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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. IPR2016-00680
Patent No. 9,095,348

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

TABLE OF CONTENTS

Page

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

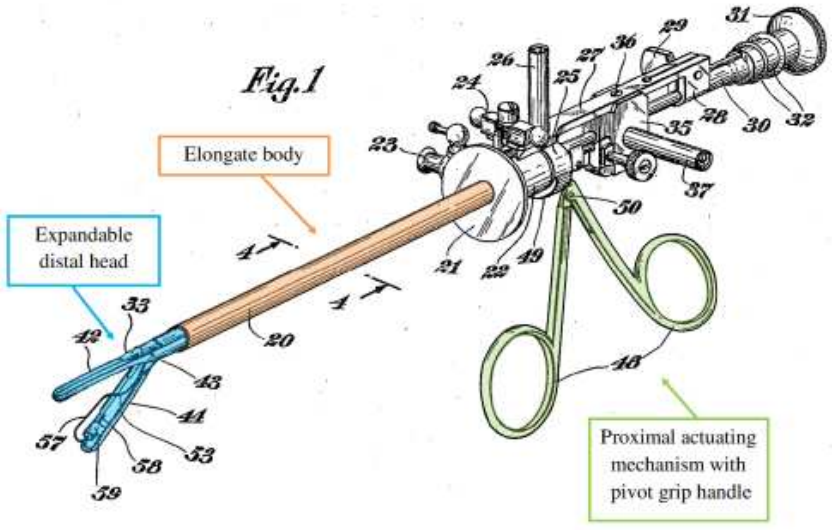
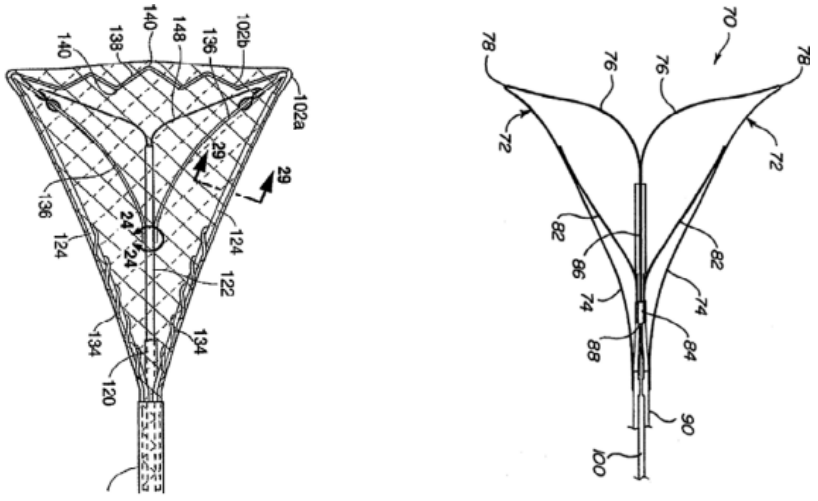


figure (annotated by Petitioner's expert) from U.S. Patent No. 2,004,559 (entitled "Method and Instrument for Electrosurgical Treatment of Tissue"). Ex. 1002 ¶ 14; Ex. 1016 at FIG. 1 (annotated figure shown).

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:

'348 Patent **Prior Art**



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.

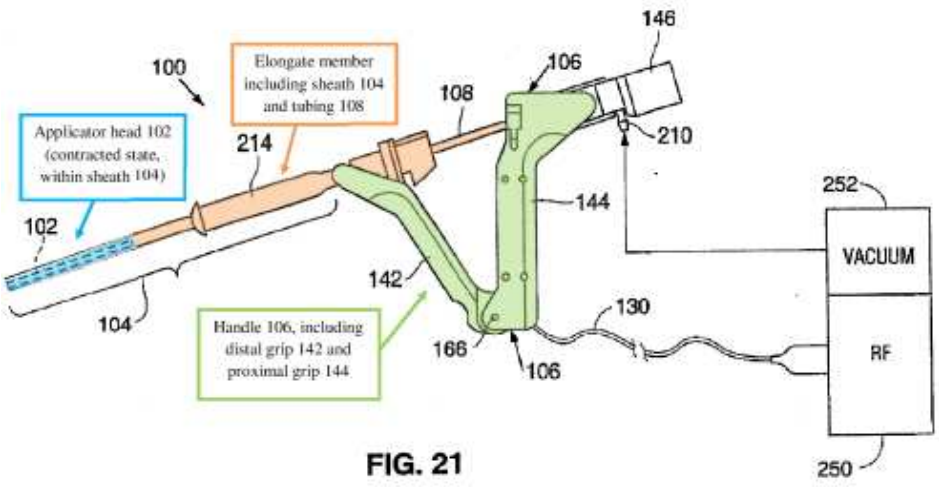


FIG. 21

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.

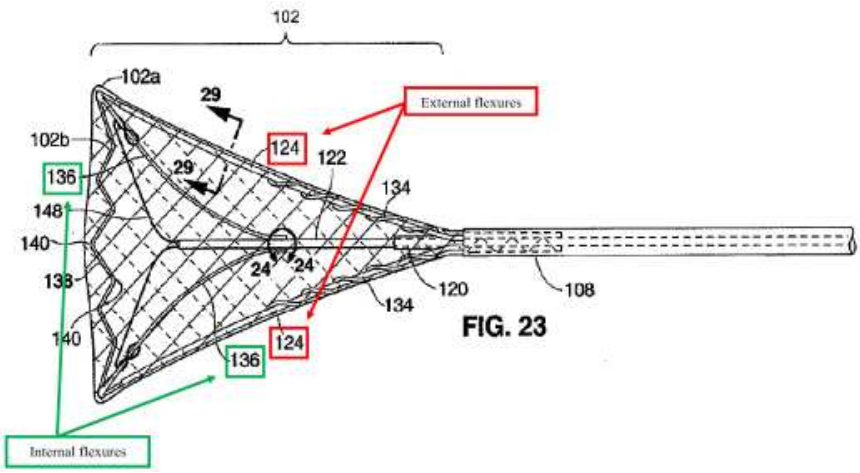


FIG. 23

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 at 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 in fact 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.

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[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 measurement 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); Ex. 1002 ¶¶ 31, 33.

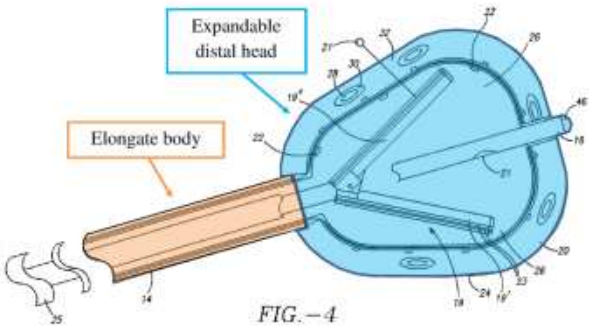
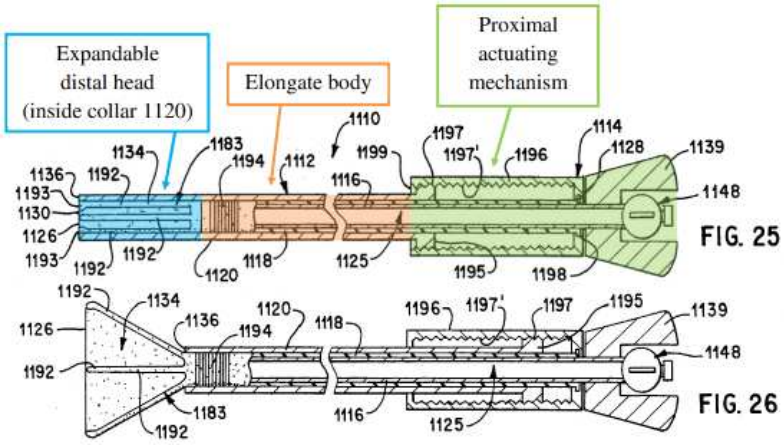


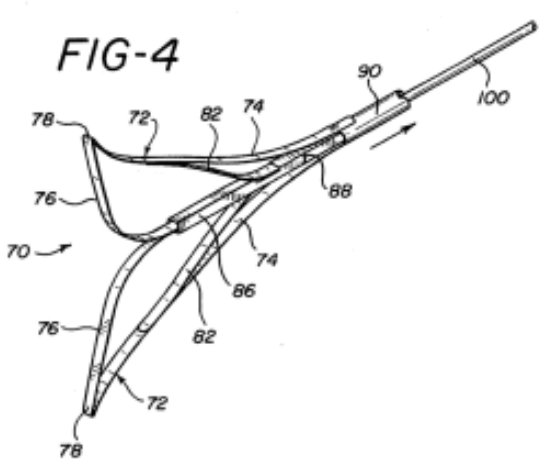
FIG.—4

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.



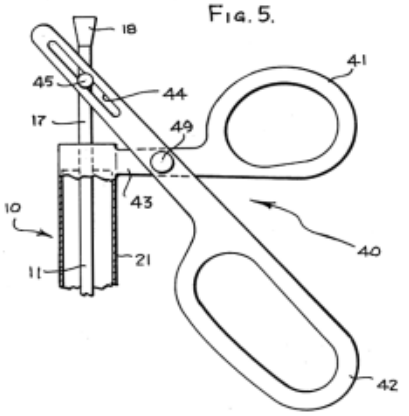
In addition, a triangular assembly of flexible support components actuated using telescoping tubes or sleeves was also well known in the medical device art prior to the '348 patent. Ex. 1002 ¶ 35. For example, U.S. Patent No. 5,358,496 to

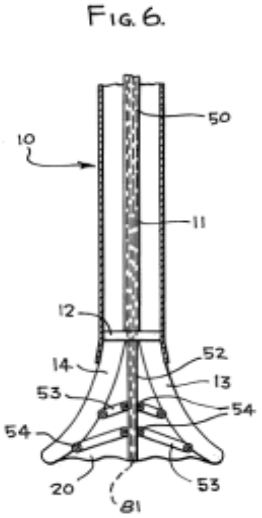
Ortiz *et al.*, ("Ortiz," submitted as Ex. 1006), discloses "an improved tissue manipulator which is adapted for insertion through an endoscopic device into a body cavity to manipulate internal body tissue therein." Ex. 1006 at 2:32-35; *see also* 2:42-47. The expandable platform of Ortiz is formed from "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 above); *see also* Ex. 1002 ¶ 35.



