

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

Case IPR2016-00680
Patent 9,095,348 B2

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

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Minerva Surgical, Inc. (“Petitioner”) filed a Petition (Paper 3, “Pet.”) requesting an *inter partes* review of claims 1–15 (“the challenged claims”)

of U.S. Patent No. 9,095,348 B2 (Ex. 1001, “the ’348 Patent”). Petitioner supported the Petition with a Declaration from John Anthony Pearce, Ph.D. (Ex. 1002). Hologic, Inc. (“Patent Owner”) filed a Preliminary Response (Paper 7, “Prelim. Resp.”).

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

B. Related Proceedings

We are informed that Petitioner is named as a defendant in a federal district court case involving the ’348 Patent (Case No. 1:15-cv-01031-SLR pending in the U.S. District Court for the District of Delaware). Pet. 14. We also are informed that Petitioner has filed a second Petition for *inter partes* review of the ’348 Patent (IPR2016-00685). *Id.*

C. The ’348 Patent

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

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

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

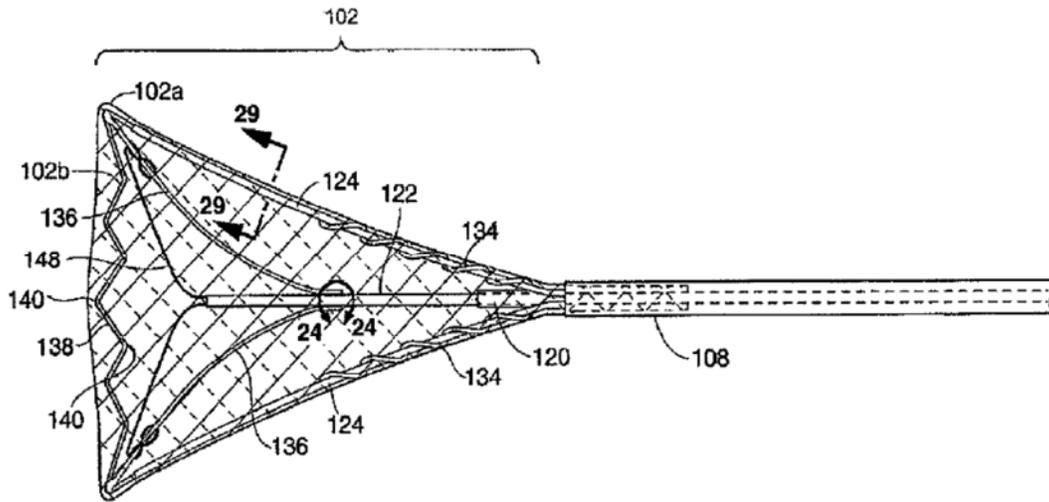


Figure 23 illustrates applicator head 102 in the expanded or deployed state.¹ *See id.* at Fig. 23. Applicator head 102 includes: external electrode array 102a, which is formed of a stretchable metallized fabric mesh; an internal deflecting mechanism 102b, which is used to expand and tension the electrode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

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

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

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

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

Id. at 14:25–31.

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

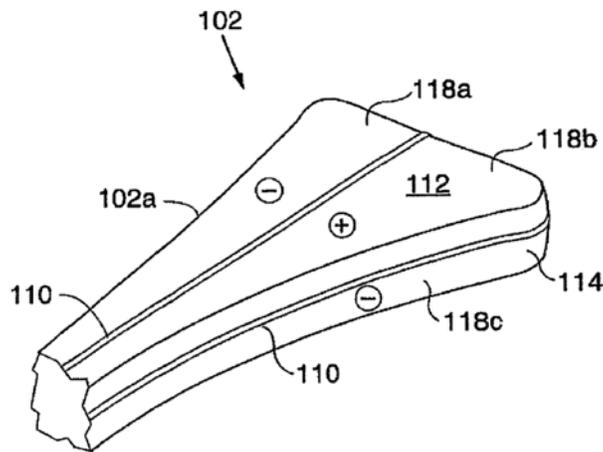


Figure 34 is a side elevation view of handle 106 as depicted in Figure 21 (reproduced above). *Id.* at 4:19–21.

As the distal and proximal grips are moved towards one another, sheath 104 is withdrawn from array 102a until female coupler 176 contacts and bears against frame member 178. *Id.* at 17:54–59, Fig. 37A, 37B.

“Continued motion between the grips causes a relative rearward motion in the frame which causes the same rearward relative motion in external hypotube 120.” *Id.* at 17:59–61. “An opposing force is developed in yoke 168, which causes a relative forward motion in hypotube 122.” *Id.* at 17:61–63, Figs. 37A, 37B. “The relative motion between the hypotubes causes deflection in flexures 124, 136 which deflect in a manner that deploys and tensions the electrode array.” *Id.* at 17:63–66.

