pawl 73 in or out of engagement with the teeth 71. *See* Ex. 1008 at 10:27-39, FIG. 11 (lever 84A in the pawl-engaged position), FIG. 12 (lever 84A in the pawl-disengaged position); Ex. 1002 ¶ 143.

With respect to claim 9, Lichtman further discloses that the adjustable locking mechanism prevents the proximal and distal grips from being moved closer together. Lichtman teaches that the ratchet locking mechanism can be used in combination with a reversing-gear mechanism in which the gear rack tube 36 is mechanically coupled to the distal grip (handle member 14A) via an “idler gear 344,” such that proximal movement of the gear rack tube 36 is actuated by moving the distal grip towards the proximal grip (handle member 16). *See* Ex. 1008 at 14:46-49, 52-67, FIG 20; *see also* Ex. 1002 ¶ 146. Thus, restricting the proximal movement of the gear rack tube 36 would likewise prevent movement of the distal grip towards the proximal grip. Ex. 1002 ¶ 146. Therefore, Lichtman discloses an adjustable locking mechanism configured to limit a distance by which a user can move the proximal grip and the distal grip closer together. *Id.* Accordingly, claims 8, 9, and 14 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. *Id.* at ¶¶ 142-147, 163.

Claims 10 and 15: Claims 10 and 15, which depend from claims 1 and 11, respectively, require that “the . . . external flexures each have a distal end, and wherein the . . . internal flexures are coupled to the . . . external flexures at a location proximal to the distal ends of the . . . external flexures.”

Ortiz discloses this limitation. For example, the particular flexure configuration required by this claim can be found in Figure 7 (annotated here).

Ex. 1006 at FIG. 7; *see also id.* at 4:63-66 (“Each finger 72 includes a flexible strut 82 with its distal end secured to an intermediate portion of the outer strip 74



adjacent to the finger tip 78”); Ex. 1002 ¶¶ 148-149. Accordingly, claims 10 and 15 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. Ex. 1002 ¶¶ 148-150, 164.

Claim 12: Claim 12, depending from claim 1, requires that “the applicator head is configured to expand until limited by the dimension of the uterus.”

Edwards discloses this limitation, describing a “[c]ell necrosis apparatus 10 [that] automatically conforms to the interior of the uterus.” Ex. 1005 at 6:34-48. Edwards explains that its applicator head expands until coming into contact with the uterus walls, for example stating that “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; *see also id.* at 7:40-44; Ex. 1002 ¶ 160. Accordingly, claim 12 would have been obvious in view of Edwards, Ortiz, Lichtman, and Jing. Ex. 1002 ¶ 161.

iv. Rationale to Combine

As discussed above and in Dr. Pearce's declaration, it would have been obvious to combine Edwards, Ortiz, Lichtman, and Jing to achieve an endometrial ablation device utilizing the components claimed in the '348 patent for a number of reasons. Ex. 1002 ¶¶ 60-71; *see also* Section I.C.

As an initial matter, all the cited references are similarly directed to minimally invasive surgical devices. Both Edwards and Ortiz are similarly directed to minimally invasive surgical devices having a collapsed configuration for insertion into the body and an expanded configuration for engaging with internal tissues. *See, e.g.*, Ex. 1005 at 2:53-56; Ex. 1006 at Abstract; Ex. 1002 ¶ 61. As Dr. Pearce testifies, in considering reasonable modifications to an ablation device as in Edwards, a person of ordinary skill in the art of medical device design would logically have looked to similar surgical instruments for guidance in identifying known prior art approaches. Ex. 1002 ¶ 61.