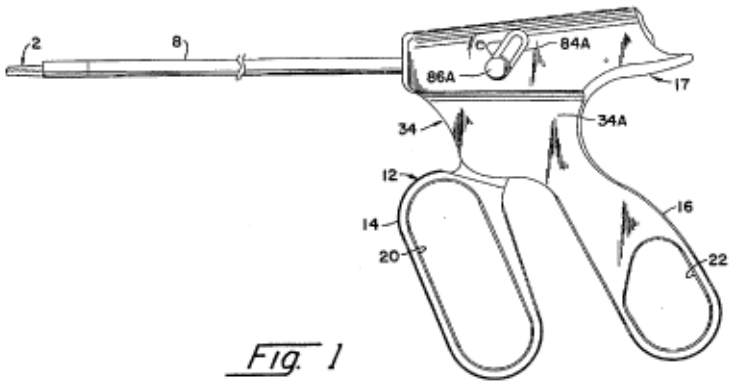
Another example of a minimally invasive surgical device that utilized flexible supports for an expandable distal head is seen in Nady-Mohamed. Nady-Mohamed discloses "an expandable device useful for gripping or manipulating a uterus or other similar organ within the body through engagement of the walls 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 early1970s 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	Claims	Description
1	1-7, 10-13, and 15	Obvious under 35 U.S.C. § 103 over Yoon, Nady-Mohamed, Ortiz, and Jing

2	8, 9, and 14	Obvious under 35 U.S.C. § 103 over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman

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 Yoon, a U.S. Patent qualifying as prior art under 35 U.S.C. § 102(b). The grounds in the concurrently-filed petition rely on Edwards, a U.S. Patent qualifying as prior art under 35 U.S.C. § 102(e). 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 1-7, 10-13, and 15 are Obvious under 35 U.S.C. § 103 over Yoon, Ortiz, Nady-Mohamed, and Jing

Yoon, issued May 7, 1996, Nady-Mohamed, issued October 11, 1994, Ortiz, issued October 25, 1994, 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 1-7, 10-13, and 15 of the '348 patent would have been obvious to one of ordinary skill in the art in view of Yoon, Nady-Mohamed, Ortiz, and

Jing. Ex. 1002 ¶¶ 167-246.

Yoon[2] describes an endometrial ablation device including an elongated design, a distal applicator head including a spine member for mechanical expansion within the uterus, and a proximal handle to facilitate operation by a physician. Ex. 1007 at Abstract, 20:34-38, 26:37-50, 26:43-48, FIG. 26; *see also* Ex. 1002 ¶¶ 32, 34. Thus, Yoon discloses the main elements of the ablation device described in the '348 patent, consistent with similar minimally invasive surgical devices at the relevant time. *See, e.g.*, Ex. 1002 ¶ 14; Section I.C, *supra*.

Yoon describes numerous exemplary applicator head designs and expressly states that other known designs for mechanically expanding the applicator head can also be used in its ablation device. *See* Ex. 1007 at 25:23-30, 26:34-39; *see also* Ex. 1002 ¶ 170. Nady-Mohamed and Ortiz[3] describe known designs for expandable device heads used to manipulate tissues in minimally invasive surgical procedures. In particular, Nady-Mohamed discloses an expandable distal head with flexible arms that is actuated by two coaxially slidable sleeves to engage the inner walls of the uterus. Ex. 1009 at 2:38-43, 3:55-4:7, 5:18-26; *see also* Ex.

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[2] While Yoon was disclosed during *ex parte* prosecution in an IDS along with over 300 other references, this reference was never applied against the claims in an Office Action. Ex. 1004 at 120, 98.

[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.

1002 ¶¶ 37-39. Ortiz describes a similar minimally invasive device utilizing an expandable frame with interconnected flexures. Ex. 1006 at 2:42-27, 4:52-66, 5:28-31; *see also* Ex. 1002 ¶ 35. One of ordinary skill would have recognized Nady-Mohamed's uterine manipulator as a logical choice for an expansion mechanism in an endometrial ablation device as disclosed in Yoon, and would also have recognized Ortiz' flexible construction as well suited for improving contact with the uterine wall during ablation. Ex. 1002 ¶¶ 170-173. Additionally, such a configuration would have simplified the design disclosed in Yoon, for example, by reducing the need for fluid expansion components. *Id*.

Yoon 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 uterine manipulation devices described in Nady-Mohamed. In particular, Nady-Mohamed discloses that its device utilizes a pivot grip "scissors-like" handle mechanism to actuate the expansion of the distal head within the uterus. Ex. 1009 at 4:53-62, 5:12-18; *see also* Ex. 1002 ¶¶ 37-39. A pivot grip handle as disclosed in Nady-Mohamed enables one-handed operation of the instrument, and would benefit the operation of an ablation device as in Yoon by allowing one-handed deployment of the applicator head. Ex. 1002 ¶ 174.

Regarding an "indicator mechanism" as recited in the '348 patent claims, a person of ordinary skill in the art would have recognized that the relative dimensions of the applicator head and the target site should optimize contact between the device and uterine wall in order to efficiently deliver ablation energy

to the endometrial lining. *Id.* ¶ 176. Indeed, Yoon teaches that the expandable applicator head of its ablation device should conform to the uterine morphology and contact the entire uterine wall, and encourages adjusting the size, shape, and position of the applicator head according to the particular treatment procedure. Ex. 1007 at 3:12-14, 26:9-13; *see also* Ex. 1002 ¶ 176. A skilled artisan would have recognized that using known devices to measure the dimensions of the uterus would allow for more accurate adjustments to an expandable ablation device as in Yoon. Ex. 1002 ¶ 176. Jing describes a known design for an indicator mechanism incorporated in an elongate device inserted into the uterus. Ex. 1002 ¶¶ 40-41. In particular, 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 allow for cost-effective measurement of patient-specific uterine morphology and thus improve ablation therapy with an expandable device as in Yoon. Ex. 1002 ¶¶ 175-176.

The discussion below further illustrates that each and every element of claims 1-7, 10-13, and 15 of the '348 patent would have been obvious to one of ordinary skill in the art in view of Yoon, Nady-Mohamed, Ortiz, and Jing. The particular citations listed are intended to be illustrative, not exhaustive. A detailed discussion of rationale to combine follows the discussion of individual claims. *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 Yoon, Nady-Mohamed, Ortiz, and Jing.

'348 Patent	Yoon, Nady-Mohamed, Ortiz, and Jing
1. A device for treating a uterus comprising:	**Yoon discloses:** ". . . the instrument 410 can be used for electrical coagulation or cautery, such as to perform uterine ablation." 20:34-38; *see also* 1:18-24. **Nady-Mohamed discloses:** "[T]he present invention provides 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 . . . ." 2:38-43. **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. **Jing discloses:** "The present invention relates to . . . a computer-controlled measurement apparatus for measuring the morphology of a woman's uterine cavity and obtaining data thereof." 3:5-7. *See also* Ex. 1002 ¶¶ 178-179.

Yoon, Nady-Mohamed, and Jing each expressly disclose a device for treating a uterus. Ex. 1002 ¶¶ 178-179. For example, Yoon is directed to "multifunctional medical instruments for performing various diverse procedures in anatomical cavities" and teaches an instrument that "can be used for electrical coagulation or cautery, such as to perform uterine ablation." Ex. 1007 at 1:18-24, 20:34-38. 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. Likewise, Jing discloses that "[t]he 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 thereof." Ex. 1011 at 3:5-7; *see also* Ex. 1002 ¶ 178. Ortiz, meanwhile, discloses endoscopic devices for treating internal body tissues. Ex. 1002 ¶ 178. For example, Ortiz discloses that "[t]he present invention relates to . . . 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.

This combination also discloses **limitation 1.1**:

'348 Patent	**Yoon, Nady-Mohamed, Ortiz, and Jing**
[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;	**Yoon discloses:** "Body assembly 1112 for multifunctional instrument 1110 includes inner member 1116, middle member 1118 receiving inner member 1116, a collar 1120 disposed around middle member 1118 and an expandable spine 1183 for mechanically shaping and/or expanding the middle member 1118." 26:43-48. "Head assembly 1114 includes handle 1139 mounting the inner member proximal end 1124, operating member 1196 mounting the middle member proximal flange 1128 and the collar proximal flange 1195 and a valve assembly 1148." 27:58-61; *see also* FIGS. 25-27. **Nady-Mohamed discloses:** ". . . there is shown in FIG. 1 a cylindrical tube 10 within which is slidably disposed a plunger 11. The plunger 11 passes through a disc 12, and is fixed to the disc such that any longitudinal movement of the plunger within the tube is also imparted to the disc." 3:44-51; *see also* 4:58-62. "FIG. 6 shows the apparatus, wherein the plunger 11, which terminates at the disc 12, is provided with a longitudinal bore, within which is slidably disposed a rod 50 having a longitudinal bore and an open distal end 81." 5:14-18; *see also* FIGS. 5, 6. *See also* Ex. 1002 ¶¶ 180-185.