D. Illustrative Claims

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

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

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

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

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

Id. at 19:9–42.

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

a handle coupled to the proximal portion;

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

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

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

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

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

Id. at 20:17–47.

E. The Asserted References

Petitioner relies upon the following references (Pet. 14–15):

Reference	Patent No./Pub. No.	Date	Exhibit No.
Yoon	US 5,514,091	May 7, 1996	Ex. 1007
Nady-Mohamed	US 5,353,784	Oct. 11, 1994	Ex. 1009
Ortiz	US 5,358,496	Oct. 25, 1994	Ex. 1006
Jing	CN 1060594A	Published Apr. 29, 1992	Exs. 1010, 1011 (translation)
Lichtman	US 5,620,459	Apr. 15, 1997	Ex. 1008

F. The Asserted Grounds

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

References	Basis	Claim(s) Challenged
Yoon, Nady-Mohamed, Ortiz, and Jing	§ 103(a)	1–7, 10–13, and 15

References	Basis	Claim(s) Challenged
Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman	§ 103(a)	8, 9, and 14

II. ANALYSIS

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

A. Level of Skill in the Art

Dr. Pearce testifies that a person of ordinary skill in the art would include someone who had, through education or practical experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering, or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices. Ex. 1002 ¶ 47. Patent Owner does not provide evidence or argument on the level of ordinary skill. Prelim. Resp. 11 n.3. We adopt Dr. Pearce's definition for purposes of this Decision.

B. Claim Construction

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

Inc., 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes express constructions for two claim terms, “frame” and “flexure.” Pet. 15–17. Patent Owner does not propose an express construction for any claim term. Prelim. Resp. 9–10,

1. “*frame*”

Claim 1 recites “a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a *frame*” (emphasis added). Petitioner proposes to construe the term “frame” “to include a structure coupled (*e.g.*, removably or continuously) to a handle grip, that surrounds or encloses another component (*e.g.*, inner sleeve).” Pet. 16.

We have considered Petitioner’s proposed claim construction, but determine that the term “frame” does not require explicit construction for purposes of our Decision. We note, however, that this term was construed in a related case (IPR2016-00685).

2. *flexures*

Claim 1 recites “a deflecting mechanism including *flexures* disposed within the applicator head” (emphasis added). Petitioner argues that the term “flexure” “should be construed to include a component designed to be bent or curved.” *Id.* at 17. Petitioner asserts that its proposed claim construction is consistent with the use of “flexure” in the Specification and

the term's ordinary meaning. *Id.* at 16–17 (citing Ex. 1001, 13:65–67, 13:56–14:31, Figs. 23, 30; Ex. 1002 ¶¶ 54–56; Ex. 1013, 3).

We do not agree with Petitioner's proposed construction because it is not consistent with the Specification's description of flexures 124, 136 as strips that are capable of being bent or curved. *See, e.g.*, Ex. 1001, 4:1–9, 13:8–14:31, Figs. 23, 28–30. Figures 23 and 28, for example, depict flexures 124 as strips that have been bent or curved as the result of relative motion between hypotubes 120 and 122. *Id.* at 13:8–15, 14:29–30, Figs. 23, 28. Indeed, Petitioner's declarant, Dr. Pearce, testifies that “a person of skill in the art would understand the term ‘flexure’ to refer to a component capable of being bent or curved.” Ex. 1002 ¶ 56.

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

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (“POSA”) to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A patent claim composed of several elements, however, is not proved obvious merely by demonstrating that each

of its elements was known, independently, in the prior art. *Id.* at 418. In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, when in evidence. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In this case, Petitioner challenges claims 1–15 as unpatentable for obviousness. Pet. 14–15. Specifically, Petitioner contends that claims 1–7, 10–13, and 15 would have been obvious over Yoon, Nady-Mohamed, Ortiz, and Jing and claims 8, 9, and 14 would have been obvious over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman. *Id.* For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