Edwards expressly encourages the use of various designs for the expandable head: "it will be appreciated that other devices capable of being in confined non-deployed states, during their introduction into the desired body organ or lumen, and thereafter expanded to deployed states, can be utilized." Ex. 1005 at 4:57-62; *see also id.* at 6:4-8 (explaining that the expandable head can be mechanically deployed using "formed spring wires"). Ortiz describes just such a design for a triangular shaped, expandable head that could be deployed with flexures following introduction into the uterus. Ex. 1002 ¶ 62. In view of such teachings, a person of ordinary skill in the art would have viewed Ortiz's expansion mechanism as a

reasonable alternative design choice for mechanically deploying the endometrial ablation applicator head described in Edwards. *Id.*

Moreover, 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. *Id.* ¶ 63. The mechanical expansion design disclosed in Edwards utilizes two rigid arms extending outward toward the walls. *See, e.g.*, Ex. 1005 at 7:19-36 (discussing frame 19 and “one or more arms 19”), FIG. 4. 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. Ex. 1006 at 4:34-42, 52-55; Ex. 1002 ¶ 63.

Dr. Pearce further testifies that a person of ordinary skill in the art would have recognized that a device as described in Edwards would benefit from a design that included aspects as described in Ortiz. *Id.* ¶ 63. For example, the skilled artisan would have recognized that there was good reason to replace the use of fluid or gaseous media for expanding the Edwards device with mechanical expansion elements such as taught by Ortiz in order to simplify the device design and obviate potential safety issues such as fluid leakage or contamination. *Id.* Indeed, Edwards expressly encourages the use of mechanical expansion as an alternative to fluid-based expansion. Ex. 1005 at 6:4-8; *see also* Ex. 1002 ¶ 64.

It would further have been obvious to one of ordinary skill in the art that an ablation device such as disclosed by the combination of Edwards and Ortiz could

make use of a pivot grip handle mechanism, as such a design was already known for decades prior to the '348 patent and taught by Lichtman. Ex. 1002 ¶¶ 14, 65. Lichtman, like Edwards and Ortiz, discloses an endoscopic surgical device including expandable elements for interacting with tissue. *See, e.g.*, Ex. 1008 at 2:53-67. Additionally, Edwards and Lichtman are similarly directed to electrosurgical instruments. *See, e.g.*, Ex. 1005 at 5:28-30; Ex. 1008 at 3:37-39. As Dr. Pearce explains, a person of ordinary skill in the art would naturally have looked to known medical instruments with similar structure and functionality when making improvements to an existing device. Ex. 1002 ¶ 65.

Moreover, Dr. Pearce testifies that the Ortiz and Lichtman devices operate according to nearly identical mechanical principles. *Id.* ¶ 66. For example, both devices utilize a pair of telescoping inner and outer shafts to mechanically expand a distal device head, a very common design feature among minimally invasive surgical devices during the relevant time period. *See, e.g.*, Ex. 1006 at 5:28-31; Ex. 1008 at 5:62-6:2; Ex. 1002 ¶ 66. Lichtman's pivot grip handle mechanism would have been recognized by the skilled artisan as a sensible design choice for actuation of expandable members in an electrosurgical instrument that could also be employed in other electrosurgical instruments. Ex. 1006 ¶ 66. Accordingly, it would have been obvious, as well as technically feasible, to use a pivot grip handle as taught by Lichtman to actuate an expandable frame as taught by Ortiz, to deploy an ablation head as disclosed by Edwards. *Id.*

The device obtained by combining the teachings of Edwards, Ortiz, and Lichtman would have been appreciated by a skilled artisan at the time as one

providing greater ease of use and flexibility in operation. *Id.* ¶ 67. For instance, Dr. Pearce explains that Lichtman’s pivot grip handle mechanism allows for one-handed movement and expansion and contraction of the surgical device head. *Id.* This is an advantage over the handle design in Edwards, which discloses two-handed operation. Ex. 1005 at 10:33-39, FIG. 2; Ex. 1002 ¶ 67. Moreover, Lichtman’s disclosure that its handle mechanism “can be held and operated in either a scissors or a pistol-grip manner,” would have further motivated one of ordinary skill to combine Lichtman’s handle mechanism with Ortiz’s expandable frame and Edward’s ablation device in order to provide the user with more options for holding and operating the device. Ex. 1008 at 2:24-26; 3:1-5; Ex. 1002 ¶ 68. As Dr. Pearce explains, the scissors-type and pistol-grip design features are both commonly used features of minimally invasive surgical devices. Ex. 1002 ¶ 68.

