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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.

Patent No. 9,247,989

PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO. 9,247,989

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I. INTRODUCTION

Pursuant to the provisions of 35 U.S.C. § 321, and to 37 C.F.R. Part 42, Minerva Surgical, Inc. ("Petitioner") hereby requests post-grant review of U.S. Patent No. 9,247,989 to Truckai (hereinafter "the '989 patent," Ex. 1001) which issued on February 2, 2016 and is currently assigned to Hologic, Inc. ("Patent Owner"). This Petition demonstrates that it is more likely than not that claims 1-19 of the '989 patent are unpatentable for failing to satisfy the written description and enablement requirements of 35 U.S.C. § 112. Thus, claims 1-19 of the '989 patent should be found unpatentable and canceled.

The plain language of both independent claims of the '989 patent requires a method of endometrial ablation utilizing a device with ***both*** a particular internal spring member ("flexures") mechanical expansion means and an internal inflation expansion means for expanding the tissue-contacting exterior of the device inside the uterus. But the specification describes something quite different. The written description and figures of the patent describe devices and methods that use ***either*** mechanical expansion (e.g., as shown here in Figure 10) ***or*** inflation expansion (e.g., as shown here by balloons 52 in figure 20), but not both.

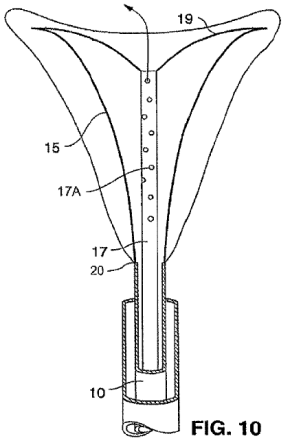

FIG. 10

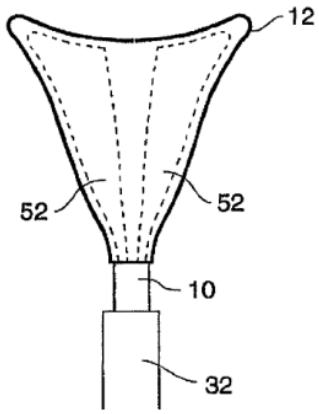

FIG. 20

In fact, the different mechanical and inflation expansion means described in the ’989 patent are incompatible with each other and presented as mutually exclusive alternatives, not combinable elements as claimed. As confirmed by supporting testimony from technical expert Dr. Pearce (Ex. 1002) and Mr. Csaba Truckai (Ex. 1014), the sole inventor named on the ’989 patent, the ’989 patent now improperly claims different aspects of two distinct and mutually exclusive embodiments into a single, nonsensical amalgamation. This claimed subject matter is not described anywhere in the ’989 patent or its priority documents, was never meant to be described, and, in fact, could not be a functional combination.

For this reason, and as discussed in further detail below, the claims of the ’989 patent are unsupported by adequate written description. Likewise, the claims are not enabled by the specification because undue experimentation would have been required to make and use the claimed invention, particularly because a person of skill in the art would have been forced to deviate from the teachings of the specification and develop an entirely new design to do so. Moreover, while the ’989 patent claims priority to a chain of continuation applications dating back to 1998, those applications similarly do not disclose an ablation device utilizing both mechanical and inflation expansion means. As such, the ’989 patent is eligible for PGR review based on the same deficiency that renders its claims unpatentable under § 112.

Taken together, this petition and supporting evidence demonstrates that a person of skill in the art, like the inventor himself, would not have understood the now claimed invention as having been described in the ’989 patent, the application

as filed, or any of the priority applications. In addition to lacking description, the '989 patent and application as filed provide insufficient guidance as to how to make and use the claimed subject matter without undue experimentation.

A. Brief Overview of the '989 Patent

The '989 patent is entitled "MOISTURE TRANSPORT SYSTEM FOR CONTACT ELECTROCOAGULATION." The '989 patent relates to devices and methods for ablation or coagulation of tissues in the interior linings of the uterus – a procedure known as endometrial ablation. Ex. 1001 at 1:20-22; Ex. 1002 ¶ 13.

The '989 patent describes the ablation device as containing three main parts: an RF applicator head, a main body or sheath, and a handle. Ex. 1001 at 4:59-62, 11:65-67. The claims of the '989 use different words from the specification and refer to the RF applicator head as an "energy applicator." The RF applicator head includes an array of electrodes on its exterior surface and is expandable, taking a compressed form for insertion into the uterus and then expanding into its open state once inside the uterus to position the device for ablation. *See, e.g., id.* at 2:51-57, 9:29-32, 9:58-61; Ex. 1002 ¶ 14. See, e.g., Figures 1 and 2 of the '989 patent (shown here).

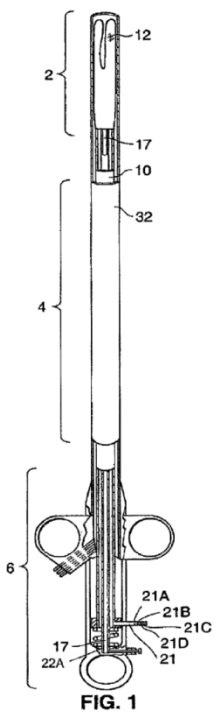

FIG. 1

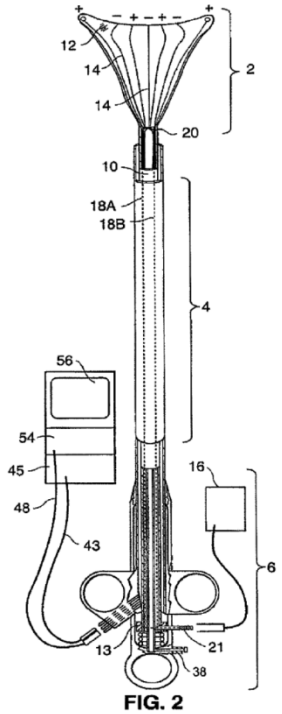

FIG. 2

Claim 1 of the ’989 patent is representative of the claims at issue and recites the following:

> A method for performing endometrial ablation comprising:
>
> transcervically positioning a distal portion of an ablation device into a uterus, the distal portion comprising an energy applicator, the energy applicator comprising a tissue contacting surface and an expandable-contractible carrying member, the expandable-contractible carrying member including first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve and the first and second inner flexures being coupled to an inner sleeve, the inner sleeve being slidably and coaxially disposed within the outer sleeve;
>
> actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus, the handle comprising a proximal grip and a distal grip pivotally attached to one another at a pivot point, and wherein actuating the handle includes moving the proximal grip and the distal grip closer together while translating the inner sleeve relative to the proximal grip;
>
> actuating an inflation source to further expand the energy applicator in the uterus; and
>
> delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus.

The plain language of claim 1 requires two types of actuation to expand the energy applicator. First, the claim requires a mechanical expansion, reciting actuation of a pivot grip handle that translates an inner sleeve relative to the handle which results in expansion of the claimed inner and outer flexure components of

the expandable-contractable carrying member. Second, the claim requires further expansion of the energy applicator brought about by actuation of an inflation source. Ex. 1002 ¶ 12.

The figures and written description of the '989 patent are organized into descriptions of a "First Exemplary Embodiment" and a "Second Exemplary Embodiment." Ex. 1002 ¶ 17. Figures 1-20 and column 4, line 58 through column 11, line 55 are directed to a "First Exemplary Embodiment," while Figures 21-37B and column 11, line 56 through column 19, line 11 are directed to a "Second Exemplary Embodiment." *Id*. No embodiment describes an ablation device utilizing mechanical expansion provided by flexures, telescoping sleeves, and a pivot grip handle, in combination with inflation-based expansion, as claimed in the challenged claims. *Id*. at ¶ 17.

The First Exemplary Embodiment provides for a mechanical expansion of the RF applicator head (incluidng electrode carrying means 12), whereby, after insertion, the handle is used to pull spring members 15 and 19 into an open position, expanding the electrode carrying means as depicted in Figures 7 and 10. *Id*. at 7:66-8:14, 9:58-62; Ex. 1002 ¶¶ 15, 70.

The First Exemplary Embodiment also mentions that the device may use a pair of balloons as shown in Fig. 20 as an ***alternative*** to the mechanical explansion via the spring members assembly. *Id*. at 8:66-9:7 ("Alternatively, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in FIG. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52."). *Id*.; Ex. 1002 ¶¶ 15, 23.

The Second Exemplary Embodiment "differs from the first embodiment primarily in it electrode pattern and in the mechanism used to deploy the electrode applicator head or array." *Id*. at 11:59-61. Where the First Exemplary Embodiment describes a syringe-like handle comprising a "finger cutout 37" and a pair of "spaced rails 35a and 35b," the Second Exemplary Embodiment utilizes a "distal grip section 142 and a proximal grip section 144 that are pivotally attached to one another at pivot pin 166." *Id*. at 7:55-64, 16:17-20; *see also, e.g., id*. at Figs. 7, 21; Ex. 1002 ¶¶ 22, 72; Ex. 1014 ¶ 5.

The Second Exemplary Embodiment differs from the First not only in its description of a mechanical apparatus for expanding the energy applicator within the uterus, but also in its omission of any discussion of inflation-based expansion. Ex. 1002 ¶ 72. Where the First Exemplary Embodiment includes an alternative to the spring members in the form of two balloons that receive an inflation medium, the Second Excemplary Embodiment lacks any similar disclosure. *Id*.

Again, the '989 patent specification does not describe or suggest any embodiment or example utilizing both the spring-member mechanical expansion and inflation expansion of of the applicator head or carrying member 12. Ex. 1002 ¶ 46.

B. Brief Overview of the Prosecution History

Application No. 14/635,957 was filed on March 2, 2015 and issued on February 2, 2016 as U.S. Patent No. 9,247,989. The '989 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 ’957 application, like other applications in the priority chain, was subject to unexplained modifications to the listing of named inventors. The ’957 application was originally filed listing Csaba Truckai, Russel Sampson, Stephanie Squarcia, Alfonso Ramirez, and Estela Hilario as inventors. Ex. 1005 at 0003-0004. Substitute statements were subsequently filed on behalf of nonsigning inventors Alfonso Ramirez, Stephanie Squarcia, and Csaba Truckai. Ex. 1005 at 0014-0019. Prior to the first Office Action, Patent Owner removed Russel Sampson, Stephanie Squarcia, Alfonso Ramirez, and Estela Hilario as inventors, leaving only non-signing inventor Csaba Truckai as the sole inventor and removing the inventors who provided signed declarations. Ex. 1005 at 0119-0121.

The prosecution involved two Office Actions. In the first office action, the Office rejected claims 9, 12, and 13 as being indefinite. Ex. 1005 at 0151. Claims were also rejected as being anticipated by Yoon (U.S. Patent 5,451,204) and anticipated by Edwards (U.S. Patent 5,505,730), and obvious over those references. Ex. 1005 at 0153-0159. Lastly, claims 1, 5 and 14 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting (Ex. 1005 at 0159-0160) as being unpatentable over U.S. Application No. 13/267,258 to Truckai (“the ’258 application”, Ex. 1006). However, U.S. Application 13/267,258 to Truckai is owned by Petitioner Minerva Surgical, Inc., ***not*** by Hologic, and was therefore not co-owned by the ’989 Patent Owner. Therefore, the assertion by the Office that the claims of the ’947 application were not patentably distinct from the claims of the ’258 application should have elicited an interference inquiry as opposed to a nonstatutory double patenting rejection.

Claim amendments during prosecution were substantial. In response to the first Office Action, the Patent Owner amended claim 1 as recited below:

> A method for performing endometrial ablation comprising:
>
> transcervically positioning a distal portion of an ablation device into a uterus, the distal portion comprising an energy applicator, the energy applicator comprising a tissue contacting surface and an expandable-contractible carrying member, the expandable-contractible carrying member including first and second inner flexures and first and second outer flexures, the first and second outer flexures being coupled to an outer sleeve and the first and second inner flexures being coupled to an inner sleeve, the inner sleeve being slidably and coaxially disposed within the outer sleeve;
>
> actuating a handle coupled to a proximal portion of the ablation device to cause the carrying member to expand the energy applicator in the uterus, the handle comprising a proximal grip and a distal grip, and wherein actuating includes moving the proximal grip and the distal grip closer together while translating the inner sleeve relative to the proximal grip;
>
> actuating an inflation source to further expand the energy applicator in the uterus; and
>
> delivering energy through the energy applicator to thereby deliver energy to endometrial lining tissue of the uterus.