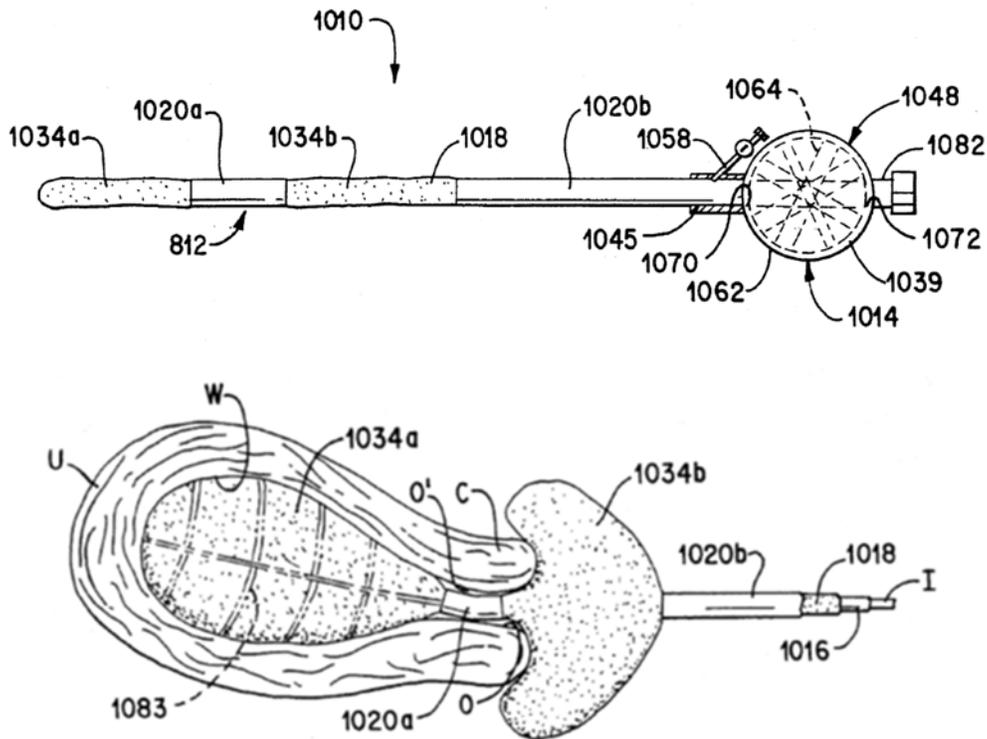
1. Overview of Asserted References

a. Yoon

Yoon discloses several distinct embodiments, including multifunctional instrument 410, which can be used for performing various diverse operative procedures, including uterine ablation. Ex. 1007, 20:9–38.

Instrument 410 includes inner member 416 and middle member 418. *Id.* at 20:19. Middle member 418 is made as a collapsible bag, balloon, or membrane. *Id.* at 19:67–20:5. The middle member defines expandable portions 434a and 434b, which have “preformed predetermined” shapes. *Id.* at 19:55–59. Expandable portions 434 are introduced through an opening in the body in a collapsed state, and fluid is supplied between middle member 418 and inner member 416 to move the expandable portions from the collapsed state to an expanded state in which they form enlargements or protrusions having configurations corresponding to the preformed predetermined shapes. *Id.* at 20:9–38, Fig. 13. Middle member 418 may include electrically conductive material, such as an electrically conducting spine, for use in performing uterine ablation. *Id.* at 20:34–38

Yoon also discloses multifunctional instrument 1110. *Id.* at 24:63–29:7, Figs. 23–27. Figures 23 and 24 are reproduced below.



As shown in Figure 26, spine 1183 is biased to, or normally disposed in, an expanded position wherein legs 1192 are disposed angularly outwardly of inner member 1116. *Id.* at 26:61–63. The legs are equally spaced about a longitudinal axis of the instrument. *Id.* at 26:56–61. Yoon discloses that:

As shown in FIG. 26, operating cylinder 1196 is rotated until forward edge 1136 of collar 1120 is disposed proximally of expandable portion 1134 causing spine 1183 to move automatically to the expanded position with legs 1192 disposed in a direction angularly outwardly of the instrument longitudinal axis as shown in FIG. 26.

Id. at 28:41–46. Yoon also discloses that:

Movement of spine 1183 to the expanded position causes movement of expandable portion 1134 to the expanded position forming an enlargement or protrusion between end wall 1126 and collar forward edge 1136. *If desired, fluid can be supplied to expandable portion 1134 via valve assembly 1148 and the lumen 1125 of inner member 1116 to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position. In the expanded position, the expandable portion 1134 can be used to manipulate tissue or organ structure in the anatomical cavity for various medical procedures.*

Id. at 28:46–57 (emphasis added).

b. Nady-Mohamed

Nady-Mohamed relates to barrier-forming or shielding means insertable into a cavity within the body through a small incision. Ex. 1009, 1:6–10. A disclosed embodiment includes cylindrical tube 10, plunger 11, and flexible arms 13, 14, which are preformed to their operative extended shapes. *Id.* at 3:45–4:6. “A membrane 20 is disposed between the arms 13 and 14, and is fixed to each arm along the lengths of its outer edges.” *Id.* at 3:67–4:1. Nady-Mohamed discloses:

In the retracted position, as illustrated in FIG. 1, the membrane 20 is folded or otherwise compressed for storage between the arms. In the extended position, as illustrated in FIGS. 2 and 3, the previously deformed arms 13 and 14 attain their natural shape, and membrane 20 is thereby spread to occupy the space between them.