This limitation is disclosed by the combination of Yoon and Nady-Mohamed. Ex. 1002 ¶ 180. Yoon discloses an instrument 1110 with an elongate body assembly 1112. As illustrated in, for example, Figure 25 (shown here), the elongate member has a proximal portion including "handle 1139" and a distal

portion including "expandable spine 1183." *See* Ex. 1007 at 26:43-48, 27:58-61, FIG. 25; *see also* Ex. 1002 ¶ 180. Yoon teaches that the elongate body assembly 1112 is composed of a series of coaxial sleeves disposed within each other, including an "inner member 1116," "middle member 1118 receiving inner member 1116," and "a collar 1120 disposed around middle member 1118." Ex. 1007 at 26:43-48, FIG. 25; *see also* Ex. 1002 ¶ 181.

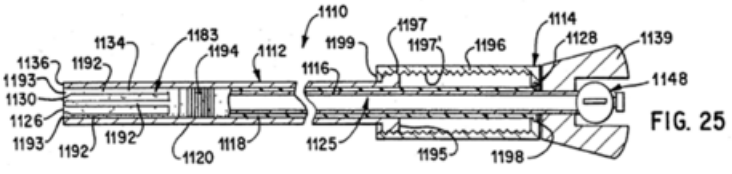
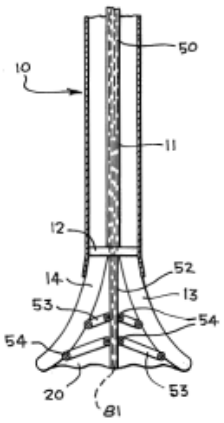


FIG. 25

To the extent that Yoon does not expressly describe an inner sleeve slidably disposed within the outer sleeve as recited in the claim, these aspects of the limitation are fully disclosed by Nady-Mohamed. Ex. 1002 ¶ 182. Nady-Mohamed discloses an elongate member with proximal and distal portions. *See, e.g.*, Ex. 1009 at 3:44-46 (describing "cylindrical tube 10"), FIG. 6 (shown here); Ex. 1002 ¶ 182. "Flexible arms 13 and 14" are affixed to a "disc 12" positioned at the distal portion of the tube 10. *Id.* at 3:49-51. The proximal portion of the tube 10 is connected to "a scissors-like mechanism 40." Ex. 1009 at 4:58-62, FIG. 5; *see also* Ex. 1002 ¶ 182.

FIG. 6.



Nady-Mohamed teaches that the elongate member includes an inner sleeve slidably and coaxially disposed within the outer sleeve. Ex. 1002 ¶ 183. Specifically, Nady-Mohamed states that the "plunger 11 [i.e., the outer sleeve], which terminates at the disc 12, is provided with a longitudinal bore, within which

is slidably disposed a rod 50 [i.e., the inner sleeve] having a longitudinal bore and an open distal end 81." Ex. 1009 at 5:14-18, FIG. 6; *see also* Ex. 1002 ¶ 183.

One of ordinary skill in the art would have incorporated an expansion mechanism as in Nady-Mohamed into an ablation device as disclosed by Yoon, because Yoon teaches that different expansion mechanism designs can be used and Nady-Mohamed's mechanical expansion elements are specifically designed for engaging the uterine walls. Ex. 1002 ¶¶ 169-171, 184. In addition, as Dr. Pearce also explains, use of the mechanical expansion elements taught by Nady-Mohamed, including the inner sleeve slidable within an outer sleeve, would have been preferable over the fluid expansion media disclosed in Yoon because it would have simplified the device design and obviated potential safety issues such as fluid leakage or contamination. *Id*. at ¶¶ 173, 184; *see also* Section VII.A.iv, *infra*.

This combination also discloses **limitation 1.2**:

'348 Patent	**Yoon, Nady-Mohamed, Ortiz, 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 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;	**Yoon discloses:** "[T]he expandable portions 434 are introduced through an opening in tissue or organ structure of the body in the non-expanded or collapsed position. As shown in FIG. 13, the expandable portion 434a is introduced in the uterus U through the cervix C." 20:8-16. "[E]xpandable portion 434a can have an external size in the expanded position to fill the uterus U and contact the internal uterine wall. Where the middle member 418 includes electrically conductive material within or forming the middle member, such as an electrically conducting spine, the instrument 410 can be used for electrical coagulation or cautery, such as to perform uterine ablation." 20:31-38; *see also* FIGS. 13, 25-27. *See also* Ex. 1002 ¶¶ 186-189.

Yoon on its own fully discloses the recited elements of limitation 1.2. Ex. 1002 ¶ 186. Yoon describes an instrument with an expandable applicator head portion. *See, e.g.*, Ex. 1007 at FIG. 13, FIGS. 25-27 (depicting contracted and expanded states of expandable portion 1134). The applicator head has a contracted state configured for transcervical insertion. *Id*. at 20:8-16 ("[T]he expandable portions 434 are introduced [to] the body in the non-expanded or collapsed position . . . . through the cervix C."), FIG. 13. The applicator head also has an expanded state configured to conform to the shape of the uterus, as can be seen in Figure 13 (shown here). *See also id*. at 20:31-34 (describing "expanded position to fill the uterus"); Ex. 1002 ¶ 187.

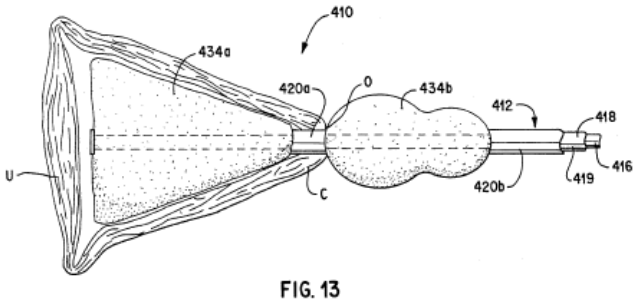


FIG. 13

Yoon also discloses that the middle member 418 which forms the expandable portion 434a can include electrical elements which serve as electrodes for endometrial ablation. Ex. 1007 at 20:34-38 ("electrically conducting spine" portion of middle member 418 used for "uterine ablation"); *see also* Ex. 1002 ¶ 188. Accordingly, the prior art discloses this limitation. Ex. 1002 ¶ 189.

This combination also discloses **limitation 1.3**:

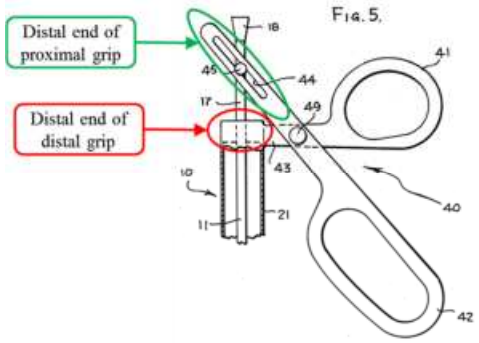
'348 Patent	Yoon, Nady-Mohamed, Ortiz, and Jing
[1.3] a handle coupled to the proximal portion of the elongate member,	**Yoon discloses:** "Head assembly 1114 includes handle 1139 mounting the inner member proximal end 1124, operating member 1196 mounting the middle member proximal flange 1128 . . . ." 27:58-61. "[T]he expandable portion 1134 is disposed in collar 1120 to be in

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;	the non-expanded position shown in FIG. 25." 28:27-30. "Once the distal end of body assembly 1112 is positioned in the anatomical cavity, operating cylinder 1196 is manually rotated while gripping handle 1139 . . . causing spine 1183 to move automatically to the expanded position with legs 1192 disposed in a direction angularly outward of the instrument longitudinal axis as shown in FIG. 26. Movement of spine 1183 to the expanded position causes movement of expandable portion 1134 to the expanded position." 28:37-50; *see also* FIGS. 25-26. **Nady-Mohamed discloses:** "The plunger 11 passes through a disc 12, and is fixed to the disc such that any longitudinal movement of the plunger within the tube is also imparted to the disc. Flexible arms 13 and 14 are also fixed, at their proximal ends 23 and 24, to the disc 12." 3:46-51; *see also* 3:25-28, 3:67-4:1. "The plunger is slidably disposed within the tube 10, and the arms and membrane are expelled from the distal end of the tube or withdrawn into the tube by sliding the plunger in the desired direction. . . . FIG. 5 illustrates a preferred embodiment, comprising a scissors-like mechanism 40 having scissor arms 41 and 42 which are pivotally attached near their midpoints with a rivet 49 or other similar pivotal attachment means. A first scissor arm 41 is fixed at its distal end 43 to the outer surface 21 of the tube, while a second longer scissor arm 42 having a longitudinal aperture 44 is coupled to a coupling means 45 affixed to the plunger. When the finger rings of the scissor arms 41 and 42 are brought together, the coupling means 45 is caused to slide within the longitudinal aperture 44, thereby causing the plunger 11 to be moved toward the distal end of the tube." 4:53-5:3. ". . . the distal end of the tube is inserted through the cervix and into the uterus, whereupon the arms and membrane are extended from within the tube. Upon full deployment, the arms and membrane will firmly engage the walls of the lumen." 5:64-6:2; *see also* FIGS. 1, 2, 5. *See also* Ex. 1002 ¶¶ 190-200.

Each of Yoon and Nady-Mohamed discloses that their devices include a handle coupled to the proximal portion of the elongate member. Ex. 1002 ¶¶ 190-200. For example, Yoon discloses a "head assembly" which includes a "handle."