Ex. 1005 at 0211. The Patent Owner did not take any action to overcome the double patenting rejection in the initial response.

A final office action was issued on August 11, 2015, rejecting claims 1-4, 6-13 and 15-22 as being anticipated by U.S. Patent No. 5,769,880 ("the'880 patent"), to which the '957 patent had claimed priority at the time of filing but was subsequently removed from the priority chain. Ex. 1005 at 0219-0220, 0231-0236.

In response to an interview with the Examiner, the Patent Owner further amended the claims to further define the mechanical expansion means including the flexures structure as including the proximal grip and the distal grip "pivotally attached to one another at a pivot point," while arguing that the '880 patent does not show or suggest the claimed subject matter.[1] Ex. 1005 at 0277.

With regard to the double patenting rejection, there is no indication the Examiner was ever informed that the '258 application was not owned by Hologic, but instead is owned by Minerva Surgical Inc.

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

Petitioner's technical expert, Dr. John Anthony Pearce, is the retired Temple Foundation Professor of Electrical Engineering at the University of Texas at Austin. Ex. 1002 ¶ 1. Dr. Pearce has worked in the field of electrosurgery and biomedical instrumentation since the early 1970s and is therefore familiar with the knowledge and level of skill in the field relevant to the '989 patent. *Id.* ¶¶ 1-7; *see also* Ex. 1003. Dr. Pearce explains that his analysis is based on the understanding of a person of skill in the art as of March 2, 2015, the filing date of the application for the '989 patent, and that his opinions as set forth in his declaration do not

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[1] The '880 patent identically includes the "First Exemplary Embodiment" disclosure also found in the '989 patent. The "Second Exemplary Embodiment was later added as a continuation-in-part. Ex. 1014 ¶ 5. As explained above, the "First Exemplary Embodiment" disclosure is the only embodiment in the '989 patent mentioning any balloon expansion (Fig. 20).

change if based on the perspective of a person of skill in the art at any point between May 8, 1998—the earliest claimed priority date—and March 2, 2015, including specifically May 8, 1998 and October 19, 2009 (the date of the latest filed application in the priority chain prior to the March 16, 2013 date for determining PGR eligibility). Ex. 1002 ¶¶ 32-33, 47-49.

II. GROUNDS FOR STANDING

Petitioner certifies that, under 37 C.F.R. § 42.204(a), the '989 patent is available for post-grant review, and Petitioner is not barred or estopped from requesting post-grant review of the '989 patent on the ground identified.

The '989 patent claims priority to a provisional application filed on May 8, 1998. However, as discussed below in Section VI, at least one claim of the '989 patent has an effective filing date on or after March 16, 2013. In addition, the '989 patent issued on February 2, 2016 and this petition is being filed no later than nine months from that date. Accordingly, the claims of the '989 patent are available for post-grant review. *See* 35 U.S.C. § 321(c); 37 C.F.R. § 42.202(a).

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 '989 patent against Petitioner in United States District Court for the District of Delaware, Case No. 1:15-cv-01031-SLR (attached as Ex. 1016). Petitioner has filed a petition for *inter partes* review against U.S. Patent No. 6,872,172 (IPR2016-00868). In addition, Petitioner has also filed petitions for *inter partes* review

against U.S. Patent No. 9,095,348 (IPR2016-00680 and IPR2016-00685).

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)

Service Information – 37 C.F.R. § 42.8(b)(4). Petitioners hereby consent to electronic service.

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

Petitioners request review of claims 1-19 of the '989 patent under 35 U.S.C. § 321. The grounds for relief are expressly limited to a determination that each of claims 1-19 of the '989 patent be canceled as unpatentable as follows:

- Ground 1: Claims 1-19 fail to satisfy the written description requirement of 35 U.S.C. § 112; and
- Ground 2: Claims 1-19 fail to satisfy the enablement requirement of 35 U.S.C. § 112.

V. CLAIM CONSTRUCTION

A claim subject to post-grant review receives the broadest reasonable construction in light of the specification of the patent in which it appears. *See* 37 C.F.R. § 42.200(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142-45

(2016). 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. One term that warrants discussion is identified and discussed below.

"flexure": Independent claims 1 and 14 require flexures that are disposed within the energy applicator, and specifically recite "outer flexures" and "inner flexures" coupled to the outer and inner sleeves, respectively. Ex. 1002 ¶ 37.

The '989 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 "outer flexures" and "inner flexures" recited in the claims, respectively. *Id*. at 13:56-14:31; Ex. 1002 ¶ 38. 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 ¶ 38.

As Dr. Pearce explains, 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 ¶ 39. 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 expandable-contractible carrying member, as well as the plain and ordinary meaning of the term. Ex. 1007 at 3 ("a bent part"). The term "flexure" therefore, should be

construed to include a component capable of being bent or curved.

VI. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS

The '989 patent is not entitled to priority any earlier than its actual filing date, despite on its face claiming priority to a chain of applications dating back to 1998.[2] Because none of the applications in its continuation chain filed before March 16, 2013 support the issued claims of the '989 patent, the patent is eligible for PGR.

The post-grant review provisions of Section 6(d) of the AIA only apply to patents subject to the first-inventor-to-file provisions of the AIA, i.e., to a patent with at least one claim that has an effective filing date on or after March 16, 2013. *See* AIA §§ 6(f)(2)(A); 3(n)(1). The definition of "effective filing date" referred to in § 3(n)(1) provides that:

> (A) if subparagraph (B) does not apply, the actual filing date of the patent or the application for the patent containing a claim to the invention; or
>
> (B) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority under section 119, 365(a), or 365(b) or to the benefit of an earlier filing date under section 120, 121, or 365(c).

35 U.S.C. § 100(i)(1). Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365 is premised on disclosure of the claimed invention "in the

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[2] Moreover, as discussed below in Section VII.A., the '989 patent is not entitled to priority any earlier than the date the specific subject matter recited in the claims was added through amendment.

manner provided by § 112(a) (other than the requirement to disclose the best mode)" in the earlier application. *See* 35 U.S.C. §§ 119(e), 120.

Accordingly, a patent issuing from an application filed after March 16, 2013 is available for post-grant review, notwithstanding any priority claim to an application filed before March 16, 2013 if the patent includes "at least one claim that was not disclosed in compliance with the written description and enablement requirements of § 112(a) in the earlier application." *Inguran, LLC v. Premium Genetics (UK) Ltd*., PGR2015-00017, Paper 8 at 11 (Dec. 22, 2015). Entitlement to the priority of an earlier application is not demonstrated merely because claims at issue appear in a continuation of the earlier application. *See In re NTP, Inc.,* 654 F.3d 1268, 1276-77 (Fed. Cir. 2011). Rather, the written description in the earlier application must be sufficient to reasonably convey to a person of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

Moreover, the disclosure must describe the claimed invention with all its limitations; a disclosure that merely renders the claimed invention obvious is not sufficient to meet the requirements of § 112(a). *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998). Further, it is not enough that the individual elements of the claimed invention are disclosed; the claimed combination of those elements must be described to satisfy the written description requirement. *Hyatt v. Dudas*, 492 F.3d 1365, 1369-71 (Fed. Cir. 2007).

A. The claims of the '989 patent require mechanical expansion *and* inflation-based expansion

The plain language of the '989 patent claims requires a method of ablation utilizing an ablation device comprising both mechanical ***and*** inflation-based expansion means to expand the energy applicator inside the uterus. For example, claim 1 requires "actuating a handle . . . to cause the carrying member to expand the energy applicator in the uterus," where the handle includes "a proximal grip and a distal grip pivotally attached to one another at a pivot point," and results in "translating an inner sleeve" that is recited as coupled to "first and second inner flexures" that are components of an "expandable-contractible carrying member." Ex. 1001 cl. 1. These elements of claim 1 form the requirement for a mechanical mode of expanding the energy applicator. Ex. 1002 ¶¶ 12, 16. Additionally, claim 1 requires "actuating an inflation source to further expand the energy applicator in the uterus," such that the recited ablation device must have a means of inflating the energy applicator in addition to mechanically expanding it. Ex. 1001 cl. 1; Ex. 1002 ¶¶ 12, 16.

Independent claim 14 contains nearly identical requirements, including "actuating a handle" to "cause the expandable-contractible carrying member to develop an expansion force against the tissue carrying member," where the expandable-contractible carrying member includes "first and second inner flexures and first and second outer flexures." Ex. 1001 cl. 14. Like claim 1, claim 14 also requires "actuating an inflation source to further expand the energy applicator in the uterus" and therefore requires both mechanical and inflation expansion. *Id*.;

Ex. 1002 ¶ 113. Dependent claims 2-13 and 15-19 all depend from either claim 1 or 14 and thus also require mechanical and inflation expansion. Ex. 1002 ¶ 114.

B. The '506 application describes mechanical expansion and inflation expansion only as mutually exclusive alternatives

The '989 patent claims priority to a chain of five earlier applications as well as a provisional application. Ex. 1001 at (60). The specifications of each application in the chain differ only in their originally filed claims. Ex. 1002 ¶ 122-143. None of the applications disclose an ablation device utilizing a combination of mechanical and inflation expansion means as claimed in the '989 patent. For the purposes of analyzing PGR eligibility, Petitioner focuses on U.S. Application No. 12/581,506 ("the '506 application). The '506 application was filed on October 19, 2009 and is the latest filed application in the priority chain that was filed before March 16, 2013. As such, the '506 application demonstrates that the '989 patent claims were not supported by the priority applications as of the relevant date for determining PGR eligibility.

As Dr. Pearce explains, the identical disclosures of the '989 patent and the parent '506 application do not describe an endometrial ablation device, or method of using such a device, with an applicator head containing ***both*** a mechanical expansion means ***and*** an inflation means. Ex. 1002 ¶ 46. Instead, the specification describes mechanical expansion and inflation as ***alternative*** methods of expanding and providing structural integrity to the applicator head, and these alternative approaches are mutually exclusive. *Id.*

Specifically, the '506 application explains that "the electrode carrying means 12 may be provided to have additional components inside it that add structural integrity to the electrode carrying means when it is deployed within the body." Ex. 1008 at 16:20-25. Dr. Pearce explains that this structural integrity would enable the RF applicator head to both expand inside the uterus and to maintain contact with the endometrial wall during ablation treatment. Ex. 1002 ¶ 47.

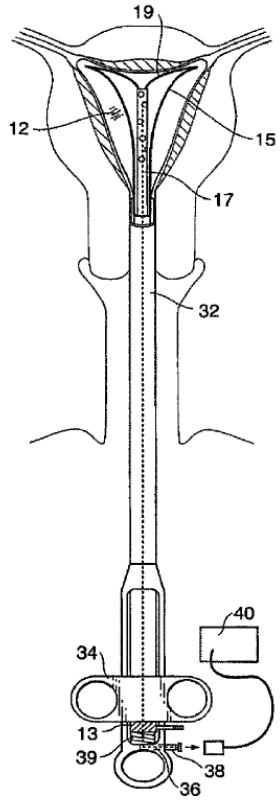

FIG. 7

The specification describes two alternative types of components that could be added to directly provide expansion means. First, the specification describes the use of mechanical springs to expand the applicator head. For example, the specification describes a "slidably mounted" handle 34 that is used to apply a pulling force to spring member components that in turn expand the RF applicator head. Ex. 1008 at 17:6-9 ("The movement of the shaft 10 relative to the suction/insufflation tube 17 causes the shaft 10 to pull proximally on the passive spring member 15."); Ex. 1002 ¶ 48. The use of spring members 15 and 19 to mechanically expand the RF applicator head in the uterus is depicted, for example, in Figure 7 (shown here).

