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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. 6,872,183

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,872,183

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I. INTRODUCTION

Minerva Surgical, Inc., ("Petitioner") hereby requests *inter partes* review of United States Patent No. 6,872,183 to Sampson *et al.* (hereinafter "the '183 patent," Ex. 1001) that issued on March 29, 2005, and is currently assigned to Hologic, Inc. ("Patent Owner"). This petition demonstrates that there is a reasonable likelihood that claims 1-15 of the '183 patent are unpatentable over the cited prior art. Claims 1-15 of the '183 patent should be found unpatentable and canceled.

The '183 patent claims are vast in scope, and broadly directed to an ablation procedure in which the uterus is inflated with fluid in a conventional manner and checked for perforations using a pressure sensor. Ex. 1002 ¶¶ 11-12. Endometrial ablation procedures at the time conventionally distended the uterus with fluid in order to increase the available working space and expose the interior surfaces to ablation treatment. *Id.* In such procedures, it was important to monitor for any perforation in the uterine wall that would result in fluid leakage from the uterus into the body (*e.g.*, due to instrument damage or disease), since unintended leakage could harm the patient. *Id.* Pressure measurements were a logical approach for detecting uterine perforations causing such leaks, since pressure would necessarily be lost when fluid escaped through the perforations. *Id.* Indeed, uterine ablation devices equipped with pressure sensors and having leak/perforation detection functionality were already well known and described in the prior art before the '183 patent. *Id.*

A. Brief Overview of the '183 Patent

The '183 patent relates to devices for ablation or coagulation of tissues in the interior linings of the uterus, known as endometrial ablation. Ex. 1001 at 1:22-28. Specifically, the ablation approach described in the '183 specification involves introducing fluid into the uterus and detecting perforations in the uterus in conjunction with providing ablation treatment. Ex. 1002 ¶¶ 11-14.

Claim 1 of the '183 patent is representative of the claims at issue and recites the following:

> A method of ablating a uterus, comprising the steps of:
> inserting an ablation device into a uterus;
> flowing an inflation medium into the uterus;
> monitoring for the presence of a perforation in the uterus using a pressure sensor; and
> treating the interior of the uterus using the ablation device.

The '183 specification describes an ablation method in which the uterus is distended with fluid and checked for a loss of pressure, which can indicate damage to the uterine wall. Ex. 1002 ¶ 13. Specifically, "a fluid . . . is delivered into a body cavity to slightly pressurize the cavity [and a] pressure sensing system monitors the pressure within the cavity." Ex. 1001 at 1:49-54. "If cavity pressure is not substantially sustained . . . the physician is alerted." *Id.* at 1:54-60. As discussed below, it was already well known to monitor intrauterine pressure before or during ablation to ensure that the uterus was not leaking or damaged. Ex. 1002 ¶ 13.

The other independent claim of the '183 patent, claim 9, recites substantively similar requirements as claim 1, with the primary difference being

that claim 9 requires that ablation of the uterus be prevented if a perforation is detected. Other requirements recited in the dependent claims relate to minor variations or common features of electrosurgical devices and other types of minimally invasive surgical tools. *Id.* ¶ 15.

As discussed in more detail below, fluid inflation of the uterus was a conventional aspect of ablation methods in the years leading up to the '183 patent. It was additionally well known specifically in the field of ablation devices as well as generally in the field of uterine treatment devices to monitor fluid pressure in the uterus in order to detect damage to the uterine wall—such as a perforation—and potentially harmful leakage of fluid into the body. *Id.* ¶ 16.

B. Brief Overview of the Prosecution History

Application No. 10/852,648 was filed on May 24, 2004 and issued on March 29, 2005 as U.S. Patent No. 6,872,183. The '183 patent on its face identifies a chain of related U.S. Applications extending back to Provisional Application No. 60/164,482, filed on November 10, 1999. No rejections based on prior art were made during prosecution. *See* Ex. 1004.

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

As explained in detail in the corresponding Declaration of John Anthony Pearce, Ph.D. (Exhibit 1002) and addressed in further detail below (Section VI), the involved claims would not have been considered new or non-obvious to a person of ordinary skill in the art ("POSA") at the relevant time. The ablation methods recited in the '183 patent claims, including use of an inflation medium and pressure-based perforation detection, were conventional aspects in uterine

treatment approaches at the time. Ex. 1002 ¶ 23.