Id. at 4:1–6. Figure 3 of Nady-Mohamed is reproduced below.

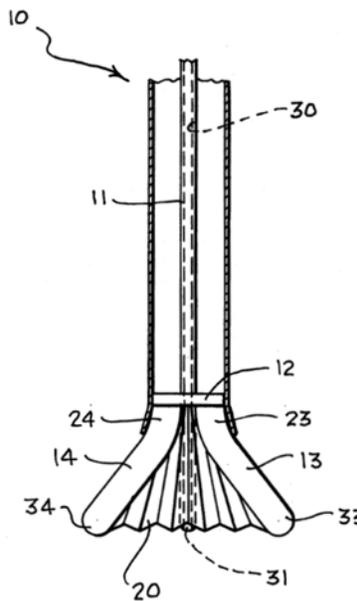
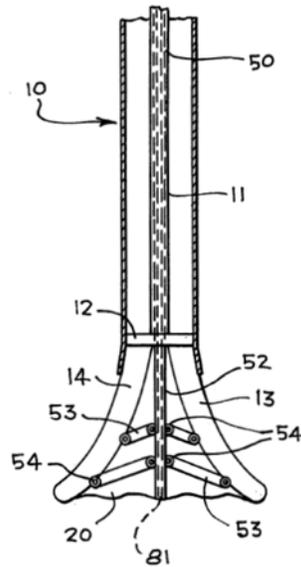


Figure 3 is a cross-section view of the barrier-forming apparatus showing plunger 11 and arms 13, 14 in an extended position, with membrane 20 spread between them. *Id.* at 3:17–19. Plunger 11 is slidably disposed within tube 10, “and the arms and membrane are expelled from the distal end of the tube or withdrawn into the tube by sliding the plunger in the desired direction.” *Id.* at 4:53–56. In use, for example, “the distal end of the tube is placed in the vicinity of the organ or tissue of interest, and the membrane and arms are extended from within the tube, thereby forming a solid barrier for shielding or retraction of the organ.” *Id.* at 5:52–56.

Figure 6 of Nady-Mohamed, reproduced below, depicts a structure for adding rigidity to arms 13, 14 in their extended position. *Id.* at 5:12–14.