The specification provides another example of mechanical expansion using spring members with respect to Figure 11 (shown below), describing "alternative spring members 15a, 19a." Ex. 1008 at 18:26-19:4; Ex. 1002 ¶ 49. These alternative spring members are "biased such that, when in a resting state, the spring

members are positioned in the fully resting condition shown in FIG. 11 [and] would spring to the resting condition upon withdrawal of the sheath 32 from the RF applicator head 2." Ex. 1008 at 18:26-19:4. In other words, the main difference between the mechanical spring members depicted in Figure 7 versus those shown in Figure 11 is that spring members 15 and 19 in Figure 7 are biased toward the collapsed condition, such that continued force is required to keep the spring members in the expanded state, whereas spring members 15a and 19a in Figure 11 are biased toward the expanded state. *Id*. at 17:8-16, 18:26-19:4; *see also* Ex. 1002 ¶ 50.

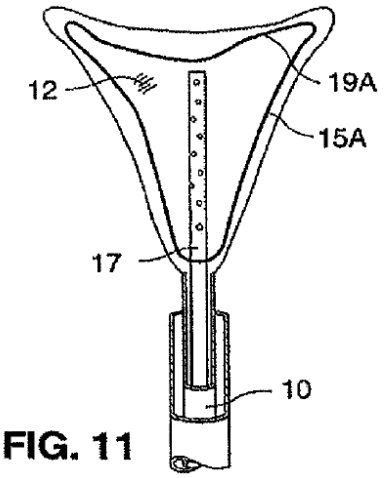

FIG. 11

Immediately after the specification's discussion of mechanical spring member expansion, the specification goes on to describe use of inflatable balloons to provide structural integrity as an alternative approach:

> ***Alternatively***, a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in FIG. 20 and connected to a tube (not shown) extending through the shaft 10 and into the balloons 52. After insertion of the apparatus into the organ and following retraction of the sheath 32, the balloons 52 would be inflated by introduction of an inflation medium such as air into the balloons via a port similar to port 38 using an apparatus similar to the suction/insufflation apparatus 40.

Ex. 1008 at 19:5-12 (emphasis added). Dr. Pearce testifies that this is the ***only*** discussion of inflation-based expansion in the detailed description of the invention.

Ex. 1002 ¶ 51. The only figure in the '506 application depicting any form of inflation-based expansion is corresponding Figure 20 (shown here), which depicts the balloons 52 discussed in the quoted excerpt above. *Id.* Figure 20 lacks the spring members seen in other figures, such as Figures 7 and 11. *Id.* A person of skill in the art would therefore have understood that the '506 application expressly discloses mechanical expansion and inflation as ***alternative*** means to expand the applicator head and provide structural integrity to allow the applicator head to contact the uterine lining. *Id.*

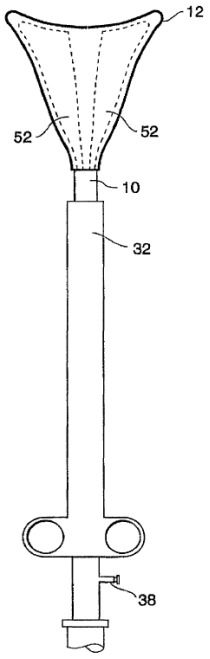

FIG. 20

C. The '506 application does not provide written description support for a device containing both mechanical and inflation expansion means

Beyond the fact that the '506 application refers to mechanical expansion and inflation-based expansion only as alternative means of expanding the applicator head, nothing else in the specifications of the '989 patent, the application as originally filed, or any of the priority documents supports the methods now claimed in the '989 patent. Ex. 1002 ¶ 52. As discussed in Dr. Pearce's declaration and below, nothing in the '506 application describes or depicts a device utilizing both mechanical and inflation-based expansion, nor does the '506 application provide any disclosure guiding a person of skill in the art to combine its discrete mechanical and inflation expansion embodiments into a single device, or a corresponding method of use. Ex. 1002 ¶¶ 52-95; *see also* Ex. 1014 ¶¶ 13-21

For example, the Background of the Invention describes a pair of prior art patents that utilize expandable thermal outer balloon designs—as distinct from the interior balloons of the invention. Ex. 1008 at 2:3-13; Ex. 1002 ¶ 56; Ex. 1014 ¶ 23. The background section goes on to explain the drawbacks of these outer balloon designs, including an inability to draw moisture away from the interface between the RF applicator head and the uterine tissues, which led to poorly controllable heating, poor treatment outcomes, and unintended burning of tissue. Ex. 1008 at 2:14-3:27; Ex. 1002 ¶ 57; Ex. 1014 ¶ 23. When discussing these drawbacks, the background section specifically refers to the prior art devices employing an inflation means to expand an applicator head mentioned in the preceding paragraph, or more generally refers to RF ablation techniques without reference to a particular mode of expansion. Ex. 1008 at 2:14-3:26; Ex. 1002 ¶ 57. These paragraphs do not describe mechanical expansion of an applicator head. *Id*. Finally, the background section explains that the invention of the '506 application is intended to offer a solution "eliminat[ing] the above-described problem of steam and liquid buildup at the ablation site." Ex. 1008 at 4:1-6. As Dr. Pearce explains, nothing in the background section describes an ablation device utilizing a combined mechanical and inflation expansion design. Ex. 1002 ¶ 58.

The Summary of the Invention likewise focuses on the key inventive feature of moisture removal via a permeable outer electrode array, and fails to describe a device employing a combination of mechanical expansion and inflation of an applicator head. Ex. 1008 at 4:11-13 ("The electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having

insulating regions and conductive regions thereon."); *see also* Ex. 1002 ¶ 59; Ex. 1014 ¶ 25.

Turning to the detailed description, neither the first exemplary embodiment nor the second exemplary embodiment disclose a device utilizing a combination of mechanical expansion and inflation expansion. With respect to the first exemplary embodiment, the specification describes the device at a high level as comprising "three major components: RF applicator head 2, main body 4, and handle 6." Ex. 1008 at 9:20-22. The initial paragraphs describing this embodiment are directed to aspects other than the expansion of its applicator head, such as the configuration of the external electrodes that deliver RF energy for the ablation treatment. Ex. 1008 at 10:15-16:2; Ex. 1002 ¶ 60.

The specification's description of the expansion of the applicator head begins with reference to Figures 6 and 7. Ex. 1008 at 16:2-17:16; Ex. 1002 ¶ 61. Specifically, the specification describes the actuation of the handle, which "causes the shaft 10 to pull proximally on the passive spring member 15." Ex. 1008 at 16:23-17:16. This proximal movement "pulls against the active spring member 19, causing it to move to the opened condition shown in FIG. 7." *Id*. The next paragraph further describes expansion of the spring members by actuation of the handle. Ex. 1008 at 17:17-20. These paragraphs only describe mechanical expansion of the applicator head, and do not mention or otherwise suggest inflation expansion of the applicator head. Ex. 1002 ¶¶ 61-62.

The next paragraph describes the operation of the suction/insufflation tube. Ex. 1008 at 17:21-18:9; Ex. 1002 ¶ 63. The specification recites that "[t]he

proximal end of the suction/insufflation tube 17 is fluidly coupled to the flow pathway so that gas fluid may be introduced into, or withdrawn from the suction/insufflation tube 17 via the suction/insufflation port 38." *Id*. The specification states that "suction/insufflation unit 40 . . . causes water vapor within the uterine cavity to pass through the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40 via the port 38." *Id*. The specification also explains that "insufflation gas, such as carbon dioxide" can be introduced into the uterus through the "suction/insufflation tube 17 via the port 38." *Id*. The introduced gas "travels through the tube 17, through holes 17a, and into the uterine cavity through the ***permeable*** electrode carrying member 12." *Id* (emphasis added). Dr. Pearce explains that a person of skill in the art would understand that the introduction of gas by the insufflation unit would serve to insufflate the uterus, and not to expand the applicator head as recited in the claim. Ex. 1002 ¶ 63. Furthermore, the described permeability of electrode carrying member 12 would prevent inflation of that component. *Id*. Therefore, this portion of the specification does not provide guidance to construct a device containing both mechanical expansion and inflation means to expand the applicator head. *Id*.

Subsequent paragraphs of the specification describe use of additional components may be provided for endoscopic visualization purposes (Ex. 1008 at 18:10-19) and the need for structural integrity to hold the electrode carrying means "in contact with the interior surface of the organ to be ablated" (*Id*. at 18:20-25). No specific disclosure of particular components providing the structural integrity is

discussed in these paragraphs, and this portion of the specification does not mention or otherwise suggest using a combination of mechanical expansion means and inflation means to provide structural integrity. *Id.*; *see also* Ex. 1002 ¶¶ 64-65.

The '506 application then goes on to describe an alternative to spring members 15 and 19, disclosing the use of mechanical spring members 15a and 19a to expand the electrode carrying means. Ex. 1008 at 18:26-19:4; Ex. 1002 ¶ 66. As Dr. Pearce explains, and as discussed above in Section VI.B., a primary difference between spring members 15 and 19 versus spring member 15a and 19a is their direction of bias. Ex. 1002 ¶¶ 50, 66. Spring members 15 and 19 have a resting state in the collapsed configuration, whereby the RF applicator head is not expanded unless a pulling force is applied, whereas spring members 15a and 19a have a resting state in the open configuration whereby the spring members will naturally open to the expanded configuration once freed from sheath 32. Ex. 1008 at 17:8-16; 18:26-19:4; Ex. 1002 ¶ 66. While the disclosure of spring members 15a and 19a does provide an additional ***mechanical*** means of expanding the applicator head, the discussion is purely directed to mechanical expansion and does not mention or otherwise suggest inflation expansion of the applicator head. Ex. 1002 ¶ 66.

The specification then turns to its only discussion of the use of inflation-based expansion in the context of the described invention. The next paragraph describes the use of "a pair of inflatable balloons" as an alternative to the mechanical expansion described in the previous paragraphs. Ex. 1008 at 19:5-12; Ex. 1002 ¶ 67. As previously stated, a person of skill in the art would have

understood that the '506 application teaches mechanical expansion and inflation as ***alternative*** means to expand the applicator head and/or provide structural integrity to allow the applicator head to contact the uterine lining. Ex. 1002 ¶¶ 46-51; *see also* Section VI.B., *supra*. As such, this paragraph fails to provide guidance on the construction of a device with both mechanical means and inflation means. Ex. 1002 ¶ 67.

The next paragraph states that structural integrity can be added through suction of the uterus via the suction/insufflation tube 17, which "would draw the organ tissue towards the electrode carrying means 12 and thus in better contact with the electrodes 14." Ex. 1008 at 19:13-18; *see also* Ex. 1014 ¶ 31. Dr. Pearce testifies that this paragraph only describes the use of the suction/insufflation source as a means to contract the uterus towards the electrode carrying means and, therefore, does not describe mechanical expansion or inflation expansion of the electrode carrying means. Ex. 1002 ¶ 68.

The next instance that either mechanical expansion or inflation is described is in regard to the use of carbon dioxide to expand the uterus in order to observe the internal cavities using a fiberoptic cable, i.e., the insufflation function mentioned earlier in the specification. Ex. 1008 at 20:16-21:2; *see also* Ex. 1002 ¶ 69; Ex. 1014 ¶ 30. This paragraph only describes inflation as a means to ***inflate the uterus***, and does not described mechanical expansion or inflation expansion of the applicator head. Ex. 1002 ¶ 69.

The next paragraph describes the two-stage mechanical expansion of the electrode carrying member through actuation of the handle using the device as

configured in first exemplary embodiment Fig. 10, which is similar to the device depicted in Figure 7. Ex. 1002 ¶ 70; *see also* Ex. 1008 Figs. 7, 10. The '506 application states that after insertion of the device into the uterus, "the handle 34 is withdrawn until it abuts the collar 13," at which point "the electrode carrying member 12 is not yet fully expanded (see FIG. 9), because the spring members 15, 19 have not yet been moved to their open condition." Ex. 1008 at 21:3-11. Following that, "handle 34 is withdrawn further" pulling shaft 10 and "causing the passive spring members 15 to pull the active spring members 19, causing them to open into the opened condition shown in FIG. 10." *Id*. Dr. Pearce explains that this paragraph is directed solely to mechanical expansion of the applicator head and provides no description of guidance with respect to of the applicator head. Ex. 1002 ¶ 70.