Ex. 1007 at 27-58-61; *see also* FIGS. 25, 26 (elements 1114 and 1139); Ex. 1002 ¶ 190. Yoon discloses that that the head assembly, including the handle, is operated to transition an expandable portion 1134 from a contracted state to an expanded state. Ex. 1002 ¶ 191. Following transcervical insertion, actuation of the operating member 1196 of the head assembly 1114 "while gripping handle 1139" expands the applicator head. *See* Ex. 1007 at 28-37-50, FIG. 26; Ex. 1002 ¶ 191.

While Yoon discloses a handle, it does not expressly discuss two handle grips pivotally attached to each other as required by this limitation. Such a handle design, however, was well-known in the prior art and is described at the time, as illustrated in Nady-Mohamed. Ex. 1002 ¶¶ 14, 192; *see also* Section I.C. Specifically, Figure 5 of Nady-Mohamed, annotated by Dr. Pearce as shown here, illustrates the proximal portion of the elongate apparatus (tube 10) including a "scissors-like actuation means" 40 which satisfies the recited handle limitation. *See id.* ¶ 193; Ex. 1009 at 3:25-28. The two scissor arms 41 and 42 serve as the claimed grips "pivotally attached" to each other. Ex. 1009 at 4:58-66; *see also* Ex. 1002 ¶ 193.

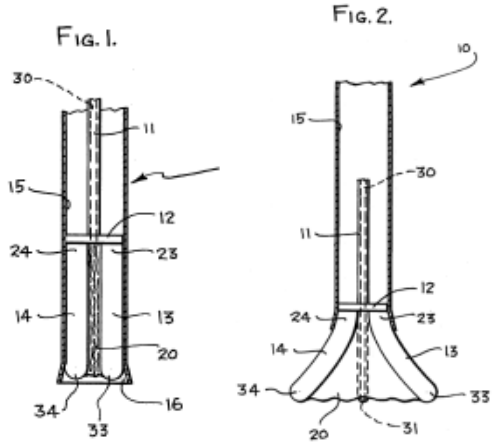


As can be seen in annotated Figure 5, the scissors arms 41, 42 cross at the pivot point 49 such that the distal end 43 of the scissor arm 41 is actually located distally to the distal end of the scissor arm 42. Accordingly, Dr. Pearce explains that at the point of attachment to the elongate member (tube 10), the scissor arm 41 is effectively the distal grip and the scissor arm 42 is effectively the proximal grip.

Ex. 1002 ¶ 194. In other words, despite the fact that the finger hole of scissor arm 41 is located proximal to the user compared to the finger hole of scissor arm 42, a person of ordinary skill in the art would consider scissor arm 42 as serving as a "proximal grip" as claimed because the portion of that arm extending above the pivot point is closer to the user than the corresponding portion of scissor arm 41, or even the finger hole of arm 41. *Id*.

With respect to the claimed "frame," Dr. Pearce testifies that, under the broadest reasonable interpretation of the claim term "frame," a person of ordinary skill would consider the distal end 43 of the first scissor arm 41 to satisfy the frame limitations of claim 1. Ex. 1002 ¶ 195; Ex. 1009 at, *e.g.*, 4:58-66, FIG. 5.

Nady-Mohamed discloses that the handle is used to operate an expandable surgical head having a contracted state configured for transcervical insertion and an expanded state configured to conform to the shape of the uterine cavity. *See*, *e.g.*, Ex. 1009 at 3:49-51 (describing "flexible arms 13 and 14"), 3:67-4:1 ("membrane 20 disposed between the arms 13 and 14"); *see also* Ex. 1002 ¶ 196. The expandable head can be transitioned from a contracted state within the tube 10 (Figure 1, shown here) to an expanded state extending outward from the tube 10 (Figure 2, shown here). Nady-Mohamed expressly discloses a transcervical procedure in which "the distal end of the tube is inserted through the cervix and into the uterus, whereupon the arms and membrane are extended from within the



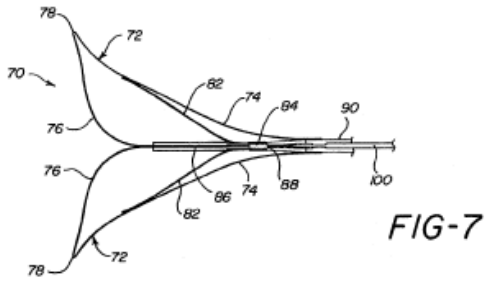
tube" and "firmly engage the walls of the lumen." Ex. 1009 at 5:64-68, 6:1-2; *see also* Ex. 1002 ¶ 196.

Nady-Mohamed also discloses that the scissor-arm handle described above is operably coupled to the expandable head. *See, e.g.*, Ex. 1009 at 4:62-66 (scissor arm 41 is "fixed . . . to the outer surface 21 of the tube," while scissor arm 42 "is coupled . . . to the plunger), 3:46-51 ("longitudinal movement of the plunger . . . is imparted to the disc" fixed to flexible arms 13 and 14); *see also id*. at FIG. 5; Ex. 1002 ¶ 197. Therefore, movement of the pivotally attached scissor arm grips closer together causes the applicator head to transition from the contracted state to the expanded state. Ex. 1009 at 4:53-5:3 ("finger rings of scissor arms 41 and 42 are brought together" to cause expansion of flexible arms); Ex. 1002 ¶ 198.

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 already 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. *Id.* ¶ 174, 199; *see also* Section VII.A.iv, *infra*. Accordingly, the combination of Yoon, Nady-Mohamed, Ortiz, and Jing discloses this limitation. *Id*. ¶ 200.

This combination also discloses **limitation 1.4**:

'348 Patent	Yoon, Nady-Mohamed, Ortiz, and Jing
[1.4] a deflecting mechanism including flexures disposed within	**Yoon discloses:** "It should also be appreciated that various mechanical spine members can be utilized to move the expandable portions 1034 between the non-expanded and expanded positions." 26:34-39; *see also* 26:43-48, 26:53-56, 27:9-11.

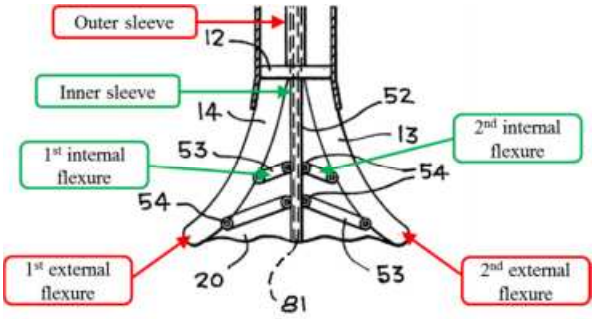
the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism 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;	**Nady-Mohamed discloses:** "The plunger 11 passes through a disc 12, and is fixed to the disc such that any longitudinal movement of the plunger within the tube is also imparted to the disc. Flexible arms 13 and 14 are also fixed, at their proximal ends 23 and 24, to the disc 12." 3:46-51. "The plunger is slidably disposed within the tube 10, and the arms and membrane are expelled from the distal end of the tube or withdrawn into the tube by sliding the plunger in the desired direction." 4:53-5:3; *see also* 4:62-66. "The rod near its distal end 52 is provided with a plurality of rigid ribs 53 which are pivotally joined to the outer surface of the rod at pivotal joints 54. The rods extend laterally from the rod and are pivotally joined at their opposite ends to the arms 13 and 14, such that, when the arms are urged by the plunger to their extended position, the rod is drawn forward with the arms, and the ribs are spread by the expansion of the arms." 5:18-26; *see also* 5:32-42, FIGS. 2, 5, 6 **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 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." 4:52-5:10, FIGS. 3, 7. *See also* Ex. 1002 ¶¶ 201-212.  FIG-7

The combination of Yoon, Nady-Mohamed, Ortiz, and Jing teaches the

precise features of the applicator head as set forth in limitation 1.4. For example, Yoon discloses flexures disposed within the applicator head to transition the applicator head from the contracted state to the expanded state. Ex. 1002 ¶ 201. Yoon's device includes "an expandable spine 1183 for mechanically shaping and/or expanding the middle member 1118" which forms the expandable portion 1134. Ex. 1007 at 26:43-48. The "expandable spine 1183 [includes] a plurality of legs 1192" which "can have curved distal tips 1193 for smoothly contouring middle member 1118." *Id.* at 26:53-56, 27:9-11. Accordingly, the spine 1183 serves as a support structure for expanding the applicator head, while the legs 1192 teach or suggest flexures disposed within the applicator head. Ex. 1002 ¶ 201.

Although Yoon discloses a support structure including flexures disposed within the expandable applicator head, Yoon does not specifically describe internal and external flexures coupled to the outer and inner sleeves or expanding the applicator head by translating the inner sleeve relative to the frame. However, these aspects of the limitation are fully disclosed by Nady-Mohamed, whose flexible arms 13, 14 are connected to the plunger 11 via the disc 12 and thus correspond to the first and second external flexures coupled to the outer sleeve. Ex. 1007 at 3:46-51; Ex. 1002 ¶ 202. Nady-Mohamed further teaches "a plurality of rigid ribs 53 . . . pivotally joined to the outer surface of the rod," which Dr. Pearce explains correspond to the first and second internal flexures coupled to the inner sleeve. Ex. 1009 at 5:18-21; Ex. 1002 ¶ 203. The correspondences between the elements recited in the limitation and the components of the Nady-Mohamed device are illustrated in the annotated version of Figure 6 shown here.

As Dr. Pearce testifies, the flexible arms 13, 14, which are clearly depicted in Figure 6 as being curved, would be considered to be "flexures" by a person of ordinary skill in the art.