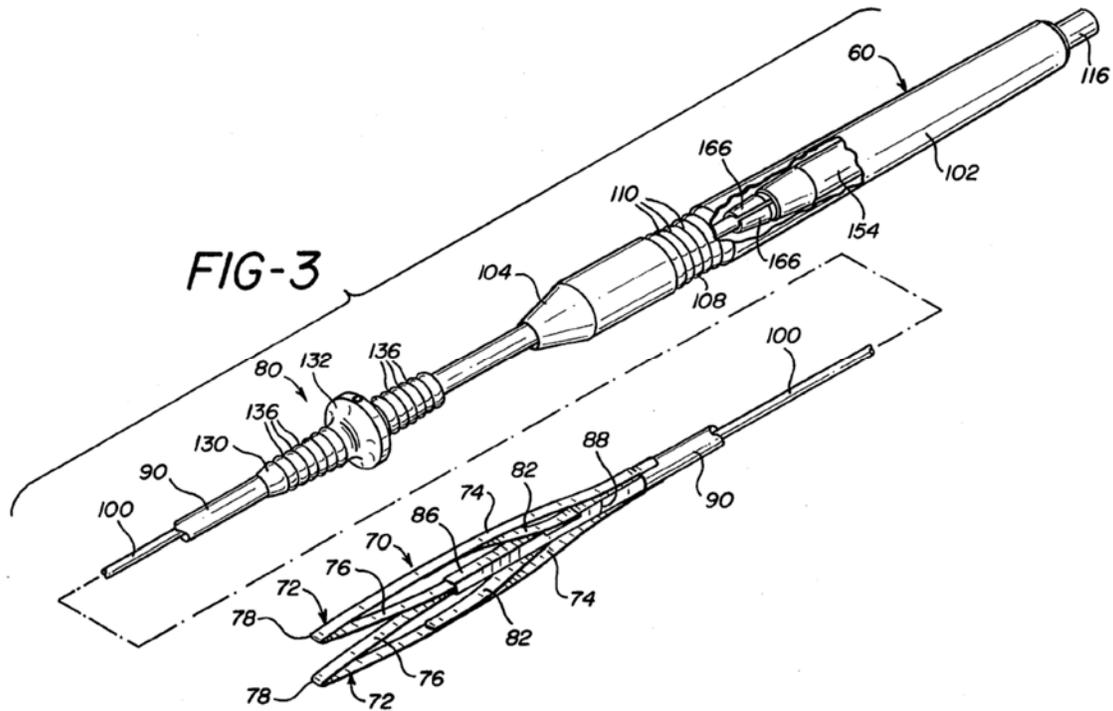


As shown in Figure 6, plunger 11 terminates at disc 12, which has a longitudinal bore within which rod 50 is slidably disposed. *Id.* at 5:14–17. “The rod near its distal end 52 is provided with a plurality of *rigid* ribs 53 which are pivotally joined to the outer surface of the rod at pivotal joints 54.” *Id.* at 5:18–21 (emphasis added). “The ribs 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.” *Id.* at 5:21–26. A locking feature prevents movement of the rod toward the proximal end of the apparatus. *Id.* at 5:32–39. “The locking feature is of *critical importance* in applications in which it is necessary for the arms to resist a collapsing force.” *Id.* at 5:39–43 (emphasis added).

c. Ortiz

Ortiz relates to an endoscopic tissue manipulator that can be inserted through an endoscopic tube to enable a surgeon to manipulate tissue inside a body cavity. Ex. 1006, 1:10–12. A preferred embodiment includes a

proximal handle assembly and a distal expandable platform 70. *Id.* at 4:37–39. Figure 3 of Ortiz is reproduced below:



As shown in Figure 3, platform 70 consists of a plurality of flexible, interconnected strips adapted to expand laterally outward to form a pair of fingers 72. *Id.* at 4:52–55. Each of fingers 72 comprises outer strip 74 and inner strip 76. *Id.* at 4:55–58. Outer strip 74 is attached to the distal end of actuator tube 90, and inner strip 76 is attached to the distal end of shaft or push rod 100 inside of actuator tube 90. *Id.* at 4:59–63. “[W]hen actuator tube 90 is retracted, i.e., moved proximally relative to the support shaft 100, the fingers 72 are spread apart and the platform 70 is expanded into a tulip-shaped configuration.” *Id.* at 5:28–31. “The outer strips 74 are pulled in the proximal direction by the actuator tube 90 and the guide tube 86 is moved proximally along the inner strips 76 by the struts 82.” *Id.* at 5:32–34.

Figure 7 of Ortiz is reproduced below.

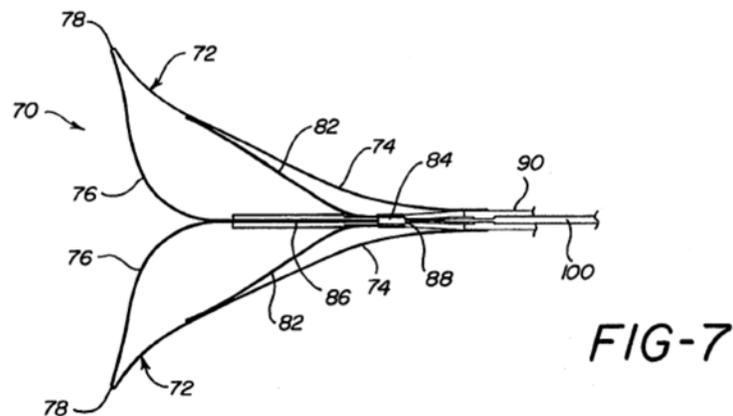


Figure 7 depicts a longitudinal cross section illustrating platform 70 in a tulip-shaped configuration. *Id.* at 3:29–30, 4:10–11. As shown in Figure 7, each of fingers 72 comprises flexible strut 82, having its distal end secured to outer strip 74 and its proximal end attached to connector sleeve 84,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

d. Jing

Jing relates to a computer-controlled apparatus for measuring and displaying data of the morphology of a woman’s uterine cavity. Ex. 1011, 3:5–7, 20–23, 4:25–30.² “An object of the present invention is to provide a computer-controlled measurement apparatus for measuring and displaying data of the morphology of the uterine cavity, thereby increasing the success

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

rate of the IUD technique and facilitating the modification of IUDs.” *Id.* at 3:20–23. Figure 2 of Jing is reproduced below.

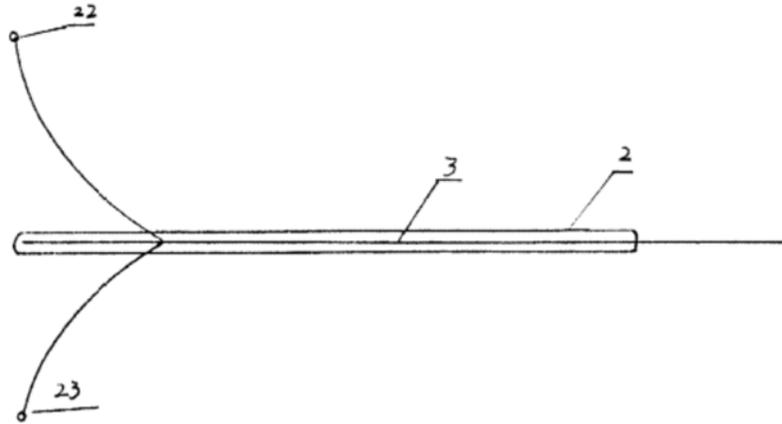


Figure 2 illustrates measuring rod 3 and dovetail-type contacts 22, 23. *Id.* at 5:9–13. Jing discloses:

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

Id.