Endometrial ablation was known at the time as a treatment for abnormal uterine bleeding. *Id.* ¶ 24. As is reflected in the Background section of the '183 patent, by the mid- to late-1990s there were many known ablation methods, including "circulation of heated fluid inside the organ" and "resistive heating using application of RF energy to the tissue to be ablated." Ex. 1001 at 1:28-33. Likewise, there were numerous ablation devices which were transcervically inserted for ablating the interior lining of the uterus. *Id.* at 1:35-38. For example, the '183 patent incorporates by reference U.S. Patent Application No. 09/103,072 (*see* Ex. 1001 at 2:60-64), which issued as U.S. Patent No. 6,813,520 ("the '520 patent," Ex. 1005). The '520 patent discloses an ablation device very similar to the one described in the '183 patent. *See* Ex. 1002 ¶ 24 (comparing FIGS. 21, 23 of the '520 patent to FIGS. 2A, 2B of the '183 patent).

Many ablation methods prior to the '183 patent used an inflation medium to pressurize and expand the uterine cavity for treatment. *Id.* ¶ 25. In fact, this was a conventional approach for surgical procedures within the uterus, since the uterine cavity normally has a flattened, slit-like shape – as early as 1908, surgeons were using fluid to distend the uterine cavity in order to create space for operating within the uterus. Ex. 1014 at 29. In the specific context of endometrial ablation, fluid distension of the uterus also ensured the entire endometrial lining was exposed and ablated. *See* Ex. 1013 at 1:50-59; *see also* Ex. 1002 ¶ 25.

There are numerous examples of endometrial ablation methods predating the '183 patent that used an inflation medium to distend the uterus. Ex. 1002 ¶ 26.

For instance, U.S. Patent No. 5,891,094 to Masterson *et al.* ("Masterson," Ex. 1006) discloses "methods and devices for heating a thermally (and usually electrically) conductive medium within . . . the uterus, to necrose or ablate the mucosa or endothelial lining." Ex. 1006 at 3:48-51, 3:52-4:2. In particular, Masterson describes "introducing a thermally conductive fluid" in order to "pressurize and distend the uterus" for ablation. Ex. 1006 at 9:43-45, 14:26-29; *see also* Ex. 1002 ¶ 26.

As another example, PCT Application No. WO 97/24074 to Isaacson *et al.* ("Isaacson," Ex. 1007) discloses an "an intralumen or intracavity electrosurgical device . . . for surgical procedures within the uterine cavity," including "endometrial ablation." Ex. 1007 at 2:18-21, 3:23-26. Isaacson's method involves delivering "an isotonic distention fluid" into the uterus prior to performing ablation with a resectoscope. Ex. 1007 at 16:27-31; *see also* Ex. 1002 ¶ 27.

Likewise, U.S. Patent No. 5,503,623 to Goldrath ("Goldrath," Ex. 1013) discloses methods for "hysteroscopic surgery performed in conjunction with delivery of fluid to the uterine cavity," including "thermally ablating the lining of the uterus." Ex. 1013 at 1:14-23. Goldrath explains that "[s]uch procedures often require the continuous introduction of large amounts of fluid into the uterine cavity so as to expand the size thereof." *Id.* at 4:44-46; *see also* Ex. 1002 ¶ 28.

When using an inflation medium to distend the uterus, it was important to monitor whether fluid was escaping from the uterus and into the rest of the body. Ex. 1002 ¶ 29. Unwanted leakage could compromise treatment efficacy and even injure the patient, particularly during ablation treatments using heated fluids to

destroy tissue. *See* Ex. 1006 at 1:26-39; Ex. 1013 at 1:39-59; *see also* Ex. 1002 ¶ 29. Masterson, for example, expressly describes detection of fluid leakage from the uterus in the context of thermal ablation. Ex. 1006 at 17:41-46; *see also* Ex. 1002 ¶ 29.