Ex. 1002 ¶ 204. Moreover, Nady-Mohamed describes element 53 connected to the external flexures and inner sleeve about pivot points. While element 53 themselves are described as "rigid ribs," the configuration including pivotally connecting between the inner sleeve 81 and the outer flexures 13, 14 provides the functionality of the inner flexures disclosed in the '348 patent. Like the inner flexures described in the '348 patent, the ribs 53 are connected to outer flexures (flexible arms 13, 14) and allow movement such that the outer flexures can be collapsed to a non-expanded state, while also providing structural support for the outer flexures in the expanded state. Ex. 1002 ¶¶ 204-205.

To the extent the ribs 53 pivotally coupled to the sleeve 81 and flexures 13, 14 themselves do not satisfy as flexures, it would have been obvious to use bendable components such as those described in Ortiz. *Id.* ¶ 206. Ortiz discloses an expandable platform including "a plurality of flexible, interconnected strips" that satisfy the requirement of 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 here), 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 ¶ 206. Ortiz illustrates the use of inner flexures 82, a design

alternative to rigid ribs connected to external flexures about a pivot point, to flex and reinforce outer flexures 72. Ex. 1002 ¶ 207. Dr. Pearce explains that it would have been obvious to a person of ordinary skill in the art to implement flexible reinforcing ribs capable of achieving some degree of curvature, since this would merely be a simple substitution of one known element for another. *Id*. Substituting pivoting ribs 53 with fixed flexible members would still provide structural definition for the expandable device while at the same time providing flexibility and ability to conform to the walls of the uterus. *Id*.

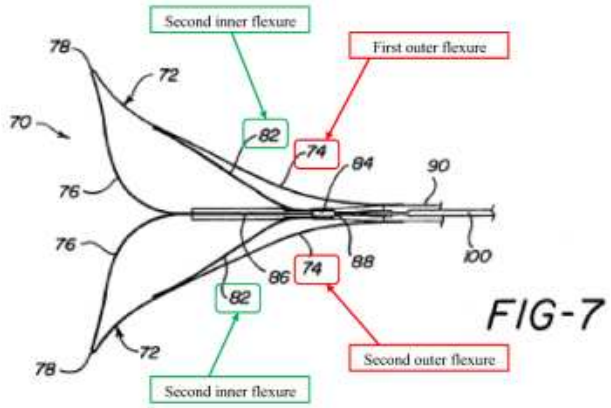


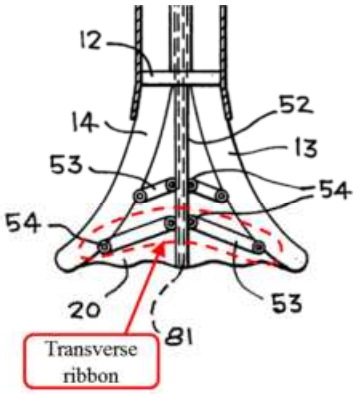
FIG-7

Additionally, a person of ordinary skill would reasonably have incorporated a flexible design as in Ortiz's expandable platform, including its bendable inner flexures, into an ablation device such as disclosed by Yoon. *Id.* ¶¶ 172-173. Utilizing a "plurality of flexible, interconnected strips" and "flexible struts" such as taught by Ortiz would further improve the ability of the device to conform to the shape of the uterus and accommodate different morphologies while also providing sufficient support to maintain an appropriate shape for uterine treatment. Ex. 1006 at 4:34-42, 52-55; Ex. 1002 ¶¶ 172-173; *see also* Section VII.A.iv, *infra*.

The claim further recites "the deflecting mechanism is configured so that translation of the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state." Ex. 1002 ¶¶ 208. This

feature is disclosed by Nady-Mohamed. As discussed above with respect to claim limitation 1.3, translational movement of the outer sleeve (plunger 11) towards the distal end of the tube 10, and therefore relative to the frame (distal end 43 of scissor arm 41, affixed to the tube), causes expansion of the applicator head. *See* Ex. 1009 at 4:535-3, 4:62-66, FIG. 5; *see also* Ex. 1002 ¶ 208. Furthermore, Nady-Mohamed indicates that the inner sleeve (rod 50) moves in concert with the plunger 11, as "when the arms [13 and 14] are urged by the plunger to their extended position, the rod is drawn forward with the arms." Ex. 1009 at 5:21-26, FIG. 6. Accordingly, Nady-Mohamed discloses the deflecting mechanism (including arms 13, 14 and ribs 53) configured such that translation of the inner sleeve (rod 50) relative to the frame (distal end 43) causes the applicator head (arms 13, 14 and membrane 20) to assume the expanded state. Ex. 1002 ¶ 208.

Additionally, Nady-Mohammed teaches or suggests that its deflecting mechanism includes a transverse ribbon. Specifically, as shown here in the annotated version of Nady-Mohamed's Figure 6, the transverse ribbon is taught or suggested by Nady-Mohamed's distal pair of ribs 53. *Id*. ¶ 209. The distal ribs 53 are coupled to and extend between the distal ends of the first and second external flexures (arms 13, 14). The ribs 53 would be compressed together between the arms 13, 14 when the applicator head is in the contracted state within the tube. *See* Ex.1009 at 5:21-26, FIG 2; *see also* Ex. 1002 ¶ 209.



Ortiz likewise discloses a transverse ribbon. Specifically, Ortiz discloses a transverse ribbon extending between the pair of fingers forming its platform, which Ortiz refers to as "inner strip 76," comprised of "an elongated, flat metal strap." *See* Ex. 1006 at 4:55-59; Ex. 1002 ¶ 210. This ribbon is shown in Figure 7 of Ortiz, which has been annotated by Dr. Pearce as seen here. Accordingly, the combination of Yoon, Nady-Mohamed, Ortiz, and Jing teaches or suggests this limitation. *Id*. ¶ 212.

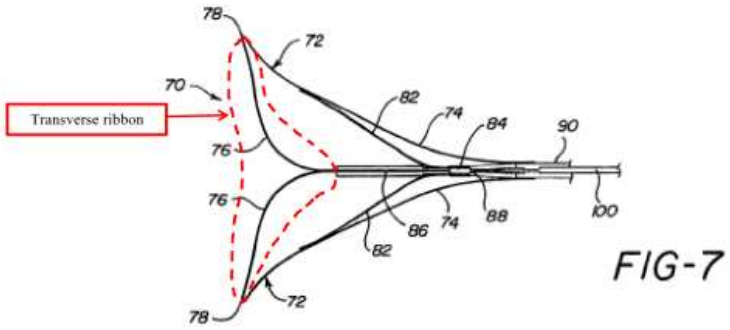


FIG-7

This combination also discloses **limitation 1.5**:

'348 Patent	Yoon, Nady-Mohamed, Ortiz, and Jing
[1.5] an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.	**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; *see also* 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 expend [*sic*] to the transverse dimension being measured." 5:9-13; *see also* FIGS. 1, 2. *See also* **Yoon** at 3:12-14, 26:9-13; Ex. 1002 ¶¶ 110, 213-217.

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; *see also* Ex. 1002 ¶¶ 110, 213.

Placement of indicator components, such as contacts 22, 23 of Jing, on an expandable applicator head of an endometrial ablation device as described by Yoon would allow measurement of a dimension of the uterus. Ex. 1002 ¶¶ 214-215. This 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 measuring rod 3 and dovetail-type contacts 22, 23) would be integrated into the deflecting mechanism of Nady-Mohamed and the applicator head of Yoon so as to be mechanically expanded within the uterus by actuation of the inner sleeve as taught by Nady-Mohamed (rod 50, *see* above discussion of limitation 1.1). *Id.* In such a manner, the Jing indicator components would be considered to be "operably coupled to the inner sleeve." *Id*.

One of ordinary skill in the art would have had good reason to utilize

dimension data from a measurement apparatus, as described in Jing, when operating an expandable ablation device, as disclosed by the combination of Yoon, Nady-Mohamed, and Ortiz. *Id.* ¶¶ 175-176. Dr. Pearce explains that close contact between the device and uterine wall is desirable for ablation therapy. *Id.* Indeed, Yoon teaches expanding the applicator head to contact the entire uterine wall. Ex. 1007 at 3:12-14, 26:9-13. A person of ordinary skill would reasonably have incorporated the components of Jing's measurement apparatus into an ablation device in order to provide dimension information that would assist a physician in accounting for patient-to-patient variations in uterine morphology, and thereby increase the safety and efficacy of the ablation treatment. Ex. 1002 ¶ 176; *see also* Section VII.A.iv, *infra*.

Accordingly, the combination of Yoon, Nady-Mohamed, Ortiz, and Jing renders obvious claim 1. *Id.* ¶ 217.

ii. Independent Claim 11

As Dr. Pearce explains, independent claim 11 is rendered obvious by the combination of Yoon, Nady-Mohamed, Ortiz, and Jing for reasons similar to those discussed above for claim 1. Ex. 1002 ¶¶ 243-251. 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. *Id.* ¶ 245.

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 Nady-Mohamed, which describes a deflecting mechanism configured so that translating one of the inner and outer sleeves relative to the other causes expansion of the applicator head. *Id.* ¶ 247. Dr. Pearce explains that the transition between the contracted and expanded states involves the flexible arms 13, 14 spreading outward, and this outward motion involves translation of the inner sleeve (rod 50) relative to the outer sleeve (plunger 11), as "the rod is drawn forward with the arms." Ex. 1009 at 4:53-5:3, 5:21-26, FIGS. 1, 2, 6; Ex. 1002 ¶ 247. Accordingly, Nady-Mohamed discloses the inner sleeve (rod 50) translating relative to the outer sleeve (plunger 11) in order to produce expansion of the applicator head. Ex. 1002 ¶ 247.