One of ordinary skill in the art would reasonably have incorporated the uterine measurement apparatus taught by Jing into the endometrial ablation device disclosed by the combination of Edwards, Ortiz, and Lichtman. *Id.* ¶ 69. Jing, like Edwards, is directed to a device for use in the uterus. *See, e.g.*, Ex. 1011 at 3:5-7. Similar to Edwards, Ortiz, and Lichtman, Jing teaches an expandable device head and a deployment mechanism with slidable inner and outer shafts. *Id.* at 5:9-13 (discussing expandable “dovetail-type contacts”), 4:27-5:16 (describing “dimension measuring rod” received within “measurement sleeve”), FIGS. 1, 2; Ex. 1002 ¶ 69. A skilled artisan would have recognized that the components of Jing’s measurement apparatus could also be employed in other minimally invasive devices that are expanded within the uterus. Ex. 1002 ¶ 69.

One of ordinary skill in the art would have had good reason to incorporate the uterine measurement apparatus of Jing into the device disclosed by the combined teachings of Edwards, Ortiz, and Lichtman. *Id.* ¶ 70. Such a combination would result in an endometrial ablation device capable of concurrently obtaining uterine morphology data, and Edwards teaches that morphology data is useful for determining appropriate control parameters for the ablation procedure. *Id.* For example, Edwards expressly discloses using ultrasound “to create a map of the interior of the uterus” and inputting this information into a controller for the ablation electrodes. Ex. 1005 at 6:50-54. Edwards also teaches that ultrasound data can also be used for diagnostics and feedback control of the ablation device. *See id.* at 6:23-46. As Dr. Pearce explains, the Jing measurement apparatus would provide dimension information indicative of the morphology of the uterine cavity, and would be less costly compared to an ultrasound imaging system. Ex. 1002 ¶ 70. Thus, a person of ordinary of ordinary skill in the art would have been motivated to combine Edwards, Ortiz, Lichtman, and Jing in order to obtain a cost-efficient endometrial ablation device with built-in uterine measurement capabilities. *Id.*

VIII. CONCLUSION

For the reasons set forth above, claims 1-15 of the '348 patent are unpatentable, and an *inter partes* review of these claims should be instituted.

Respectfully submitted,

Dated: March 4, 2016

/ Michael T. Rosato /

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IX. PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15(A) AND 42.103

The required fees are submitted herewith. If any additional fees are due at any time during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 23-2415.

X. APPENDIX – LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,095,348 to Truckai <i>et al.</i>
1002	Declaration of John Anthony Pearce, Ph.D.
1003	John Anthony Pearce <i>curriculum vitae</i>
1004	File History of 13/962,178 to Truckai <i>et al.</i>
1005	U.S. Patent No. 6,024,743 to Edwards
1006	U.S. Patent No. 5,358,496 to Ortiz <i>et al.</i>
1007	U.S. Patent No. 5,514,091 to Yoon
1008	U.S. Patent No. 5,620,459 to Lichtman
1009	U.S. Patent No. 5,353,784 to Nady-Mohamed
1010	Chinese Patent Publication No. CN 1060594A to Jing <i>et al.</i>
1011	Certified English Translation of CN 1060594A to Jing <i>et al.</i> with Translation Certification Statement
1012	Complaint for Patent Infringement, Hologic, Inc. et al. v. Minerva Surgical, Inc., 15-cv-01031-SLR (November 6, 2015)
1013	<i>Flexure, Frame</i> , Webster's Desk Dictionary (2001)

1014	<i>Frame</i> , Merriam-Webster Dictionary (1998)
1015	U.S. Patent No. 5,374,261 to Yoon
1016	U.S. Patent No. 2,004,559 to Wappler <i>et al.</i>

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), this is to certify that I caused to be served a true and correct copy of the foregoing Petition for Inter Partes Review of U.S. Patent no. 9,095,348 (and accompanying Exhibits 1001 through 1016) by overnight courier (Federal Express or UPS), on this 4th day of March, 2016, on the Patent Owner at the correspondence address of the Patent Owner as follows:

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