Moreover, uterine perforations were known to cause fluid leakage from the uterus, and it was known to check for such perforations in connection with ablation therapy, as evidenced by Isaacson. *See* Ex. 1007 at 14:24-29; *see also* Ex. 1002 ¶ 30. Pressure measurement was a recognized and logical basis for perforation detection. The uterus acts as a container to fluid in such a distention procedure, and fluid leakage would be detected by pressure loss – that is, escaping fluid would compromise the uterus' ability to maintain pressure. Ex. 1002 ¶ 30. A person of ordinary skill would recognize this to be true of virtually any container leaking fluid. *See* Ex. 1009 at 1:10-13 ("A common method of determining fluid leakage characteristics of a container is to measure pressure decay following pressurizing of the container with a suitable fluid"); *see also* Ex. 1002 ¶ 30.

Indeed, U.S. Patent No. 3,871,374 to Bolduc *et al.* ("Bolduc," Ex. 1008), discloses monitoring uterine integrity (*e.g.*, whether the uterus is intact or perforated) based on pressure. Ex. 1008 at 1:51-2:1; *see also* Ex. 1002 ¶ 31. Goldrath discloses measuring pressure to detect whether fluid is escaping from the uterus into the patient's circulation. Ex. 1013 at 2:48-59. In fact, many ablation devices at the time, including those disclosed by Masterson and Isaacson, incorporated pressure sensors for monitoring intrauterine pressure. *See* Ex. 1006 at 11:8-15; Ex. 1007 at 13:31-34; *see also* Ex. 1002 ¶ 32. These devices would have

provided the pressure-based perforation detection recited in the '183 patent claims. Ex. 1002 ¶ 32.

Other aspects and features as claimed by the '183 patent, such as preventing treatment until after a pressure monitoring step had been carried out, performing a pressure monitoring step for a predetermined time, and providing a user override allowing treatment to continue even if a perforation is detected were also known before the '183 patent. *See, e.g.*, Ex. 1008 at 7:41-8:44 (describing that the pressure monitoring step must be successfully completed before treatment step); Ex. 1009 at 1:22-37 (describing conducting a pressure test for "preselected period of time"); U.S. Patent No. 5,785,658 to Benaron *et al.* ("Benaron," Ex. 1010) (describing a "safety interlock" feature that "can be overridden and/or disabled"); Ex. 1002 ¶ 33.

For these reasons, and as described in greater detail below and in Dr. Pearce's declaration, the methods for treating a uterus as recited in claims 1-15 were well known in the field prior to November 10, 1999. Ex. 1002 ¶ 34.

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

Petitioner's technical expert, Dr. John Anthony Pearce, is the Temple Foundation Professor of Electrical Engineering at the University of Texas at Austin. Ex. 1002 ¶ 1. Dr. Pearce has worked in the field of electrosurgery and biomedical instrumentation since the early 1970s and is therefore familiar with the knowledge and level of ordinary skill prior to the '183 patent. *Id.* ¶¶ 1-7; *see also* Ex. 1003. As Dr. Pearce explains, a POSA in the relevant field prior to November 10, 1999 would include someone who had, through education or practical

experience, the equivalent of a bachelor's degree in biomedical engineering, electrical engineering, mechanical engineering or a related field and at least an additional two to three years of work experience developing or implementing electrosurgical devices. Ex. 1002 ¶ 38.

A POSA in the relevant field would have been aware of developments in the field of electrosurgical devices and would have been working with trends from the mid- to late-1990s, including trends toward increasing the effectiveness, safety, and ease of operation of such devices. *Id.* ¶ 39. Such a person would also have been familiar with known techniques for uterine surgery, such as those described above in Section I.C. *Id.* ¶ 40.

II. GROUNDS FOR STANDING

Petitioner certifies that, under 37 C.F.R. § 42.104(a), the '183 patent is available for *inter partes* review, and Petitioner is not barred or estopped from requesting *inter partes* review of the '183 patent on the grounds identified.

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

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

Related Matters (37 C.F.R. § 42.8(b)(2)): Patent Owner has asserted the '183 patent against Petitioner in United States District Court for the District of Delaware, Case No. 1:15-cv-01031-SLR. *See* Ex. 1011.