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 Yoon, Nady-Mohamed, Ortiz, and Jing discloses this limitation. Ex. 1002 ¶¶ 135-136, 235-238, 250. 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"). Jing further discloses that the computer may be configured to send the data to other components connected to the device, as the "computer control system" can include "an output port." *See id.* at 4:2-5; Ex. 1002 ¶¶ 135-136.

While Jing does not specifically describe whether these other components would include a generator configured to deliver current to the electrodes, this aspect of the limitation would have been obvious in view of Yoon. Ex. 1002 ¶ 235. Yoon discloses a device operably coupled to a generator to deliver current to the electrodes. *Id.* ¶ 236. Dr. Pearce testifies that one of ordinary skill in the art would understand that such a device such as Yoon that "can be used for electrical coagulation or cautery, such as to perform uterine ablation" would include a generator for delivering current to the ablation electrodes in order to function. Ex. 1007 at 20:34-38, 16:27-31 (describing "connection to a source of electrical energy"); Ex. 1002 ¶ 236. As Dr. Pearce explains, it would have been obvious prior to the May 1998 time frame to use uterine morphology data as an input for determining control parameters for the ablation procedure, particularly in view of Yoon's disclosure of providing the treating physician an indication of the configuration of the expandable applicator head within the uterus. Ex. 1002 ¶ 237; Ex. 1007 at 27:58-65. Thus, a person of ordinary skill in the art would have been motivated to combine Jing and Yoon in this manner in order to obtain automatic transmission of data useful for controlling the generator without requiring manual data entry, thus improving user convenience. Ex. 1002 ¶ 237.

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

'348 Patent	**Yoon, Nady-Mohamed, Ortiz, and Jing**
11. A device for treating a uterus comprising:	**Yoon** at 1:18-24, 20:34-38. **Nady-Mohamed** at 2:38-43. **Ortiz** at 1:8-12. **Jing** at 3:5-7. *See* Ex. 1002 ¶ 243; *see also* discussion of claim 1 preamble.
[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;	**Yoon** at 26:43-48, 27:58-61, FIGS. 25-27. **Nady-Mohamed** at 3:44-51, 4:58-62, 5:14-18, FIGS. 5, 6. *See* Ex. 1002 ¶ 244; *see also* discussion of claim 1, limitation 1.1.
[11.2] a handle coupled to the proximal portion;	**Yoon** at 27:58-61, 28:27-30, 28:37-50, FIGS. 25-26. **Nady-Mohamed** at 3:25-28, 3:46-51, 3:67-4:1, 4:53-5:3, 5:64-6:2, FIGS. 1, 2, 5. *See* Ex. 1002 ¶ 245; *see also* discussion of claim 1, limitation 1.3.
[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;	**Yoon** at 20:8-16, 20:31-38, FIGS. 13, 25-27. *See* Ex. 1002 ¶ 246; *see also* discussion of claim 1, limitation 1.2.
[11.4] a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and	**Nady-Mohamed discloses:** "The plunger 11 is slidably disposed within the tube 10, and the arms and membrane are

second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating one of the inner and outer sleeves relative to the other causes the applicator head to transition from the contracted state to the expanded state; and	expelled from the distal end of the tube or withdrawn into the tube by sliding the plunger in the desired direction." 4:53-56; *see also* 4:56-5:3. ". . . when the arms are urged by the plunger to their extended position, the rod is drawn forward with the arms, and the ribs are spread by the expansion of the arms." 5:18-26. **Yoon** at 26:34-39, 26:43-48, 26:53-56, 27:9-11. **Nady-Mohamed** at 3:46-51, FIGS. 1, 2, 5, 6. **Ortiz** at 4:52-5:10, FIGS. 3, 7. *See* Ex. 1002 ¶¶ 247-248; *see also* discussion of claim 1, limitation 1.4.
[11.5] an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus; and	**Jing** at Abstract, 3:26-28, 5:9-13, Figs. 1, 2. **Yoon** at 3:12-14, 26:9-13. *See* Ex. 1002 ¶ 249; *see also* discussion of claim 1, limitation 1.5.
[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	**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. **Yoon discloses:** "Handle 1139 has a configuration indicative of the configuration of expandable portion 1134 in the expanded position and/or the anatomical cavity in which the instrument 1110 is designed to be used." 27:58-65. "Where the middle member 418 includes electrically conductive material within or forming the middle member, such as an electrically conducting spine, the instrument 410 can be used for electrical coagulation or cautery, such as to perform uterine ablation." 20:34-38. "Additionally, head assembly 14 can be

	provided with a terminal for connection to a source of electrical energy to allow treatment of tissue with electrical energy via the middle member 18." 16:27-31. *See also* Ex. 1002 ¶¶ 235-238, 250.

Accordingly, the combination of Yoon, Nady-Mohamed, Ortiz, and Jing renders obvious claim 11. Ex. 1002 ¶ 251.

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, Nady-Mohamed discloses such a ribbon in its distal pair of ribs 53. Ex. 1002 ¶ 218. As shown in Figure 6, the distal ribs 53 are coupled to and extend between the distal ends of the first and second external flexures (arms 13, 14). Ex. 1009 at FIG. 6; *see also* Ex. 1002 ¶ 218. The ribs 53 would be compressed together between the arms 13, 14 when the applicator head is in the contracted state within the tube. *See* Ex. 1009 at FIG. 2; *see also* Ex. 1002 ¶ 218. Nady-Mohamed discloses that in the expanded state, "the ribs are spread by the expansion of the arms," and would therefore be considered by a person of ordinary skill in the art to be in a "relaxed condition" relative to the contracted state. Ex. 1009 at 5:21-26; *see also* Ex. 1002 ¶ 218.

Additionally, as also discussed above with respect to claim 1, Ortiz also discloses a transverse ribbon in its element 76. 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 ¶¶ 219-220. 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. Ex. 1002 ¶ 221. 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 Yoon, Nady-Mohamed, Ortiz, and Jing. Ex. 1002 ¶ 222.

Claims 3 and 13: Claims 3 and 13, which depend from claims 1 and 11, respectively, require "longitudinally spaced apertures" on the internal flexures. As discussed above, Yoon discloses an expandable spine within its applicator head. Ex. 1007 at 26:53-56, 27:9-11; *see also* Ex. 1002 ¶ 223. Yoon further explains that "[v]arious spines useful in the present invention are disclosed in applicant's prior application Ser. No. 07/600,775, filed Oct. 1990, the disclosure of which is incorporated herein by reference." Ex. 1007 at 20:38-41. The above-referenced Application No. 07/600,775 issued on December 20, 1994 as U.S. Patent No. 5,374,261 to Yoon ("Yoon '261," submitted as Ex. 1015). Yoon '261 teaches a "spine 20 [having] lateral holes 26 therein," and "[t]he holes or perforations 26 allow selective or continuous drainage of body fluids through spine 20." Ex. 1015 at 6:69-7:8. As illustrated in Figure 3 of Yoon '261, the holes 26 are spaced longitudinally along the spine 20. *See also* Ex. 1002 ¶ 216. Thus, Yoon (via the incorporated disclosure of Yoon '261) describes a structural support for its applicator head with a plurality of longitudinally spaced apertures. *Id.* ¶ 223.

To the extent that Yoon does not expressly teach that the plurality of longitudinally spaced apertures are specifically positioned on a first internal flexure, as discussed in more detail with respect to rationale to combine, it would have been obvious to modify the Yoon ablation device to incorporate the deflecting mechanism with internal flexures as described by Nady-Mohamed and Ortiz. *Id.* ¶ 224. Nady-Mohamed, like Yoon, discloses aspiration of fluids through the structural components of the applicator head. Ex. 1009 at 5:14-18, 29-31 (discussing "longitudinal bore . . . to facilitate aspiration or irrigation"); *see also* Ex. 1002 ¶ 224. A person of ordinary skill in the art would have been motivated to add apertures to the internal flexures of Nady-Mohamed and Ortiz in order to increase the aspiration capacity by providing additional locations where aspiration can occur, and such a modification would be both obvious and technically feasible. Ex. 1002 ¶ 224. Accordingly, claims 3 and 13 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. Ex. 1002 ¶¶ 225, 254.

Claim 4: Claim 4 requires that "the proximal grip is coupled to the inner sleeve and the distal grip is coupled to the outer sleeve."

This aspect would be obvious in view of Nady-Mohamed. As shown in Figures 5 and 6, the inner sleeve (rod 50) is connected to the outer sleeve (plunger 11) via the ribs 53 and arms 13, 14, and the outer sleeve is in turn coupled to the proximal grip (scissor arm 42) via coupling means 45. *See also* Ex. 1002 ¶ 226. Thus, Nady-Mohamed teaches the proximal grip being coupled to the inner sleeve. *Id*. Additionally, the outer sleeve (plunger 11) is connected to the tube 10 by virtue of being attached to the disc 12 received within the tube 10, and the tube 10 is in

turn coupled to the distal grip (scissor arm 41). Therefore, Dr. Pearce explains that the distal grip could be considered to be coupled to the outer sleeve. *Id*.

The claimed structure would have further been obvious in view of Nady-Mohamed's express disclosure that alternative arrangements of the grips and sleeves can be used. Ex. 1009 at 5:5-11 (discussing "equivalent embodiments . . . such as one in which the fixed and slidable connections of the scissor arms are reversed such that the tube is slidable over the plunger and arms"); *see also* Ex. 1002 ¶ 227. Thus, Dr. Pearce explains that one of ordinary skill in the art would have recognized that a device configuration in which the proximal grip is coupled to the inner sleeve and the distal grip is coupled to the outer sleeve would have been a reasonable and readily apparent design variation. Ex. 1002 ¶ 228. Accordingly, claim 4 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. *Id*. ¶ 229.