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

With respect to the requirement of claims 1 and 11 for an elongate member comprising an inner sleeve slidably and coaxially disposed within an outer sleeve, Petitioner relies on Yoon’s instrument 1110 as depicted in Figure 25. Pet. 22–23. Petitioner also argues: “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.” *Id.* at 23 (citing Ex. 1002 ¶ 182). Relying on the embodiment depicted in Nady-Mohamed’s Figure 6, Petitioner asserts that Nady-Mohamed’s rod 50 (i.e., the inner sleeve) is slidably disposed

within Nady-Mohamed's plunger 11 (i.e., the outer sleeve). *Id.* (citing Ex. 1009, 5:14–18, Fig. 6; Ex. 1002 ¶ 183). As reasons for combining the teachings of Yoon and Nady-Mohammed, Petitioner asserts:

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 24 (citing Ex. 1002 ¶¶ 173, 184).

With respect to the “deflecting mechanism” limitation requiring “external flexures being coupled to the outer sleeve” and “internal flexures being coupled to the inner sleeve,” Petitioner relies on combining features of Yoon's instrument 1010 as depicted in Figures 25–27 with the embodiment depicted in Nady-Mohamed's Figure 6. *Id.* at 31–32. Petitioner asserts that Nady-Mohamed's flexible arms 13, 14 correspond to the “external flexures” limitation and that Nady-Mohamed's rigid ribs 53 correspond to the “internal flexures” limitation. *Id.* Petitioner argues that a skilled artisan would have improved Yoon's ablation device by incorporating Nady-Mohamed's mechanical expansion design:

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. [Ex. 1002 ¶ 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.

Id. at 50–51.

Petitioner additionally contends that, “[t]o 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.* at 32 (citing Ex. 1002 ¶ 206).

Petitioner asserts that “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.’” *Id.* (citing Ex. 1002 ¶ 206). As reasons to combine Yoon, Nady-Mohamed, and Ortiz, Petitioner contends:

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. [Ex. 1002 ¶ 207.] 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.*

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.

Id. at 33; *see also id.* at 51–52 (advancing similar arguments).

With respect to the requirement of claims 1 and 11 for “an indicator mechanism coupled to the inner sleeve . . . configured to indicate a dimension of the uterus,” Petitioner relies on Jing’s device for measuring a transverse dimension of the uterine cavity. Pet. 35–37. Petitioner contends that a skilled person would have incorporated Jing’s measurement apparatus into the ablation device taught by Yoon, Nady-Mohamed, and Ortiz “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.” *Id.* at 37, 52–54 (citing Ex. 1002 ¶ 176). Petitioner further argues that “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.* at 54 (citing Ex. 1002 ¶ 176).

3. Patent Owner’s Responsive Contentions

In response, Patent Owner argues, *inter alia*, that Petitioner has not explained sufficiently why a person of ordinary skill in the art would have combined the prior art teachings to arrive at the challenged claims as a whole. *See* Prelim. Resp. 14–15, 39, 60. Patent Owner argues, for example, that “Petitioner relies on a combination of three prior art references for the ‘deflecting mechanism’ limitations of claims 1 and 11,” but “fails to provide a rationale (or provides only insufficient conclusory assertions) for combining these references.” *Id.* at 29.

Patent Owner also asserts that Petitioner has failed to show why or how incorporating Nady-Mohamed's deflecting mechanism into Yoon's embodiment 1110 would have improved contact between Yoon's expandable applicator head and the uterine wall as Petitioner contends. *Id.* at 31–32. Patent Owner further argues that “the straight, rigid ribs 53 of Nady-Mohamed are not ‘flexures.’” *Id.* at 31.

Patent Owner additionally contests Petitioner's rationale “for combining Ortiz's struts 82 with Nady-Mohamed's deflecting mechanism.” *Id.* at 32–33. Patent Owner argues that, even if the references are, as Petitioner contends, in the same field of endeavor, that fact alone is insufficient to show a rationale for combining the references. *Id.* at 33. Patent Owner characterizes Petitioner's further argument that “the ‘flexible construction’ of Ortiz's struts 82 would ‘improve the ability of [Nady-Mohamed's] device to accommodate different uterine morphologies’” as conclusory and lacking “any factual support or reasoning as to how Ortiz's struts 82 could improve Nady-Mohamed's ability to accommodate different uterine morphologies if used as inner flexures.” *Id.* (quoting Pet. 51).