The '506 application goes on to describe mechanical expansion components in relation to termination of the ablation procedure. Ex. 1008 at 25:7-20; Ex. 1002 ¶ 71. Here, the '506 application describes insufflation of the uterus with carbon dioxide at a pressure of 20-200 mmHG "to lift the ablated tissue away from the RF applicator head 2 and to thus ease the closing of the RF applicator head." Ex. 1008 at 25:7-20. The paragraph then describes the mechanical contraction of the applicator head through folding of the spring members. *Id*.; Ex. 1002 ¶ 71. This paragraph therefore only describes the use of insufflation of the uterus, and does not describe the inflation expansion of the applicator head in combination with mechanical expansion. Ex. 1002 ¶ 71.

The ’506 application then shifts to a discussion of the “second exemplary embodiment.” Ex. 1008 at 25:22-26:3. The specification explains that “[t]he second embodiment differs from the first exemplary embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array.” *Id*. at 25:24-26. Dr. Pearce explains that the most significant difference between the deployment mechanisms is that whereas the first exemplary embodiment uses a syringe-style handle that slides in on the same axis as shaft 10, the second exemplary embodiment uses a handle with two grips pivotally attached to each other. Ex. 1002 ¶ 72; *See also, e.g.,* Ex. 1008 at 16:14-17:11, 36:7-20, Figs. 6, 7, 21, 22.

The ’506 application goes on to state that “aspects of the first and second exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention.” Ex. 1008 at 25:26-26:3. As Dr. Pearce testifies, a person of skill in the art would understand this to primarily refer to the components identified in the preceding sentence of the specification. Ex. 1002 ¶ 72. For example, a person of skill in the art would have understood this sentence to refer to the handle styles disclosed in the two exemplary embodiments (sliding syringe-style versus pivot grip) as being interchangeable with each other. *Id*. A person of skill in the art would have understood that the sentence regarding combinability does not suggest combinability of the mechanical expansion means ***and*** the mutually exclusive inflation means of the ablation applicator head. *Id*. Moreover, discussed in more detail in Section VI.D. below, this statement is insufficient to overcome the understanding of a person of skill in the art that the

mechanical and inflation components described in the ’989 patent could not be combined due to numerous technical barriers. *Id*.

Dr. Pearce analyzes the subsequent paragraphs describing the second exemplary embodiment and explains that none of them discuss or disclose the use of inflation for expanding the applicator head. Ex. 1002 ¶¶ 73-76. Specifically, the paragraph at 26:4-11 of the ’506 application only provides a general overview of a device according to the second exemplary embodiment. *Id*. at ¶ 73. The following paragraph, at 26:12-18, describes a mechanical deflecting mechanism as depicted in Fig. 23 and does not mention inflation expansion of the applicator head. *Id*. at ¶ 74. The next six paragraphs, spanning 26:19-28:6 of the ’506 application, describe the material composition of the applicator head as a stretchable metallized fabric mesh rather than expansion of the applicator head. *Id*. at ¶ 75. The three paragraphs after that, at 28:7-27, describe the arrangement of the electrode array on the electrode carrying means and likewise do not describe either mechanical or inflation expansion. *Id*. at ¶ 76.

The next section of the specification shifts to a discussion of the flexure system. Dr. Pearce explains that while the first paragraph of this section spanning 29:1-10 describes the deflecting mechanism depicted in Fig. 23, the paragraph fails to mention or otherwise suggest inflation expansion of the applicator head. *Id*. at ¶ 77. The four paragraphs that follow discuss the flexures in terms of their conductivity, as well as the importance of proper alignment between the conductive regions of the flexures with the electrodes, but do not describe either mechanical expansion or inflation expansion of the applicator head. *Id*. at ¶ 78.

The paragraph spanning 30:18-31:2 discusses the connectivity and composition of the internal flexures. As Dr. Pearce explains, the internal flexures described in the paragraph are used for mechanical expansion of the applicator head, and therefore the paragraph does not describe inflation expansion of the applicator head. *Id*. at ¶ 79. The following paragraph discloses that "the distal tips of the flexures 124 are sufficiently flexible to prevent tissue puncture during deployment and/or use," and does not mention or otherwise suggest inflation expansion of the applicator head. Ex. 1008 at 31:3-12; Ex. 1002 ¶ 80. The paragraph spanning 31:13-21 describes Fig. 30, which depicts alternative arrangements of the mechanical flexures that "adapt to the contour of the surface against which they are positioned." As Dr. Pearce points out, this paragraph only describes mechanical components to expand the applicator head, and fails to mention or otherwise suggest inflation components to expand the applicator head. Ex. 1002 ¶ 81. The next paragraph discusses the deployment of the mechanical deflecting mechanism by squeezing the distal and proximal grips "towards one another to withdraw the sheath and deploy the applicator head" and does not describe or otherwise suggest inflation expansion of the applicator head. Ex. 1008 at 31:2-32:2; Ex. 1002 ¶ 82.

The next two sections of the '506 application describe other aspects of the ablation device. The section spanning 32:5-33:15 describes the addition of components to measure the dimensions of the uterus, while the section spanning 33:16-36:5 describes manipulation of the arrangement and spacing of the electrodes to control the ablation depth. Ex. 1008 at 32:5-36:5. As Dr. Pearce

testifies, neither section describes or otherwise suggests inflation expansion of the applicator head. Ex. 1002 ¶¶ 83-84.

The next section spanning 36:6-40:27 shifts the focus to the pivot grip handle. As Dr. Pearce explains, this section teaches actuation of the handle to expand of the applicator head, but only in the context of mechanical expansion. *Id*. ¶ 85.

Dr. Pearce analyzes the next section of the '506 specification spanning 41:1-42:21, which describes the operation of the secondary exemplary embodiment. *Id*. ¶¶ 86-93. The first paragraph in this section describes the use of a sliding collar in order to control the degree of mechanical expansion of spring member 90, and does not describe or otherwise suggest inflation expansion of the applicator head. *Id*. ¶ 87; Ex. 1008 at 41:1-10. The paragraph that follows describes actuation of grips 142 and 144, and doesn't describe either mechanical expansion or inflation expansion of the applicator head. Ex. 1002 ¶ 88; Ex. 1008 41:11-17. The next paragraph only recites expansion of the applicator head through deployment of the mechanical deflecting mechanism following actuation of the handle, which does not encompass inflation expansion of the applicator head. Ex. 1002 ¶ 89; Ex. 1008 at 41:18-23. The paragraph that follows describes the use of a vacuum source to help "draw uterine tissue into contact with the array 102," but fails to describe or otherwise suggest either mechanical expansion or inflation expansion of the applicator head. Ex. 1002 ¶ 90; Ex. 1008 at 41:24-26. The next paragraph again describes the use of the vacuum source to "draw moisture from the uterine cavity into the hypotube 122." Ex. 1008 at 42:1-8. While this paragraph describes the

flexure system integral to the mechanical expansion aspect of the invention, it is only in the context of drawing moisture away from the uterine issue through apertures in the flexures, and thus neither mechanical expansion nor inflation expansion of the applicator head is mentioned. Ex. 1002 ¶ 91. The next two paragraphs of this section describe the termination of the ablation, followed by mechanical retraction of the applicator head. Ex. 1008 at 42:9-21. As Dr. Pearce explains, neither paragraph discloses or otherwise suggests inflation expansion of the applicator head. Ex. 1002 ¶¶92-93.

In sum, Dr. Pearce testifies that the '506 application fails to teach an ablation device containing both mechanical and inflation-based expansion means. *Id*. at ¶ 94. While individual sections of the specification may disclose either mechanical expansion means or inflation means, they are disclosed either as alternatives or would be inconsistent with the operation of the device as described. *Id*. Therefore, Dr. Pearce testifies that the '506 application fails to provide written description for a device employing a combination of mechanical expansion and inflation of an applicator head. *Id*. ¶ 95.

D. The mechanical and inflation expansion means described in the '506 application would have been incompatible

Beyond the fact that the '506 application fails to provide any guidance for the construction of a device containing both mechanical expansion means and inflation means, Dr. Pearce explains that the two expansion means are incompatible with each other. *Id*. at ¶¶ 96-112; *see also* Ex. 1014 ¶ 19. As such, Dr. Pearce explains that attempting to combine the two expansion means would

result in a device that is inoperable for the purpose of performing endometrial ablation as described in the '506 application. Ex. 1002 ¶ 96.

1. The '506 application does not support inflating the claimed tissue contacting surface itself

Claim 1 of the '989 patent requires "actuating an inflation source to further expand the energy applicator in the uterus." As Dr. Pearce explains, if the claim limitation is read in isolation, one possible interpretation of this claim limitation is that the entire energy applicator is inflated by the inflation source. *Id*. at ¶ 97. Dr. Pearce further explains such a configuration, in which the outer surface of the expandable head forms an inflatable balloon, would be directly contrary to what is described as the invention in the '506 application. *Id*. The '506 application disparages prior art RF ablation devices, particularly those using outer balloon expansion, as being incapable of sufficiently removing liquid and moisture from the ablation site. *See* Ex. 1008 at 3:13-4:6. As a solution, the '506 application proposes a permeable membrane applicator head construction of the device so as to allow fluid and gas to easily pass through the permeable membrane for moisture removal (e.g., suction removal). *Id*; *see also id*. at Abstract, 4:8-18. Dr. Pearce testifies that such a permeable membrane construction is incapable of balloon-like expansion. Ex. 1002 ¶ 97.

As Dr. Pearce explains, permeability of the membrane is described as a critical feature of the alleged invention throughout the specification. Ex. 1002 ¶¶ 98-99. The '506 specification repeatedly characterizes the applicator head as permeable to allow moisture to leave the ablation site. For example, the abstract of

the ’506 application states that “[s]uction may be applied to facilitate moisture removal” and that the “moisture permeability and/or absorbancy of the electrode carrying member allows the moisture to leave the ablation site.” Ex. 1008 at 45:2-17. The Summary of the Invention further describes that “[t]he electrode array includes a fluid permeable elastic member preferably formed of a metallized fabric having insulated regions and conductive regions therein” and that “moisture generated during dehydration is actively or passively drawn into the array and away from the tissue.” Ex. 1008 at 4:11-18.

The first and second exemplary embodiments are consistent with this characterization of permeability of the electrode carrying member as a key aspect of the invention. Ex. 1002 ¶ 100. For example, the description of the first exemplary embodiment describes permeable materials that the applicator head can be comprised therefrom such as an “open cell sponge, foam, cotton, fabric, or cotton-like material… [or] metallized fabric.” Ex. 1008 at 12:3-11. Dr. Pearce explains that none of these materials would be suitable for making the electrode-carrying means an inflatable balloon. Ex. 1002 ¶ 100.

The description spanning 17:21-18:5 further defines the need for a permeable applicator head through the use of a “suction/insufflation tube 17.” For example, the application of suction through the suction/insufflation tube “causes water vapor within the uterine cavity to pass through the permeable electrode carrying means 12, into the suction/insufflation tube 17 via holes 17a, through the tube 17, and through the suction/insufflation unit 40.” Ex. 1008 at 17:21-18:5; Ex. 1002 ¶ 101. The specification also provides an example of utilizing the

suction/insufflation tube to introduce gas "into the uterine cavity through the permeable electrode carrying member 12" in order to insufflate the uterine wall. *Id*.