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."

The limitations of this claim are fully taught by Nady-Mohamed, which discloses an introducer sheath, wherein the inner and outer sleeves are disposed within the introducer sheath when the applicator head is in the contracted state. Ex. 1002 ¶ 230. As described in Nady-Mohamed, the device includes "a

cylindrical tube 10 within which is slidably disposed a plunger 11." Ex. 1009 at 3:44-46. The tube 10 discloses the claimed introducer sheath, as when the applicator head is in the contracted state, the outer sleeve (plunger 11) is disposed within the introducer sheath (tube 10). *Id*. at FIG. 1; *see also* Ex. 1002 ¶ 230. Since the inner sleeve (rod 50) is received within the outer sleeve (plunger 11), the inner sleeve would also be disposed within the introducer sheath (tube 10) when the applicator head is in the contracted state. *Id*.

Moreover, when the finger rings of the scissor arms are brought together, the distal ends of the scissor arms pivot about the rivet 49 towards each other, resulting in a proximal movement of the distal end 43 of the distal grip (scissor arm 41). *See* Ex. 1009 at FIG. 1, 4:67-5:3; *see also* Ex. 1002 ¶ 231. Additionally, as discussed above with respect to limitation 1.3 of claim 1, movement of the scissor arms 41, 42 towards each other causes the applicator head (arms 13, 14 and membrane 20) to be pushed out from the distal end of the introducer sheath (tube 10), effecting a movement of the introducer sheath relative to the applicator head. Ex. 1009 at 4:53-56; 4:66-5:3; *see also* Ex. 1002 ¶ 231. Thus, the Nady-Mohamed device meets the limitation of having a distal grip 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. Ex. 1002 ¶ 231. Accordingly, claim 5 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. *Id*. ¶ 232.

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."

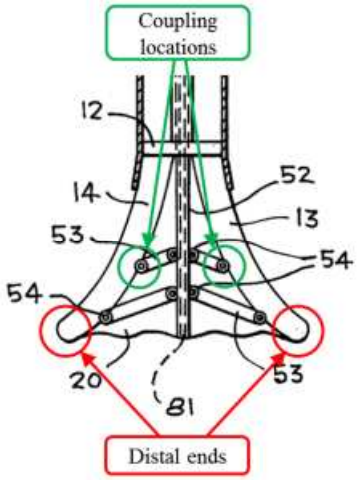
This limitation is fully disclosed by Nady-Mohamed. Nady-Mohamed teaches that the inner sleeve (rod 50) moves in coordination with the outer sleeve (plunger 11). Ex. 1009 at 5:21-26 ("when the arms are urged by the plunger to their extended position, the rod is drawn forward with the arms"), FIG. 6; *see also* Ex. 1002 ¶ 233. Furthermore, the transition between the contracted and expanded states involves the arms 13, 14 spreading outwards, and this outwards motion would result in relative movement between the inner sleeve (rod 50) and the outer sleeve (plunger 11*). See* Ex. 1009 at FIGS. 1, 2, 6; *see also* Ex. 1002 ¶ 233. Dr. Pearce testifies that a person of ordinary skill in the art would understand this to be a "continued movement," since the user can continue to move the scissor arm grips closer together over a range of movement defined by the length of the arms and their points of connection to the plunger and tube. Ex. 1002 ¶ 234. Accordingly, claim 6 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. *Id*. ¶ 227.

Claim 7: Claim 7 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 Yoon. *See* Ex. 1011 at 4:2-5, 6:5-14; Ex. 1007 at 2:34-38, 16:27-31; *see also* Ex. 1002 at ¶¶ 135-136, 235-238, 250. Accordingly, claim 7 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. Ex. 1002 at ¶ 238.

Claims 10 and 15: Claims 10 and 15 require that the internal flexures are coupled to the external flexures at a location proximal to the distal ends of the external flexures.

Nady-Mohamed discloses this limitation, teaching that the internal flexures (ribs 53) "are pivotally joined at their opposite ends to the arms 13 and 14." Ex. 1009 at 5:21-56. As shown here in Dr. Pearce's annotated version of Figure 6, the coupling locations of the first and second internal flexures (ribs 53) to the first and second external flexures (arms 13, 14) are proximal to the distal ends of the first and second external flexures. Ex. 1002 ¶ 239.



Ortiz likewise discloses this limitation. For example, the particular flexure configuration required by this claim can be found in Figure 7 of Ortiz, annotated here by Dr. Pearce. 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 ¶¶ 240-241. Accordingly, claims 10 and 15 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. *Id*. ¶ 242, 255.

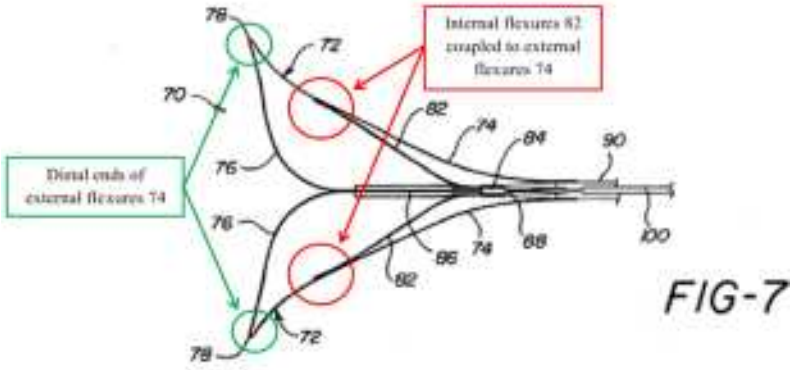


FIG-7

Claim 12: Claim 12, which depends from claim 1, requires that "the applicator head is configured to expand until limited by the dimension of the uterus."

Yoon discloses this limitation. As previously discussed with respect to the limitation 1.2 of claim 1, the expandable portion of the Yoon device, which satisfies the claimed applicator head limitation, is inflated with fluid until it contacts the uterine wall. *See also* Ex. 1007 at 20:31-34, FIG. 13; Ex. 1002 ¶ 252. Thus, the expansion of the applicator head is constrained by the internal uterine morphology. Ex. 1002 ¶ 252. This morphology would include at least the transverse and longitudinal uterine dimensions measured by the Jing indicator mechanism, as discussed above with respect to the limitation 1.5 of claim 1. *Id.* Accordingly, claim 12 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, and Jing. *Id.* ¶ 253.

iv. Rationale to Combine

As discussed above and in Dr. Pearce's declaration, it would have been obvious to combine Yoon, Nady-Mohamed, Ortiz, and Jing to achieve an endometrial ablation device utilizing the components claimed in the '348 patent for a number of reasons. Ex. 1002 ¶¶ 168-177; *see also* Section I.C.

As an initial matter, all of the cited references are similarly directed to minimally invasive surgical devices. Both Yoon and Nady-Mohamed are similarly directed to minimally invasive surgical devices that are transcervically introduced in a contracted state, then expanded to conform to the shape of the uterine cavity. *See, e.g.*, Ex. 1007 at 20:8-16, 20:31-34; Ex. 1009 at Abstract, 5:64-68, 6:1-2; Ex.

1002 ¶ 169. As Dr. Pearce testifies, in considering reasonable modifications to an ablation device as in Yoon, a person of ordinary skill in the art of medical device design would logically have looked to similar surgical instruments for guidance in applying known prior art approaches. Ex. 1002 ¶ 169.

Yoon describes the use of flexures ("mechanical spine members") for mechanically expanding the applicator head, stating that the expansion "can be controlled in many various ways such as . . . with the use of mechanical spine members for guiding the expansion and/or configuration of the expandable portions 1034 in the expanded position." Ex. 1007 at 25:23-30. Yoon expressly encourages the use of various designs for the expandable head and flexures: "It should also be appreciated that various mechanical spine members can be utilized to move the expandable portions 1034 between the non-expanded and expanded positions." *Id.* at 26:34:-39; Ex. 1002 ¶ 170. Nady-Mohamed describes just such a design for a triangular shaped, expandable device head that is deployed with flexures following introduction into the uterus. Ex. 1002 ¶ 170. In view of such teachings, one of ordinary skill in the art would reasonably have viewed Nady-Mohamed's expansion mechanism as a reasonable design choice for deploying the expandable endometrial ablation applicator head described in Yoon. *Id*.

Moreover, a skilled artisan would have recognized that an endometrial ablation device as in Yoon would benefit from improved contact between the expandable applicator head and the uterine wall. *Id.* ¶ 171. The mechanical expansion design disclosed in Yoon utilizes straight, rigid "legs" in its "expandable spine." Ex. 1007 at 26:53-56, FIGS. 25-27 (elements 1192). Nady-Mohamed

discloses a similar triangular shape for its expandable head, but teaches the use of flexible supports for the structure, teaching that its flexible arms are beneficial for "firmly engag[ing] the walls of the lumen of the uterus without risk of tearing or other damage to the tissue." *See* Ex. 1009 at 4:30-33. It would have been apparent to the skilled artisan that this arrangement would be beneficial for maintaining stable contact between the applicator head and uterine walls during endometrial ablation. Ex. 1002 ¶ 171.