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

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

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

Petitioners request review of claims 1-15 of the '183 patent under 35 U.S.C. § 311 and AIA § 6. The specific grounds for relief are as follows:

Ground	Claims	Description
1	1, 4, 6, 7, 9, 11-13, and 15	Obvious under 35 U.S.C. § 103 over Masterson and Bolduc
2	2, 3, and 14	Obvious under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson
3	5	Obvious under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein
4	8 and 10	Obvious under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron
5	1-4, 6, 7, 9, and 11-15	Obvious under 35 U.S.C. § 103 over Isaacson and Goldrath
6	5	Obvious under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein
7	8 and 10	Obvious under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron

V. CLAIM CONSTRUCTION

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

"inflation medium": Independent claims 1 and 9 require use of an "inflation medium" that is flowed or passed into the uterus. Ex. 1002 ¶ 42.

In describing the inflation medium, the specification states that "a fluid (either a liquid or gas) is delivered into the body cavity to slightly pressurize the cavity." Ex. 1001 at 1:50-52. In view of the specification, the broadest reasonable interpretation of the term "inflation medium" includes a liquid or gas delivered into the uterus to slightly pressurize the uterine cavity. Ex. 1002 ¶¶ 43-45.

"perforation": Independent claims 1 and 9 require monitoring for the presence of a "perforation" in the uterus using a pressure sensor. Ex. 1002 ¶ 46.

The specification of the '183 patent states that the invention relates to "systems and methods for detecting the presence of perforations in body cavities," and more particularly to "detect[ing] whether the body cavity can maintain a pressurized condition." Ex. 1001 at 1:12-17. The use of the term "perforation" in the '183 patent is consistent with its common and ordinary meaning in this field,

which includes "a rupture in a body part caused especially by accident or disease." *See* Ex. 1012 at 3; *see also* Ex. 1002 ¶ 48. Accordingly, a POSA would understand the broadest reasonable interpretation of the term "perforation" to refer to damage to the wall of the uterus, such as a rupture caused by accident or disease. Ex. 1002 ¶¶ 47-49.

VI. DETAILED EXPLANATION OF GROUNDS FOR UNPATENTABILITY

A. [Ground 1] Claims 1, 4, 6, 7, 9, 11-13, and 15 are Obvious under 35 U.S.C. § 103 over Masterson and Bolduc

Masterson, filed June 17, 1997 and issued April 6, 1999, is qualified as a prior art printed publication at least under 35 U.S.C. § 102(a). Bolduc, issued March 18, 1975, is qualified as a prior art printed publication under 35 U.S.C. § 102(b). As described below, claims 1, 4, 6, 7, 9, 11-13, and 15 of the '183 patent would have been obvious to a POSA in view of Masterson and Bolduc. Ex. 1002 ¶¶ 50-52.

Masterson discloses an ablation device for heating a thermally conductive medium within the uterus in order to ablate the endothelial lining. Ex. 1006 at 3:48-51. Consistent with conventional ablation procedures at the time (*see* Section I.C., *supra*), Masterson describes distending the uterus with fluid and notifying a user if a leak is detected. Ex. 1006 at 14:26-29, 17:41-46. The device includes an intrauterine pressure sensor that alerts the user if there is an abnormal reading, *e.g.*, over or under pressure. *Id.* at 11:8-10, 18:51-57; *see also* Ex. 1002 ¶ 53.

As explained by Dr. Pearce, Masterson on its own arguably discloses each and every element of the claims challenged in this ground, and certainly renders

obvious the claimed method of using a pressure sensor to monitor for a perforation in the uterus. Ex. 1002 ¶ 54. As discussed in Section I.C. above, fluid leakage through the perforation would compromise the uterus's ability to maintain pressure, and a POSA would have understood that perforation detection was a necessary consequence of Masterson's pressure-sensing method. *Id*. To the extent Masterson does not expressly describe pressure-based perforation monitoring, a POSA would certainly have recognized this as a readily apparent application of Masterson's intrauterine pressure sensor – in view of knowledge in the art (*e.g.*, knowledge that a leaking container exhibits pressure decay) or in view of the teachings as in Bolduc. Bolduc expressly discloses using a pressure sensor to monitor uterine integrity by detecting whether a predetermined pressure is achieved in the uterus, and explains that this pressure would not be reached in a ruptured (perforated) uterus. *See* Ex. 1008 at 1:51-53, 5:46-58, 6:15-18; *see also* Ex. 1002 ¶ 55.