Figure 6 of the '506 application (shown here as annotated by Dr. Pearce) illustrates the introduction of carbon dioxide gas from the distal end of the ablation device into the uterus:

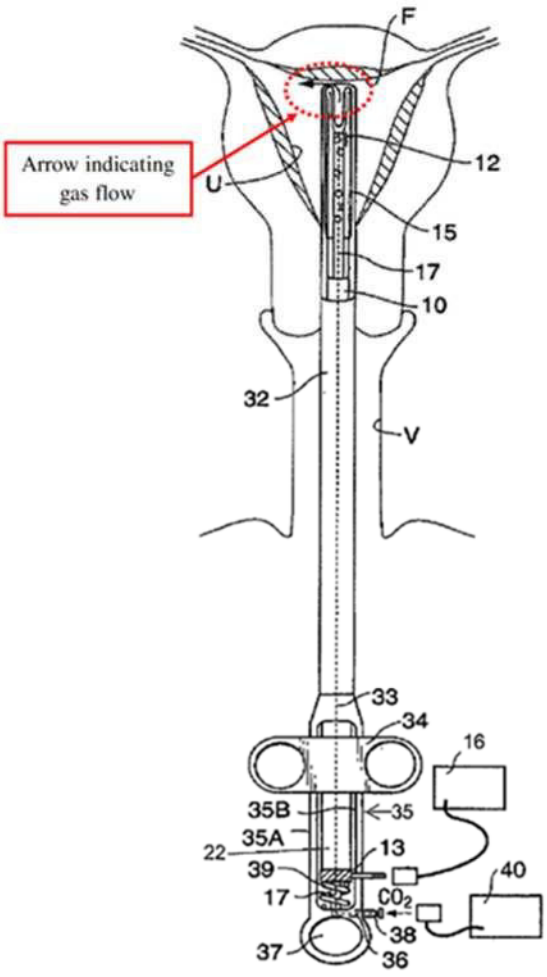

FIG. 6

Ex. 1002 ¶ 102; Ex. 1008 Fig. 6.

The specification describes the process of insufflation using carbon dioxide, in which "carbon dioxide gas is introduced into the tube 17 via the port 38, and it

enters the uterine cavity, thereby expanding the uterine cavity from a flat triangular shape to a 1-2 cm high triangular cavity." Ex. 1008 at 20:16-22. As Dr. Pearce explains, the figure depicts the applicator head in the collapsed configuration during insufflation of carbon dioxide gas, with the insufflation having no expansion effect on the applicator head due to the permeability of the material used to form the electrode carrying means. Ex. 1002 ¶ 102. Furthermore, if the electrode carrying means were formed of a non-permeable material suitable for inflation, the device would be unable to introduce carbon dioxide gas into the uterus as described in Figure 6. *Id*.

The specification outlines several operations that would be incompatible with incorporation of a balloon as the outer surface of the applicator head into the first exemplary embodiment. *Id*. at ¶ 103. Among the examples disclosed are suction/insufflation to distend the uterus to allow visual observation (Ex. 1008 at 20:16-24), to wet the electrodes to allow better electrical contact with the endometrium (Ex. 1008 at 22:3-6), to collapse the uterine cavity onto the RF applicator head (Ex. 1008 at 22:6-11), and to introduce saline solution into the uterus for aiding separation of the electrodes from the tissue surface (Ex. 1008 at 25:7-10). Ex. 1002 ¶ 103.

Dr. Pearce explains that the second exemplary embodiment also requires a permeable RF applicator head. Ex. 1002 ¶ 104. The specification describes the composition of the applicator head as utilizing "a stretchable metallized fabric mesh which is preferably knitted from a nylon and spandex knit plated with gold or other conductive material." Ex. 1008 at 26:19-22. As Dr. Pearce explains, a mesh

material such as this would allow suction to be applied through the mesh to draw the uterine walls into contact with the applicator head. Ex. 1002 ¶ 104. The specification describes that moisture can result from heating of the tissue by the RF energy, which causes "moisture to be released from the tissue." Ex. 1008 at 42:2-5. The specification further describes the use of suction in the secondary embodiment to remove said moisture:

> Vacuum source 252 (FIG. 21) is activated, causing application of suction to hypotube 122 via suction port 210. Suction helps to draw uterine tissue into contact with the array 102.

Ex. 1008 at 41:24-26.

In sum, the '506 application teaches the inclusion of an applicator head with a permeable outer surface in order to perform a number of key functionalities described in the '506 application. Dr. Pearce testifies that the invention described in the '506 application could not have included a balloon-like inflatable RF applicator head because it would have hindered the ability of the device to perform such functions because a balloon-like RF applicator head must retain fluid to enable inflation, thereby contradicting the use of a permeable applicator head Ex. 1002 ¶ 105.

2. The '506 application does not support combining its mechanical and inflation-based expansion embodiments

In addition to failing to disclose an embodiment containing both mechanical expansion means and inflation means, the '506 application also fails to provide guidance on the manner in which the two components can be combined. As Dr. Pearce testifies, there is nothing in the specification that discloses or suggests

combining together the mechanical expansion means and the alternative inflation expansion means into a single device or method, and the inflation expansion design depicted in Figure 20 could not have been combined with the mechanical expansion designs described in the remainder of the '506 application (e.g. Fig. 10, Fig. 11). *Id*. at ¶¶ 106-112.

Focusing his analysis on the devices depicted in Figures 10, 11 and 20, Dr. Pearce explains that combining the device of Figure 20 with any one of the devices depicted in Figures 10 or 11 would have been impractical, if not impossible, because the spring members 15 and 19 depicted in Figures 10 and 11 and the balloons 52 depicted in Figure 20 occupy the same physical space within the RF applicator head. *Id*. at ¶ 107. The '506 specification provides no guidance on how the two components could be arranged in three dimensional space within the applicator head in order to retain their respective operations without interfering with or preventing the operation of each respective component. *Id*.

Furthermore, Dr. Pearce outlines a number of technical issues that such a device employing both mechanical expansion components and inflation components would have. *Id*. at ¶ 108. For example, if the pair of balloons depicted in Figure 20 were added to the mechanical expansion designs outlined in Figures 10 or 11 in a stacked configuration in which the balloon pair were placed on top of the spring members so that the stack extended out of the page on the z-axis, the device would be inoperable for the applications outlined in the '506 application. *Id*.

Dr. Pearce explains that if the pair of balloons 52 in Figure 20 were directly superimposed onto flexures 15 and 19 in Figure 10 or 15a and 19a in Figure 11, it is not clear that inflation of the pair of balloons would function to expand the energy applicator at all due to the presence of the flexures. *Id*. at ¶ 109. Even if there is in fact an expansion force applied to the flexures by the balloons, this force could serve to push the potentially sharp edges of the flexures laterally and into the uterine wall, which could lead to damage to the flexures; or discomfort or injury to the subject. *Id*. It is also possible that the expansion force applied to the flexure by the balloon pair could result in rupture of the balloons due to the sharp edges of the flexures being pressed into the balloons. *Id*. Such a rupture could lead to leakage of the inflation medium into the uterine cavity and produce an inoperable device. *Id*.; *see also* Ex. 1014 ¶ 19.

Likewise, inclusion of the inflatable balloon pair would create extra space to account for when the device is in its contracted state, and Dr. Pearce explains that it is unclear how the balloon pair would allow for folding of the applicator head into the introducer sheath in the contracted state outlined in Figure 8. Ex. 1002 ¶ 110. Dr. Pearce testifies that the balloon pair would prevent full contraction of the applicator head due to the additional space required for the balloon pair. *Id*.; *see also* Ex. 1014 ¶ 19.

As discussed above in Section VI.D.1., the ability of the device to perform suction/insufflation through a permeable applicator head is a key feature emphasized in the ’506 application. However, Dr. Pearce explains that the inclusion of impermeable balloons would be impractical because it would block

the suction/insufflation tube 17 from the uterus. Ex. 1002 ¶ 111. The presence of the balloons would prevent suction of the uterus, and would instead pull the balloons into contact with the tube. *Id*. As the ability to remove moisture from the uterus using the suction/insufflation tube is described as a key differentiator over the prior art (see e.g. Ex. 1008 at 2:20-4:6), this arrangement would prevent the proposed usage of the device described in the '506 application.

In sum, Dr. Pearce explains that the combination of the balloon pair of Figure 20 with the mechanical spring member or flexure designs described in the '989 patent, as exemplified by Figures 10 and 11, would produce an inoperable device unable to perform endometrial ablation in the manner recited in the claims due to the significant number of technical obstacles presented therein. Ex. 1002 ¶ 112. At minimum, a person of skill in the art would not understand the full scope of the invention to encompass such a combination, due to the numerous technical obstacles to combining those elements and the failure of the '989 patent to address them. *Id*.

E. The earlier applications in the priority chain similarly to not support combined mechanical and inflation expansion means

As stated above, the '957 application claims priority to a chain of applications directed to similar ablation devices as described in the '957 application. A complete list of each application is recited below:

- U.S. Application No. 14/278,741, filed on May 15, 2014 ("the '741 application," Ex. 1009);

- U.S. Application No. 13/962,178, filed on August 8, 2013 ("the '178 application," Ex. 1010);
- U.S. Application No. 12/581,506, filed on October 19, 2009 ("the '506 application," Ex. 1008);
- U.S. Application No. 10/959,771, filed on October 6, 2004 ("the '771 application," Ex. 1011);
- U.S. Application No. 09/103,072, filed on June 23, 1998 ("the '072 application," Ex. 1012); and
- Provisional Application No. 60/084,791, filed on May 8, 1998 ("the '791 provisional application," Ex. 1013).

As described above with respect to Section VI.C., the '506 application fails to provide support or guidance for a device for endometrial ablation containing both mechanical expansion means and inflation means to expand an applicator head. A detailed analysis of each additional application will follow below.

1. U.S. Application No. 14/278,741

The specification and drawings of the '741 application are substantially the same as both the '907 application and '506 application. Ex. 1009; Ex. 1002 ¶ 122. Therefore, Dr. Pearce explains that the specification and drawings of the '741 application provide no written description for the device containing both a mechanical expansion and inflation means for the reasons described for the '907 and '506 applications. *Id*.

Independent claim 1 of the '741 application is reproduced below:

A method of ablating walls of a uterus using an ablation device, the ablation device comprising a tubular member coupled to a working end, the working end comprising a first electrode and a second electrode, the method comprising:

positioning the first electrode within the uterus;

delivering ablation energy through the first and second electrodes to the walls of the uterus, wherein the delivering step causes moisture to be released from the walls; and

removing the released moisture through a continuously open flow path through the tubular member during the delivering step.

Ex. 1009 at 31:2-11. Dr. Pearce explains that claim 1 does not recite a mechanical expansion means or an inflation means, or even expansion itself. Ex. 1002 ¶ 123.

Independent claim 12 of the '741 application is reproduced below:

12. A method of ablating walls of a uterus using an ablation device, the ablation device comprising a tubular member coupled to a working end, the working end comprising a first electrode and a second electrode, the method comprising:

positioning the first electrode within the uterus;

delivering ablation energy through the first and second electrodes to the walls, wherein the delivering step causes moisture to be released from the walls; and

removing the released moisture away from the walls and through an opening in the tubular member proximal to at least a portion of the first electrode.

Ex. 1009 at 32:6-15. Dr. Pearce testifies that claim 12 does not recite a mechanical expansion means or an inflation means, or even expansion itself. Ex. 1002 ¶ 124.

Independent claim 16 of the '741 application is reproduced below:

> 16. A method of ablating walls of a uterus using an ablation device, the ablation device comprising a tubular member coupled to a working end, the working end comprising a first electrode and a second electrode, the method comprising:
>
> positioning the first electrode in the uterus;
>
> delivering ablation energy through the first and second electrodes to the walls while continuing to apply suction through the tubular member, wherein the delivering step causes moisture to be released from the walls; and
>
> removing the released moisture from an interior of the uterus during the delivering step to carry the released moisture away from the walls and through the tubular member.

Ex. 1009 at 32:21-33:3. Dr. Pearce testifies that claim 16 does not recite a mechanical expansion means or an inflation means, or even expansion itself. Ex. 1002 ¶ 125.

Dr Pearce further opines that each of the claims that depend from claims 1, 12 or 16 of the '741 application provide no teaching or guidance for the ablation device containing both mechanical expansion means and inflation means. *Id.* at ¶ 126. In particular, Dr. Pearce explains that while claims 9 and 13 recite "expanding the working end of the ablation device" and claims 11 and 15 further recite "[t]he method of claim [9/12] wherein the working end includes a balloon," these claims do not disclose a combined mechanical and inflation-based expansion as recited in the '989 patent claims. *Id.* Dr. Pearce therefore opines that the '741 application as a whole does not provide guidance for the ablation device containing both mechanical expansion means and inflation means. *Id.*

2. U.S. Application No. 14/962,178

The specification and drawings of the ’178 application are substantially the same as both the ’907 application and ’506 application. Ex. 1010; Ex. 1002 ¶ 127. Therefore, Dr. Pearce explains that that the specification and drawings of the ’178 application provide no written description for the device containing both a mechanical expansion and inflation means for the reasons described above for the ’907 and ’506 applications. Ex. 1002 ¶ 127.