To the extent Nady-Mohamed's expansion mechanism does not alone fully satisfy the flexure mechanism requirements of the claims, a skilled artisan would have reasonably utilized flexible expansion elements, such as the inner flexures of the Ortiz expandable platform, in an ablation device as disclosed by the combination of Yoon and Nady-Mohamed. *Id.* ¶ 172. Ortiz also discloses a triangular shaped, expandable device that would have been recognized as well-structured for uterine application, and the "plurality of flexible, interconnected strips" and "flexible struts" taught by Ortiz, including bendable inner flexures, would further improve the ability of the device to conform to the shape of the uterus. Ex. 1006 at 4:34-42, 52-55; Ex. 1002 ¶ 172. It would have been apparent to the skilled artisan that this flexible construction would improve the ability of the device to accommodate different uterine morphologies. Ex. 1002 ¶ 172.

Dr. Pearce further testifies that a person of ordinary skill in the art would have recognized that there was good reason to replace configurations that use fluids for expanding the Yoon device with mechanical expansion elements such as taught by Nady-Mohamed or Ortiz in order to simplify the device design, improve

reliability, and obviate potential safety issues such as fluid leakage or contamination. *Id*. ¶ 173. Indeed, Yoon expressly encourages the use of mechanical expansion as an alternative to fluid-based expansion. Ex. 1007 at 14:54-63; Ex. 1002 ¶ 173.

It would further have been obvious to one of ordinary skill in the art that an ablation device such as disclosed by Yoon 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 Nady-Mohamed. Ex. 1002 ¶ 174. Dr. Pearce explains that a skilled artisan would have recognized Nady-Mohamed's pivot grip handle mechanism as a sensible design choice that would provide greater ease of use and flexibility in actuating an expandable ablation device as in Yoon. *Id*. The existing handle mechanism described by Yoon requires two hands to operate and involves rotating a cylinder. *See, e.g.*, Ex. 1007 at 28:37-40, FIG. 25 ("operating cylinder 1196 is manually rotated while gripping handle 1139"); *see also* Ex. 1002 ¶ 174. In contrast, the Nady-Mohamed scissors-type handle can be operated with one hand and involves a simple squeezing motion. *See, e.g.,* Ex. 1009 at 4:66-5:3; FIG. 5 ("[w]hen the finger rings of the scissor arms 41 and 42 are brought together, . . . plunger 11 [moves] toward the distal end of the tube"); *see also* Ex. 1002 ¶ 174. Thus, one of ordinary skill in the art would have been motivated to utilize a pivot grip handle as taught by Nady-Mohamed to allow one-handed actuation of Yoon's ablation device. Ex. 1002 ¶ 174. 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 Yoon, Nady-

Mohamed, and Ortiz. *Id.* ¶ 175. Jing, like Yoon and Nady-Mohamed, is directed to a device for use in the uterus and teaches an expandable device head. *See*, *e.g.*, Ex. 1011 at 3:5-7, 5:9-13 ("two dovetail-type contacts . . . protrude from through-holes (10) at two sides of the measurement sleeve"). Moreover, Jing, like Nady-Mohamed, discloses a deployment mechanism based on an inner shaft slidably received within an outer shaft. *See, e.g.,* Ex. 1009 at 5:14-18 ("plunger 11 . . . is provided with a longitudinal bore, within which is slidably disposed a rod 50"); Ex. 1011 at FIGS. 1, 2 (showing "dovetail-type transverse dimension measuring rod (3)" slidably received within "measurement sleeve (2)"). 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 ¶ 175.

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 Yoon, Nady-Mohamed, and Ortiz, because such a combination would result in an endometrial ablation device capable of concurrently obtaining uterine morphology data. *Id.* ¶ 176. As Dr. Pearce explains, a person of ordinary skill in the art would have recognized that the relative dimensions of the applicator head and the target site should optimize contact between the device and uterine wall in order to efficiently deliver ablation energy to the endometrial lining. *Id.* Indeed, Yoon teaches that the expandable applicator head of its ablation device should "conform[] to the size and shape of the uterus U to touch the entire or substantially the entire uterine wall W," and

discloses that the "size, shape, and position of the expandable portions are easily adjustable in accordance with procedural use." Ex. 1007 at 3:12-14, 26:9-13; *see also* Ex. 1002 ¶ 176. Uterine dimension data provided using a known measurement device as in Jing would have benefited a physician using an adjustable ablation device as in Yoon, because it would assist a physician in accurately accounting for patient-to-patient variations in uterine morphology when adjusting the expandable applicator head, and thereby increase the safety and efficacy of the ablation treatment. Ex. 1002 ¶ 176. Additionally, it would have been common sense to the skilled artisan at the time that information regarding internal morphology would be useful when operating a surgical device within a confined space such as the uterus without direct observation. *Id*. Therefore, the indicator components of Jing's apparatus would have been a logical and desirable addition to Yoon's device as providing simple and low-cost method for obtaining morphology data that would help the practitioner customize the treatment to the particular patient and increase the likelihood of successful treatment. *Id.*

B. [Ground 2] Claims 8, 9, and 14 are Obvious under 35 U.S.C. § 103 over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman

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." As described in further detail below, claims 8, 9, and 14 of the '348 patent would have been obvious to one of ordinary skill in the art in view

of Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman. Ex. 1002 ¶¶ 256-267.

With respect to claims 8 and 14, which require an adjustable locking mechanism configured to limit a degree of expansion of the applicator head, Nady-Mohamed describes a locking mechanism "for locking the second tube in a forwardly extended position" in order to "prevent collapse of the arms and membrane toward the rod" so as to maintain the expanded state. *See* Ex. 1009 at 3:35-40, 5:37-39; *see also* Ex. 1002 ¶ 261. To the extent that the combination of Yoon, Nady-Mohamed, Ortiz, and Jing does not expressly disclose an adjustable locking mechanism configured to limit a degree of expansion of the applicator head, this would have been obvious in view of Lichtman. Ex. 1002 ¶ 262.

Lichtman discloses an electrosurgical instrument featuring an expandable head, such as a pair of conductive "jaws," where the expansion is controlled by a pair of "handle member" grips connected by a "pivot pin" and further coupled to a pair of "shafts disposed in telescoping relation with one another." Ex. 1008 at 1:8-12, 3:41-51, 6:19-22. Lichtman further discloses an adjustable "locking means" to limit movement of the handle and expandable head. *See, e.g., id.* at 9:30-32; *see also* Ex. 1002 ¶ 142. Specifically, Lichtman discloses "a ratchet-type locking means for locking the two jaws against opening movement." Ex. 1008 at 9:30-32. As illustrated in Figure 9, 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

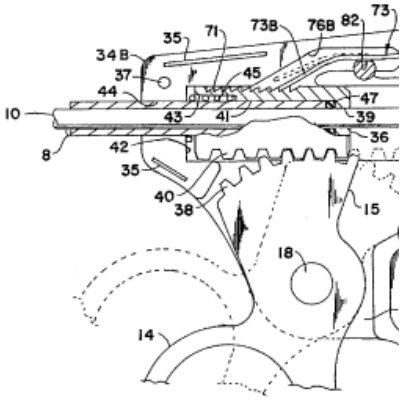


Fig. 9

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; *see also* Ex. 1002 ¶ 142. Therefore, Lichtman teaches a locking mechanism configured to limit the degree of expansion (opening) of the applicator head. Ex. 1002 ¶ 262.

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); *see also* 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. Ex. 1002 ¶ 264. 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*.

Dr. Pearce explains that one of ordinary skill in the art would reasonably

have incorporated a locking mechanism as in Lichtman with an ablation device as disclosed by Yoon, Nady-Mohamed, Ortiz, and Jing. Ex. 1002 ¶¶ 257-260. Lichtman, like Yoon, Nady-Mohamed, Ortiz, and Jing, discloses a minimally invasive surgical device including expandable elements for interacting with tissue. *See*, *e.g.*, Ex. 1008 at 2:53-67 (describing movable electrosurgical jaws). Additionally, Yoon and Lichtman are similarly directed to electrosurgical instruments. *See, e.g., id.* at 3:37-39. Lichtman, like Nady-Mohamed, discloses a handle including a pair of pivotally-attached grips that, when squeezed together, translate an inner sleeve relative to an outer sleeve in order to expand an applicator head. Ex. 1002 ¶ 258. According to Dr. Pearce, it would have been common sense for a person of ordinary skill in the art to look to known surgical instruments with similar structure and functionality when improving an existing device. *Id*.

One of ordinary skill would have recognized that an endometrial ablation device would benefit from incorporating adjustable locking of the grips and applicator head, as taught by Lichtman, because such a feature would increase safety when operating the device as well as improve ease of use by freeing the physician from having to hold the handle in a set position when maintaining the applicator head at particular degree of expansion. *Id.* ¶ 259. Furthermore, Dr. Pearce explains that Lichtman's mechanism is adjustable and allows the physician to selectively enable locking. *See* Ex. 1008 at 10:27-39; Ex. 1002 ¶ 259. This is an advantage over the fixed locking components in Nady-Mohamed's design. *See* Ex. 1009 at 5:32-36; *see also* Ex. 1002 ¶ 259. Therefore, a skilled artisan would have been motivated to utilize Lichtman's teachings to provide more convenient

and flexible locking of the expandable ablation device taught by Yoon, Nady-Mohamed, and Ortiz. *Id*. ¶¶ 259-260.

Accordingly, claims 8, 9, and 14 would have been obvious in view of Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman. *Id*. ¶¶ 261-267.

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 *et al*.
1002	Declaration of John Anthony Pearce, Ph.D.
1003	John Anthony Pearce *curriculum vitae*
1004	File History of 13/962,178 to Truckai *et al.*
1005	U.S. Patent No. 6,024,743 to Edwards
1006	U.S. Patent No. 5,358,496 to Ortiz *et al.*
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 *et al*.
1011	Certified English Translation of CN 1060594A to Jing *et al.* 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	*Flexure, Frame*, Webster's Desk Dictionary (2001)

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

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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