Patent Owner asserts that “Nady-Mohamed's arms 13 and 14 are described as ‘preformed to their operative extended shape’ and ‘attain their natural shape’ in the extended position—i.e., Nady-Mohamed's arms 13 and 14 are intended to expand to their predetermined shape regardless of whether Ortiz's struts 82 are used.” *Id.* at 33–34 (quoting Ex. 1009, 3:55–58, 4:3–6). Patent Owner additionally asserts that “Petitioner also has not provided any evidence that a person of ordinary skill would have recognized the alleged benefit of the Ortiz struts in the context of the claimed invention (i.e., to accommodate different uterine morphologies) without hindsight.” *Id.* at 34.

With respect to “an indicator mechanism operably coupled to the inner sleeve . . . configured to indicate a dimension of the uterus,” Patent Owner asserts that Jing’s transverse-dimension-measurement device is a stand-alone-apparatus with dovetail-type contacts that must extend across the full width of the uterus. *Id.* at 39–41 (Ex. 1011, 5:9–13). As such, Patent Owner argues, Jing is “inapposite to the devices described in Yoon, Nady-Mohamed, and Ortiz,” and would not satisfy the “operably coupled to the inner sleeve” aspect of the claim limitation if coupled to Nady-Mohamed’s outer sleeve to measure the width of the uterine cavity. *Id.* Patent Owner further asserts that Petitioner fails to explain sufficiently why or how a person of ordinary skill in the art would have used Jing’s apparatus in combination with Yoon’s expandable member 1034. *Id.* at 59–60.

4. Analysis

An analysis under 35 U.S.C. § 103(a) requires more than “mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Upon consideration of the Petition and the Preliminary Response, we agree with, and adopt, Patent Owner’s argument, as summarized above, that the reasons advanced by Petitioner for combining elements of Yoon, Nady-Mohamed, Ortiz, and Jing to make the claimed invention are conclusory and insufficient. We provide additional analysis below.

Petitioner primarily relies on Nady-Mohamed for the inner-sleeve-slidably-disposed-within-an-outer-sleeve requirement.³ In reference to the embodiment depicted in Nady-Mohamed's Figure 6, Petitioner identifies rod 50 of Nady-Mohamed as corresponding to the "inner sleeve" and Nady-Mohamed's plunger 11 as corresponding to the "outer sleeve." Pet. 23–24 (citing Ex. 1009, 5:14–18, Fig. 6; Ex. 1002 ¶ 183). While the identified elements would satisfy the "inner sleeve" and "outer sleeve" requirements, we determine, as discussed below, that Petitioner's asserted reasons for modifying Yoon's instrument 1110 to incorporate these and other elements are insufficient to support a legal conclusion of obviousness. *See id.* at 24.

In Yoon's instrument 1110 as depicted in Figures 25–27, cylinder 1196 is rotated to retract collar 1120 relative to spine 1183, which, when uncovered, expands automatically to deploy expandable portion 1034 via legs 1192. Ex. 1007, 28:41–46, Figs. 25–27. In the expanded position, legs 1192 extend angularly outward, and expandable portion 1134 forms an enlargement or protrusion between end wall 1126 and collar forward edge 1136. *Id.* at 28:46–50. Fluid can be supplied to expandable portion 1134 to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position. *Id.* at 28:50–54.

³ Petitioner also appears to contend that Yoon's instrument 1110 as depicted in Yoon's Figures 25–27 teaches an inner sleeve slidably disposed within an outer sleeve. *See* Pet. 22–23. Petitioner, however, does not identify the elements of Yoon's instrument 1110 that allegedly satisfy the claim requirements. Indeed, Petitioner's declarant, Dr. Pearce, testifies that "Yoon does not expressly describe an inner sleeve slidably disposed within the outer sleeve as recited in the claim." *See* Ex. 1002 ¶ 181.

Petitioner argues that Nady-Mohamed's mechanical expansion elements, including the slidable sleeves, are designed for engaging the uterine walls, but this argument does not explain sufficiently how the slidable sleeves contribute to this design, or why a skilled person would have substituted Yoon's rotatable cylinder/collar with Nady-Mohamed's slidable sleeves. *See* Pet. 24 (citing Ex. 1002 ¶¶ 173, 184). Dr. Pearce's testimony is similarly conclusory. For example, Dr. Pearce testifies:

[U]se 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. Such a combination would result in a device where an inner sleeve slidably and coaxially disposed within an outer sleeve as taught by Nady-Mohamed would be used to deploy the expandable member of Yoon within the uterus.