Independent claim 8 of the ’178 application is the first claim of that application and is reproduced below:

> A device for treating a uterus comprising:
>
> an elongate member having a proximal end and a distal end, the elongate member including a translatable sleeve;
>
> an applicator head coupled to the distal end, 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;
>
> a deflecting mechanism including flexures disposed within the applicator head and a translatable sleeve operably coupled to the flexures, wherein the deflecting mechanism is configured so that translating the translatable sleeve causes the applicator head to transition from the contracted state to the expanded state; and
>
> an indicator mechanism operably coupled to the translatable sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

Ex. 1010, claim 8. Therefore, Dr. Pearce explains that claim 8 recites a device containing mechanical expansion means only, and does not describe inflation means. Ex. 1002 ¶ 128.

Independent claim 15 of the '178 application is reproduced below:

> A device for treating a uterus comprising:
>
> an elongate member having a proximal end and a distal end;
>
> an applicator head coupled to the distal end of the elongate member, the applicator head defined by deformable walls having an expanded state and a contracted state, the expanded state being configured to conform to the shape of the uterus and the contracted state being configured for transcervical insertion;
>
> a deflecting mechanism disposed within the applicator head and configured expand the applicator head from the contracted state to the expanded state; and
>
> an indicator mechanism operably coupled to the deflecting mechansim[sic], the indicator mechanism configured to indicate a dimension of the uterus.

Ex. 1010, claim 15. Dr. Pearce testifies that claim 15 recites a device containing mechanical expansion means only, and does not describe inflation means. Ex. 1002 ¶ 129.

Dr Pearce further testifies that each of the claims that depend from claims 8 or 15 of the '178 application do not provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 130; Ex. 1010 cl. 9-14, 16-18. Therefore, Dr. Pearce opines that the '178 application as a whole does not provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 130.

3. U.S. Application No. 10/959,771

The specification and drawings of the ’771 application are substantially the same as both the ’907 application and ’506 application. Ex. 1011; Ex. 1002 ¶ 131. Therefore, Dr. Pearce explains that the specification and drawings of the ’771 application provide no written description for the device containing both a mechanical expansion and inflation means for the reasons described for the ’907 and ’506 applications. Ex. 1002 ¶ 131.

Independent claim 32 of the ’771 application is the first claim of that application and is reproduced below:

> A method of ablating walls of a hollow body organ, comprising the steps of:
>
> providing an ablation device comprising a tubular member and a mesh electrode array carried by the tubular member;
>
> positioning the array within a hollow body organ surrounded by walls;
>
> applying suction through the tubular member and the mesh array to pull interior surfaces of the walls into contact with the array; and
>
> delivering ablation energy through the array to the walls while continuing to apply suction through the tubular member.

Ex. 1011, claim 32. Dr. Pearce explains that claim 32 does not recite a mechanical expansion means or an inflation means, or even expansion itself. Ex. 1002 ¶ 132.

Claim 37, which depends from claim 32, recites expansion of the array “from a collapsed position to an expanded position”. Ex. 1011, claim 37. Dr. Pearce testifies that while claim 37 describes expansion of the array, it does not

specifically disclose use of either mechanical expansion or inflation expansion of the array. Ex. 1002 ¶ 133. Claim 38, which depends from claim 37, recites that the "expanding step includes causing the knit to stretch." Ex. 1011, claim 38. Dr. Pearce explains that claim 38 does not specifically disclose use of either mechanical expansion or inflation expansion of the array. Ex. 1002 ¶ 133.

Claim 42, which depends from claim 32, recites "the step of passing an insufflation gas through the tubular member to insufflate the body organ." Ex. 1011, cl. 42. Dr. Pearce testifies that claim 42 only describes passing insufflation gas for the purpose of insufflating the body organ, and does not disclose either mechanical expansion or inflation expansion of the array. Ex. 1002 ¶ 134. Claims 43 and 44, which depend from claim 42, describe the timing of performing the insufflation step. Ex. 1011, cl. 43, 44. Dr Pearce testifies that neither claim recites either mechanical expansion or inflation expansion of the array. Ex. 1002 ¶ 134.

Dr. Pearce further explains that the remaining dependent claims that depend from claim 32 of the '771 application do not provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 135; Ex. 1011 cl. 33-36, 39-41, 45-50. Therefore, Dr. Pearce opines that the '771 application as a whole does not provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 135.

4. U.S. Application No. 09/103,072

The specification and drawings of the '072 application are substantially the same as both the '907 application and '506 application. Ex. 1012; Ex. 1002 ¶ 136. Therefore, Dr. Pearce explains that the specification and drawings of the '072

application provide no written description for the device containing both a mechanical expansion and inflation means for the reasons described for the '907 and '506 applications. Ex. 1002 ¶ 136.

Independent claim 1 of the '072 application is reproduced below:

> A method or ablating and/or coagulating tissue, comprising the steps of:
>
> (a) providing an ablation device including an electrode array carried by an elongate tubular member, the electrode array including a fluid permeable elastic member having insulating regions and conductive regions thereon;
>
> (b) positioning the electrode array in contact with tissue to be ablated;
>
> (c) delivering RF energy through the array to the tissue to cause the tissue to dehydrate; and
>
> (d) permitting moisture generated during the dehydration of step (c) to pass into the electrode carrying member and away from the tissue.

Ex. 1012, cl. 1. Dr. Pearce explains that claim 1 does not recite a mechanical expansion means or an inflation means, or even expansion itself. Ex. 1002 ¶ 137.

Independent claim 16 of the '072 application is reproduced below:

> An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:
>
> an electrode array carried by an elongate member, the array including a fluid permeable elastic member having insulating and conductive regions thereon, the electrode array configured to permit moisture generated during ablation to pass actively and/or passively into the electrode array and away from underlying tissue;

a source of radio frequency energy electrically coupled to the conductive regions of the array.

Ex. 1012, cl. 16. Dr. Pearce testifies that claim 16 does not recite a mechanical expansion means or an inflation means, or even expansion itself. Ex. 1002 ¶ 138.

Independent claim 31 of the '072 application is reproduced below:

An ablation and/or coagulation apparatus for use in delivering energy to tissue for ablation, the apparatus comprising:

an elongate member;

a deployment mechanism carried by the elongate member, the deployment mechanism moveable between a retracted position and a plurality of laterally expanded positions;

an electrode array carried by the deployment mechanism;

a sheath slidably disposed over the electrode array;

a handle coupled to the sheath and deployment mechanism, the handle moveable between an insertion position in which the sheath is disposed over the electrode array and the array is in an unexpanded condition and a deployment position in which the electrode array extends from the distal end of the sheath and is in one of its expanded positions;

limiting means for selectively limiting lateral expansion of the deployment mechanism and for selectively limiting longitudinal extension of the array from the sheath; and

a source of radio frequency energy electrically coupled to the array.

Ex. 1012, cl. 31. Dr. Pearce testifies that while claim 31 describes a deployment mechanism, it does not disclose inflation expansion of the array. Ex. 1002 ¶ 139.

Claim 3, which depends from claim 1, recites that the electrode array is expandable, and includes the step of moving the array into an expanded condition.

Ex. 1012, cl. 3. Dr. Pearce explains that while claim 3 describes expansion of the array, it does not disclose inflation expansion of the array. Ex. 1002 ¶ 140. Claim 4, which depends from claim 3 and claim 1, recites that the "the step of moving the array to the expanded condition includes the step of expanding the flexures." Ex. 1012, cl. 4. Dr. Pearce testifies that claim 4 only discloses mechanical expansion, and does not disclose inflation expansion of the array. Ex. 1002 ¶ 140. Claim 10, which depends from claim 9 and claim 1, recites that "the array is carried by a pair of elongate flexures." Ex. 1012, cl. 10. Dr. Pearce explains that claim 10 only discloses use mechanical expansion, and does not disclose inflation expansion of the array. Ex. 1002 ¶ 140.

Claim 22, which depends from claim 16, recites that "the electrode array is carried by a deflecting mechanism movable between a retracted position and an expanded position. Ex. 1012, claim 22. Dr. Pearce testifies that while claim 22 describes expansion of the array, it does not disclose inflation expansion of the array. Ex. 1002 ¶ 141. Claim 23, which depends from claim 22 and claim 16, recites "the deflecting mechanism includes a pair of elongate flexures." Ex. 1012, claim 23. Dr. Pearce explains that claim 23 only discloses use mechanical expansion, and does not disclose inflation expansion of the array. Ex. 1002 ¶ 141.

Dr. Pearce further explains that the remaining dependent claims of the '072 application do not provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 142; Ex. 1012 cl. 2, 5-9, 11-15, 17-21, 24-30. Therefore, Dr. Pearce opines that the '072 application as

a whole does not provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 142.

5. Provisional Application No. 60/084,791

The specification and drawings of the '791 provisional application are substantially the same as both the '907 application and '506 application. Ex. 1013; Ex. 1002 ¶ 143. Dr. Pearce explains that because no claims were filed with the '791 provisional application, the application as a whole provide no written description for the device containing both a mechanical expansion and inflation means for the reasons described for the '907 and '506 applications. Ex. 1002 ¶ 143.

In sum, none of the applications to which the '989 patent claims priority provide guidance for the ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶ 144.

F. The sole named inventor confirms the invention did not encompass combined mechanical and inflation expansion means

Csaba Truckai is the sole inventor named on the '989 patent. Mr. Truckai co-founded Novacept, Inc. in 1993 and served as President until 2000.[3] Cytyc Corp. acquired Novacept, including its patents, in 2004. Cytyc was acquired by Hologic, Inc., the current assignee of the '989 patent, in 2007. Since then,

[3] Mr. Truckai has founded and served as an executive in a number of medical device companies over the past 20 years. Mr. Truckai is also the founder and current Director of Minerva Surgical, Inc.—petitioner in the present case. Ex. 1014 ¶ 1-3; Ex. 1017.

Hologic/Cytyc have filed a series of continuation applications claiming priority to Mr. Truckai's early patents/applications at Novacept. The '989 patent is one such continuation. Ex. 1014 ¶ 1-10.

Mr. Truckai testifies, however, that the '989 patent now claims an endometrial ablation method he did not invent at Novacept, and that is not described in the '989 patent, the '957 application as-filed, or any of the corresponding patents/applications to which the '989 patent claims priority benefit. Mr. Truckai explains that none of these Novacept patents/applications describe, or were ever meant to describe, an endometrial ablation device with an applicator head containing ***both*** a mechanical expansion means and an inflatable balloon expansion means as now reflected in the '989 patent claims. These expansion means were contemplated as mutually exclusive, alternate approaches—and were described in just such a manner in the '989 patent and priority applications. Ex. 1014 ¶ 11-17.

Mr. Truckai explains that, not only did he never invent the currently claimed subject matter at Novacept, but combining the spring-member expansion means and the balloon expansion means in the '989 patent would be "nonsensical." The different expansion means were never meant to be combined together, and the hypothetical combination would not lead to a properly functioning device, but would likely cause significant discomfort or injury to the patient. Ex. 1014 ¶ 18-20.

Additionally, Mr. Truckai explains he never described or even contemplated an inflation of the tissue contacting surface of an endometrial ablation device (e.g.,

where the carrying member 12 or tissue contacting surface itself acts as a balloon) as being included in any of the Novacept patent applications in the '989 patent priority chain. Instead, the '989 patent (like all the priority applications) describes a permeable membrane carrying an electrode arrangement, which is incapable of balloon inflation. Mr. Truckai testifies that removal of moisture through the permeable mesh electrode structure of the carrying member was viewed as critical to preventing formation of a low impedance liquid layer around the electrodes, and described as such in the Novacept patents/applications (including the '989 patent). Ex. 1014 ¶ 21-34.

Accordingly, Mr. Truckai's testimony corroborates that the neither the '989 patent or application as-filed, nor any of the applications to which priority is claimed, describe or were ever meant to describe the subject matter now claimed in the '989 patent.

VII. DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY

A. [Ground 1] Claims 1-19 are Unpatentable for Failure to Satisfy the Written Description Requirement

To satisfy the written description requirement under 35 U.S.C. § 112, the specification must sufficiently describe an invention understandable to a person of ordinary skill in the art and "show that the inventor actually invented the invention claimed." *ULF Bamberg v. Dalvey*, 815 F.3d 793, 797 (Fed. Cir. 2016) (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). In other words, "the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the

invention, and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.,* 541 F.3d 1115, 1122 (Fed. Cir. 2008) (internal quotations omitted).

As discussed above in Section VI.A., the plain language of the '989 patent claims requires a method of ablation utilizing an ablation device comprising both mechanical ***and*** inflation-based expansion means to expand the energy applicator inside the uterus. For example, claim 1 requires "actuating a handle . . . to cause the carrying member to expand the energy applicator in the uterus," there the handle includes "a proximal grip and a distal grip pivotally attached to one another at a pivot point," and results in "translating an inner sleeve" that is recited as coupled to "first and second inner flexures" that are components of an "expandable-contractible carrying member." Ex. 1001 cl. 1. Together, these elements of claim 1 form the requirement for a mechanical mode of expanding the energy applicator. Ex. 1002 ¶ 16. Additionally, claim 1 requires "actuating an inflation source to further expand the energy applicator in the uterus," demonstrating that the recited ablation device requires a means of inflating the energy applicatory in addition to mechanically expanding it. Ex. 1001 cl. 1; Ex. 1002 ¶ 16.

Independent claim 14 contains nearly identical requirements, including "actuating a handle" to "cause the expandable-contractible carrying member to develop an expansion force against the tissue carrying member," where the expandable-contractible carrying member includes "first and second inner flexures and first and second outer flexures." Ex. 1001 cl. 14. Like claim 1, claim 14 also

requires "actuating an inflation source to further expand the energy applicator in the uterus" and therefore requires both mechanical and inflation expansion. *Id*.; Ex. 1002 ¶ 113. Dependent claims 2-13 and 15-19 all depend from either claim 1 of 14 and thus also require mechanical and inflation expansion. Ex. 1002 ¶ 114.

As discussed above with respect to PGR eligibility and the effective filing date of the '989 patent, the specification of the patent (which is identical through the chain of applications except for the original claims filed with each) does not disclose or support an ablation device that contains both mechanical and inflation-based expansion components. Instead, the '989 patent only discloses mechanical expansion and inflation expansion as alternatives to each other, and a person of skill in the art would not have viewed those alternatives as disclosed in the '989 patent to be combinable. Ex. 1002 ¶¶ 46.

The '989 patent contains only two brief discussions of inflating an expandable ablation device. First, the background section describes a pair of prior art patents that employ an expandable bladder or balloon to contact the ablation surface with the uterine wall. Ex. 1001 at 1:39-50; *see also* Ex. 1004 at 2:11-19; Ex. 1002 ¶ 56. The background section discusses the drawbacks of these prior art devices—including steam build-up and an inability to control temperature during treatment—and explains that the invention described in the '989 patent improves on these prior devices to avoid the drawbacks. Ex. 1001 at 1:20-2:32; *see also* Ex. 1004 at 2:20-3:26, 3:21-25; Ex. 1002 ¶¶ 57-58.

Second, the first embodiment describes an ***alternative*** expansion means using "balloons 52" to expand the applicator head instead of mechanical "spring

members" or "flexures." Ex. 1001 at 8:66-9:7; *see also* Ex. 1004 at 14:9-15; Ex. 1002 ¶¶ 51, 67. These balloons are depicted in a single figure of the patent, Figure 20, which itself depicts no mechanical aspect inside the RF applicator head. *Id.*; *see also* Ex. 1001 Fig. 20. In fact, the Brief Description of Figure 20 goes so far as to note an aspect of that design (electrodes on the electrode carrying means) that has been omitted from the diagram "[f]or purposes of clarity," but makes no mention of mechanical components being similarly present although not drawn. Ex. 1001 at 3:43-4.

As Dr. Pearce testifies, neither of these two disclosures regarding inflation-based expansion, either in the prior art or as a possible configuration of the first exemplary embodiment, disclose using a combination of inflation and mechanical expansion to expand the energy applicator of an ablation device. Ex. 1002 ¶¶ 56, 67.

The remaining disclosure in the '989 patent is entirely directed to purely mechanical means of expanding the RF applicator head. For example, the first exemplary embodiment describes the use of spring members 15 and 19 (as depicted in, e.g., Figures 6, 7, and 10) to mechanically open the applicator head by pulling spring member into the open position using a sliding handle. Ex. 1001 at 7:42-8:20, Figs. 6, 7, 10; *see also* Ex. 1004 at 12:4-13:5; Ex. 1002 ¶¶ 61-62, 70. The first exemplary embodiment also describes a second spring member configuration in which spring members 15a and 19a are biased toward the open position such that they expand the applicator head upon withdrawal of sheath 32, unlike spring members 15 and 19 which require a pulling force from the handle to

open. Ex. 1001 at 8:60-65, Fig. 11; *see also* Ex. 1004 at 14:4-8; Ex. 1002 ¶ 66. Both spring member configurations—spring members 15 and 19 as seen in Figures 6, 7, and 10 and spring members 15a and 19a in Figure 11—employ solely mechanical means to expand the device, with no disclosure of combination with inflation means. Ex. 1002 ¶¶ 61, 62, 66, 70.

The second exemplary embodiment refers to "flexures" rather than "spring members" but the mechanical principle of operation is similar to the configuration of spring members 15 and 19 in, e.g., Figure 10. *See, e.g.,* Ex. 1001 at 14:26-36 ("distal and proximal grips 142, 144 forming handle 106 are squeezed towards one another to withdraw the sheath and deploy the applicator head . . . [and] relative motion between the hypotubes causes deflection in flexures 124, 136 which deploys and tensions the electrode array 102 a"), Fig,. 23; *see also* Ex. 1004 at 22:31-23:7; Ex. 1002 ¶ 82. The discussion of the second exemplary embodiment contains no discussion of utilizing inflation-based expansion, let alone any disclosure regarding combined mechanical and inflation expansion. Ex. 1002 ¶¶ 72-93.

In summary, nothing in the '989 patent discloses an ablation device utilizing both mechanical and inflation-based expansion means. Ex. 1002 ¶ 94. The first exemplary embodiment expressly discloses mechanical expansion and inflation-based expansion as alternatives. *Id*. The second exemplary embodiment discloses only mechanical expansion components. *Id*. While the background section discusses other ablation devices utilizing an expandable balloon as the exterior component of the expandable head, whereby the balloon itself comes into contact

with the uterus, no mechanical expansion aspect of those prior art devices is disclosed and such an exterior balloon configuration is inconsistent with the description of the invention. *Id*. As Dr. Pearce testifies, a person of skill in the art would not have understood the written description and figures of the '989 patent to describe a device employing a combination of mechanical expansion and inflation of an applicator head. *Id*. at ¶ 95.

Beyond the failure of the '989 to disclose an ablation device utilizing both mechanical and inflation-based expansion means, a person of skill in the art would have understood the separate mechanical and inflation expansion means that are disclosed to be incompatible with each other. Dr. Pearce testifies that combining the mechanical expansion components and inflation components described in the '989 patent into a single device as recited in the claim 1 would render the device inoperable, further demonstrating the lack of written description support for the claims. Ex. 1002 ¶ 96.

First, if the entire energy applicator were inflated by the inflation source, such that the applicator head itself served as a balloon similar to the prior art described in the background section, the device would sacrifice the applicator head permeability described as a key feature of the invention. *Id*. at ¶ 97; *see also* Ex. 1001 at 1:39-43; Ex. 1004 at 2:12-14. As discussed above (see Section VI.D.1) the '989 patent consistently describes the outer, tissue-contacting surface of its expandable RF applicator head as "permeable." *See, e.g.,* Ex. 1001 at Abstract, 2:35-47, 5:57-66; *see also* Ex. 1004 at 3:4-14, 3:28-4:4, 9:10-17; Ex. 1002 ¶ 97-100. The '989 patent explains that the reason for this permeability is to allow

suction and insufflation through the outer surface of the applicator head into the uterine cavity. *See, e.g.*, Ex. 1001 at 8:26-42; *see also* Ex. 1004 at 13:10-22; Ex. 1002 ¶¶ 99, 103. As discussed above, Dr. Pearce's annotated Figure 6 (shown here) demonstrates this flow of gas through the outer surface of the applicator head as an arrow indicating the flow of carbon dioxide gas into the uterus. Ex. 1002 ¶ 102. Dr. Pearce explains that if the electrode carrying means were instead formed of a non-permeable material suitable for inflation, the device would be unable to introduce carbon dioxide gas into the uterus as depicted in Figure 6. *Id.* The second exemplary embodiment similarly requires a permeable RF applicator head, describing a "fabric mesh" that works in conjunction with a vacuum source to apply suction. Ex. 1001 at 12:15-18, 18:44-53 ("Suction helps to draw uterine tissue into contact with the array 102."); *see also* Ex. 1004 at 19:18-19, 30:1-7; Ex. 1002 ¶ 104.

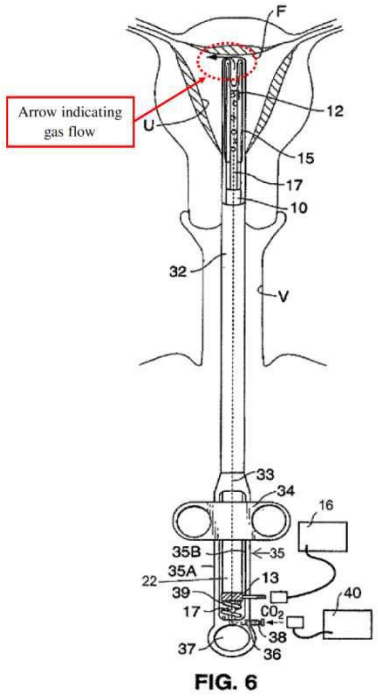

FIG. 6

Dr. Pearce explains that a person of skill in the art at the relevant time would have understood that the invention described in the '989 patent could not include a balloon-like inflatable RF applicator head, such as described in the background section of the patent, because it would prevent the suction and insufflation functions described in the specification, including the moisture removal function that is a key aspect of the invention as reflected by the Abstract, Summary of the

Invention, and consistent description throughout the specification. Ex. 1002 ¶ 105. A balloon-like RF applicator head by definition must be capable of retaining fluid to enable inflation, whereas the RF applicator head in the '989 patent is consistently described as freely allowing liquid and gas to pass through its permeable material to enable the key functions of the described ablation device. *Id*.

Second, the '989 patent specification does not support combining its mechanical and inflation expansion embodiments, because the inflatable expansion design depicted in Figure 20 could not be combined with the mechanical expansion designs described in the remainder of the '989 patent. Ex. 1002 ¶ 106.

As discussed above, the '989 patent provides no specific disclosure for combining an embodiment such as the devices depicted in Figures 10 and 11 with an embodiment such as the device depicted in Fig. 20. At a basic level, such a combination is impractical, if not impossible, because the spring members 15 and 19 depicted in Figures 10 and 11 and the balloons 52 depicted in Figure 20 occupy the same physical space within the RF applicator head. Ex. 1002 ¶ 107. As Dr. Pearce explains, the specification provides no guidance as to how the spring members, or the similar inner and outer flexures of the second embodiment, and the balloons could take up the same space in the applicator head, nor does it address how each would retain its mode of operation without interfering with the other component and preventing its normal operation. *Id*. The simple fact that these components are described as each occupying the same space in the device

demonstrates that they are ***mutually exclusive alternatives*** to each other rather than combinable elements. *Id*.