Ex. 1002 ¶ 184. Dr. Pearce's testimony fails to explain sufficiently why using an inner sleeve slidably disposed within an outer sleeve would have "simplified" Yoon's rotatable cylinder/collar deployment mechanism. Dr. Pearce's testimony also fails to explain sufficiently why substituting Nady-Mohamed's slidable sleeves for Yoon's rotatable cylinder/collar would have obviated using fluid expansion media to further shape or maintain the shape of or to increase the size of expandable portion 1134 in the expanded position (as disclosed in Yoon).

Petitioner also relies on Nady-Mohamed for "external flexures being coupled to the outer sleeve" and "internal flexures being coupled to the inner sleeve." Specifically, Petitioner contends that

Nady-Mohamed's arms 13, 14 and ribs 53 correspond, respectively, to the required "external flexures" and "internal flexures." Pet. 31–32. We agree with Patent Owner, however, that ribs 53 as disclosed in Nady-Mohamed are "rigid"; they are not flexible or bendable, and, thus, do not constitute "flexures" under a proper claim construction. *See supra* Section II.B.2; Prelim. Resp. 31.

Alternatively, Petitioner argues that Ortiz remedies the lack of "internal flexures" in Yoon and Nady-Mohamed. Pet. 32. Petitioner relies on Dr. Pearce's testimony that substituting Nady-Mohamed's rigid pivoting ribs 53 with "flexible reinforcing ribs capable of achieving some degree of curvature," such as flexible struts 82 of Ortiz, would have been obvious as "a simple substitution of one known element for another." Pet. 33 (citing Ex. 1002 ¶ 207).

We are not persuaded that substituting Nady-Mohamed's ribs 53 with Ortiz's struts 82 would have amounted to a simple substitution of one known element for another. The functions of the two elements are significantly different. The function of Nady-Mohamed's ribs 53 is to add rigidity to flexible arms 13, 14 in response to a collapsing force, while the function of Ortiz's struts 82 is to provide for shape control of outer strips 74 and platform 70 in response to an expanding force (pulling or pushing of outer strips 74 by retraction or advancement of actuator tube 90). *Compare* Ex. 1009, 5:12–43, *with* Ex. 1006, 5:28–6:6. The different known functions of ribs 53 (Nady-Mohammed) and struts 82 (Ortiz) are in keeping with the different expansion mechanisms that they complement. Flexible arms 13, 14 of Nady-Mohamed are preformed

such that they spring naturally into their extended position when unrestrained (Ex. 1009, 3:55–4:6), while Ortiz’s outer strips 74 do not expand unless pulled or pushed by retraction or advancement of actuator tube 90 (Ex. 1006, 5:28–67). We are not persuaded, therefore, that Ortiz teaches or suggests flexible reinforcing ribs as Dr. Pearce asserts, or that a skilled person would have combined the teachings of Nady-Mohamed and Ortiz as Petitioner contends.

Petitioner, moreover, has not provided a sufficient rationale for combining the teachings of Jing with those of Yoon, Nady-Mohamed, and Ortiz. Petitioner’s argument that dimension information provided by Jing’s measurement device would assist a physician in accounting for patient-to-patient variations in uterine morphology does not explain sufficiently why a person of ordinary skill in the art would have incorporated Jing’s measurement device into Yoon’s ablation device, rather than simply use Jing’s device separately to obtain the information. We are unpersuaded by Dr. Pearce’s testimony that “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.” See Ex. 1002 ¶ 176 (emphasis added); *Arendi S.A.R.L. v. Apple Inc.*, Appeal No. 2015-2073, 2016 WL 4205964, at *5 (Fed. Cir. Aug. 10, 2016) (stating that “‘common sense’ . . . cannot be used as a wholesale substitute for reasoned analysis and evidentiary support”). Dr. Pearce’s testimony does not contain sufficient reasoning or evidentiary support to explain why

obtaining a transverse dimension of the uterus while concurrently operating Yoon's ablation device would have been useful.

For these reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to independent claims 1 and 11 as obvious over Yoon, Nady-Mohamed, Ortiz, and Jing. As Petitioner's arguments and evidence with respect to dependent claims 2–10 and 12–15 do not remedy the deficiencies in the arguments and evidence with respect to the independent claims, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 2–10 and 12–15.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to: claims 1–7, 10–13, and 15 as obvious over Yoon, Nady-Mohamed, Ortiz, and Jing; and claims 8, 9, and 14 as over Yoon, Nady-Mohamed, Ortiz, Jing, and Lichtman.

IV. ORDER

In consideration of the foregoing, it is hereby:

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

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