Moreover, Dr. Pearce identifies numerous technical problems that would prevent an attempt to combine the mechanical and inflation-based components in a single device. *Id*. at ¶¶ 108-111. If the balloons depicted in Figure 20 (element 52) were added to the mechanical expansion designs depicted in Figures 10 or 11, for example in a stacked configuration in which the balloons were placed on top of the spring members so that the stack extended out of the page on the z-axis, such a device would be inoperable for use in the method of the '989 claims for a number of reasons. *Id*. at ¶ 108. If the pair of balloons 52 in Figure 20 were superimposed onto flexures 15 and 19 in Figure 10 or 15a and 19a in Figure 11, any expansion force applied to the flexures by the balloons would serve to laterally push the edges of the flexures into the uterine wall, which could lead to damage to the flexures, discomfort, or injury. *Id*. at ¶ 109; *see also* Ex. 1014 ¶ 19. In addition, the expansion force applied to the flexure by the balloons could result in rupture of the balloons due to the sharp edges of the flexures being pressed into the balloons, which could lead to leakage of the inflation medium into the uterine cavity not to mention a nonfunctional device. *Id*.

It is also unclear how the addition of the balloon pair would allow for folding of the applicator head into the introducer sleeve as depicted in Fig. 8, or into the uterus as depicted in Fig. 9. Ex. 1002 ¶ 110. Even in the deflated state, Dr. Pearce testifies that the balloon pair would prevent full contraction of the

applicator head due to the additional space required for the balloon pair. *Id*.; *see also* Ex. 1014 ¶ 19.

Additionally, use of balloons in the mechanically-expanded applicator head would interfere with the suction/insufflation functionality described as a key feature. *Id*. at ¶ 111. Specifically, adding balloons into the mechanical expansion embodiments such as Figures 10 and 11 would block the suction/insufflation tube 17 from the uterus. *Id*. This is particularly true for the suction function, because a vacuum force coming from the suction/insufflation tube would pull the balloons into contact with the tube, preventing the suction force from being having any effect outside the RF applicator head. *Id*. As the ability to perform suction/insufflation is described as a key differentiator over the prior art, this arrangement would frustrate the purpose proposed in the specification. *Id*.; *see also* Ex. 1001 at 2:27-29; 2:45-48; 8:31-36.

Accordingly, combination of the balloon pair of Fig. 20 with the mechanical spring member or flexure designs described in the ’989 patent, as exemplified by Figures 10 and 11, would not produce an operable device for performing endometrial ablation in the manner recited in the claims. *Id*. ¶ 112. At minimum, a person of skill in the art would not understand the full scope of the invention described in the ’989 patent to encompass such a combination due to the numerous technical obstacles to such a combination and the failure of the ’989 patent to address those obstacles or present any solutions to them. *Id*.

The additional claims of the ’989 patent likewise lack written description support. Independent claim 14 is substantively identical to claim 1 with respect to

the combined mechanical/inflation expansion requirement; adding only requirements that the handle further comprise a spring and that "includes moving the proximal grip and the distal grip closer together to cause the expandable-contractible carrying member to develop an expansion force against the tissue contacting member, wherein the expansion force is limited by the spring." Ex. 1001 cl. 14; Ex. 1002 ¶ 113. Dr. Pearce testifies that these aspects of the handle structure do not impact his analysis regarding the combination of the mechanical and inflation-based applicator head expansion elements described in the '989 patent, and therefore his opinion as to claim 1 equally applies to claim 14. Ex. 1002 ¶ 113. Dependent claims 2-13 and 15-19 all depend from either claim 1 or claim 14, and therefore also lack written description in the specification of the '989 patent for the combined mechanical/inflation expansion by virtue of the fact that they include the same deficiencies described above with respect to the independent claims. *Id*. ¶ 114. Accordingly, each of claims 1-19 of the '989 patent lack description and guidance for a method of performing endometrial ablation using a device containing both mechanical expansion means and inflation means. *Id*.

Furthermore, the original claims filed with the '957 application for the '989 patent do not provide written description support for the issued claims. Ex. 1002 ¶¶ 115-120. For example, neither original claim 1 nor original claim 14 specifically recites mechanical expansion of the expandable-contractible carrying member at all, let alone the specific mechanical expansion means now recited combined with an inflation expansion means. *Id*. ¶¶ 116, 119; *see also* Ex. 1004 at 31:2-11, 32:20-29. As Dr. Pearce explains, those claims read in view of the

specification are reasonably interpreted as describing solely an inflation-based expansion embodiment that involves both actuating the carrying member with balloons to release it from the sleeve (which would allow the applicator head/carrying member to unfold) and progressively inflating the balloons including actuating an inflation source. *Id*. ¶ 116. Moreover, even if the vague "actuating the carrying member" (or "actuating the carrying means") claim language is interpreted to be directed to a mechanical expansion mode, the claim recites no components for carrying out such a mechanical expansion and therefore does not describe inflation expansion combined with mechanical expansion utilizing a pivot grip handle, slidably disposed inner and outer sleeves, and first and second inner and outer flexures as specifically recited in issued claim 1. *Id*. ¶ 117. Nor would a person of skill in the art have understood original claims 1 or 14 to provide sufficient written description support for issued claim 1 when viewed along with the specification's detailed description, in view of the significant technical issues preventing combination of the mechanical and inflation-based expansion embodiments as described by Dr. Pearce. *Id*.

Original claims 2-13 of the '957 application, which depend from original claim 1, also do not recite mechanical expansion of the expandable-contractible carrying member. *Id*. ¶ 118; Ex. 1004 at 31:12-32:19. Therefore, original claims 2-13 also do not describe a device containing both a mechanical expansion means and an inflation means to expand the expandable-contractible carrying member. Ex. 1002 ¶ 118.

The inquiry into whether the issued claims of the ’989 patent are unpatentable for lack of written description can stop at the ’957 application; it is unnecessary to go back earlier in the chain to determine whether the parent applications provide written description support that is otherwise lacking in the challenged patent. *See, e.g., Reiffen v. Microsoft Corp.*, 214 F.3d 342 (Fed. Cir. 2000) (“For purposes of § 112 ¶ 1, the relevant specifications are those of the ’603 and ’604 patents [being challenged for lack of written description]; earlier specifications are relevant only when the benefit of an earlier filing date is sought under 35 U.S.C. § 120.”). However, while it is not strictly necessary for assessing validity of the ’989 claims under § 112, as discussed above in the context of determining the effective filing date for determining PGR eligibility, none of the earlier applications in the priority chain—including their originally filed claims—provide written description support for an ablation device containing both mechanical expansion and inflation means as ultimately claimed in the ’989 patent. *See* Section VI.E, *supra*; *see also* Ex. 1002 ¶¶ 121-144.

Accordingly, the ’989 specification as a whole, including the original application claims as well as the earlier applications in the priority chain, does not provide written description or guidance to construct a device containing both a mechanical expansion means and an inflation means to expand the expandable-contractible carrying member, as required by the claims of the ’989 patent. Ex. 1002 ¶ 144. Furthermore, a person of skill in the art would not have understood that the inventors were in possession of a device with ***both*** a mechanical expansion means and an inflation expansion means to expand the expandable-contractible

carrying member based on the disclosure of the specification. *Id*. As such, claims 1-19 of the ’989 patent are unpatentable for lack of written description support.

B. [Ground 2] Claims 1-19 are Unpatentable for Lack of Enablement

Claims 1-19 of the ’989 patent are also unpatentable under 35 U.S.C. § 112(a) because the specification does not enable the claimed subject matter. “Enablement requires that the specification teach those in the art to make and use the invention without ‘undue experimentation.’” *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). Factual considerations for determining whether undue experimentation is required include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

As discussed above, the claims of the ’989 patent are directed to an ablation method using a device that is disclosed nowhere in the specification, requiring both mechanical and inflation expansion means to expand the device in the uterus. The specification does not enable such a device, because it does not provide sufficient guidance to allow a person of ordinary skill in the art to construct an ablation device containing both mechanical expansion means and inflation means. Ex. 1002 ¶¶ 145-152. This lack of guidance would increase the burden placed on a person of ordinary skill in the art to be able to practice the invention as recited in claim 1 of the ’989 patent, requiring undue experimentation. *Id*. at ¶ 147.

The difficulty for a person of skill in the art to achieve the claimed subject matter in view of the specification would be compounded by the fact that the mechanical and inflation based expansion means described in claim 1 of the '989 patent are incompatible with each other. *Id.* ¶ 148. As Dr. Pearce testifies, it remains unclear how the claimed configuration could be achieved, given the issues presented above, for example the flexures puncturing a balloon occupying the same space in the applicator head, and the incompatibility with the suction/insufflation tube. *Id*; *see also* SectionVI.B., *supra*. Therefore, a person of ordinary skill in the art would have to provide experimentation beyond what would be considered routine in the relevant field of technology in order to construct a device containing both mechanical expansion means and inflation means. *Id*.

Furthermore, this experimentation would have required a complete redesign of the expansion designs disclosed in the patent, due to their incompatibility with each other. *Id.* ¶ 149. Such a redesign would take a substantial amount of time and cost to achieve despite the high level of skill in the art, further increasing the burden placed on a person of ordinary skill in the art to be able to practice the invention as recited in claim 1 of the '989 patent. *Id*. Dr. Pearce explains that requiring a person of skill in the art to construct an entirely new device in order to avoid the complications previously described would have been an unpredictable endeavor, given that the project would have necessarily deviated from the approaches described in the '989 patent. *Id.* ¶ 149.

Additionally, because the '989 patent fails to disclose any working examples of devices containing both mechanical means and inflation means to expand the

applicator head, the lack of such working examples would further increase the burden placed on a person of ordinary skill in the art to be able to practice the invention as recited in claim 1 of the '989 patent. *Id*. ¶ 150.

Therefore, Dr. Pearce explains that the experimentation needed to practice the invention as recited in claim 1 would have been undue in light of the disclosure of the '989 and the factors listed above, and the specification '989 patent does not satisfy the enablement requirement for claim 1. *Id*. ¶ 151. Moreover, because independent claim 14 is substantively identical to claim 1 for purposes of this analysis, claim 1 is also unpatentable for failure to satisfy the enablement requirement. *Id*. ¶ 152. Likewise, dependent claims 2-13 and 15-19 also fail to satisfy the enablement requirement for the same reasons as independent claims 1 and 14. *Id*. Therefore, neither the specification '989 patent nor the application as originally filed (including originally filed claims) provide enablement of claims 1-19 to allow a person of ordinary skill in the art to practice the invention recited in the claim without undue experimentation.

VIII. CONCLUSION

For the reasons set forth above, claims 1-19 of the '989 patent are unpatentable. Petitioners therefore request that a post-grant review of these claims be instituted.

Respectfully submitted,

Dated: November 2, 2016

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

IX. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 16,925 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a).

Respectfully submitted,

Dated: November 2, 2016

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
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X. 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.

XI. APPENDIX – LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,247,989 to Truckai *et al*.
1002	Declaration of John Anthony Pearce, Ph.D.
1003	John Anthony Pearce *curriculum vitae*
1004	U.S. Patent Application No. 14/635,957
1005	File History of U.S. Patent No. 9,247,989
1006	U.S. Patent Application No. 13/267,258
1007	*Flexure, Frame*, Webster's Desk Dictionary (2001)
1008	U.S. Patent Application No. 12/581,506
1009	U.S. Patent Application No. 14/278,741
1010	U.S. Patent Application No. 13/962,178
1011	U.S. Patent Application No. 10/959,771
1012	U.S. Patent Application No. 09/103,072
1013	U.S. Provisional Patent Application No. 60/084,791
1014	Declaration of Csaba Truckai

1015	NovaSure Instructions for Use and Controller Operator's Manual (2014)
1016	Complaint for Patent Infringement, Hologic, Inc. et al. v. Minerva Surgical, Inc., 15-cv-01031-SLR (November 6, 2015)
1017	Csaba Truckai *curriculum vitae*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.205(a), this is to certify that I caused to be served a true and correct copy of the foregoing Petition for Post-Grant Review of U.S. Patent no. 9,247,989 (and accompanying Exhibits 1001 through 1017) by overnight courier (Federal Express or UPS), on this 2nd day of November, 2016, on the Patent Owner at the correspondence address of the Patent Owner as follows:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752

Hologic, Inc./Cytyc Corporation
CarolAnn Mahoney, Sr. IP Paralegal
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Respectfully submitted,

Dated: November 2, 2016

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