The discussion below further illustrates that each and every element of claims 1, 4, 6, 7, 9, 11-13, and 15 of the '183 patent would have been obvious in view of Masterson and Bolduc. The particular citations listed are intended to be illustrative, not exhaustive. A detailed discussion of rationale to combine follows the discussion of the individual claims. *See* Section VI.A.iv, *infra*.

i. Independent Claim 1

Assuming that the **claim 1 preamble** is limiting, this language is disclosed by the combination of Masterson and Bolduc:

’183 Patent	Masterson and Bolduc
1. A method of ablating a uterus, comprising the steps of:	**Masterson discloses:** “The invention provides methods and devices for heating a thermally (and usually electrically) conductive medium within a hollow body organ, such as the uterus, to necrose or ablate the mucosa or endothelial lining.” 3:48-51. *See also* Ex. 1002 ¶¶ 63-64.

Masterson describes a method of ablating a uterus, specifically, “heating a thermally (and usually electrically) conductive medium within a hollow body organ, such as the uterus, to necrose or ablate the mucosa.” Ex. 1006 at 3:48-51; *see also* Ex. 1002 ¶ 63. Accordingly, the combination of Masterson and Bolduc discloses the elements of the preamble of claim 1. *Id.* ¶ 64.

The combination of Masterson and Bolduc discloses **limitation 1.1**:

’183 Patent	Masterson and Bolduc
[1.1] inserting an ablation device into a uterus;	**Masterson discloses:** “[T]he invention provides a method for thermally ablating a hollow body organ by introducing . . . a heating apparatus into the hollow body organ.” 7:6-10. “[I]ntroduction of the thermal ablation device 10 into the uterus U through the cervical canal CC will be described.” 13:47-49. *See also* FIG. 5; Ex. 1002 ¶¶ 65-66.

Masterson discloses inserting an ablation device into a uterus. For example, Masterson describes “introduction of the thermal ablation device 10 into the uterus.” Ex. 1006 at 13:47-49; *see also id.* at 7:6-10, FIG. 5; Ex. 1002 ¶ 65. Thus, the combination of prior art discloses the elements of limitation 1.1. *Id.* ¶ 66.

The combination of Masterson and Bolduc discloses **limitation 1.2**:

’183 Patent	Masterson and Bolduc
[1.2] flowing an inflation medium into the uterus;	**Masterson discloses:** “Thermal ablation according to the invention begins by introducing a thermally conductive fluid, such as a saline solution, into the uterus.” 9:43-45. “[T]he outflow lumen 54 . . . may be closed to allow the fluid F in the reservoir 74 to pressurize and distend the uterus.” 14:26-29. *See also* **Bolduc** at 4:47-50, 7:16-21; Ex. 1002 ¶¶ 67-68.

Masterson describes flowing an inflation medium into the uterus: "[t]hermal ablation . . . begins by introducing a thermally conductive fluid . . . into the uterus." Ex. 1006 at 9:43-45. This fluid is used "to pressurize and distend the uterus." *Id.* at 14:26-29; *see also* Ex.1002 ¶ 67. Accordingly, the combination of Masterson and Bolduc discloses the elements of limitation 1.2. Ex. 1002 ¶ 68.

The combination of Masterson and Bolduc discloses **limitation 1.3**:

'183 Patent	Masterson and Bolduc
[1.3] monitoring for the presence of a perforation in the uterus using a pressure sensor; and	**Masterson discloses:** "[D]evice 10 includes a pressure sensor 31 that is disposed to monitor the intrauterine pressure when device 10 is the in the patient. Sensor 31 preferably comprises a transducer which is electrically connected to a controller . . . so that the intrauterine pressure may be externally monitored." 11:8-15. "[T]he care giver may be alerted to the possibility of a leak that is occurring within the hollow body organ." 17:44-46. "[C]ontroller 170 maybe provided with a variety of alarms to indicate abnormal operating conditions, such as . . . over or under pressure." 18:51-59. **Bolduc discloses:** "The balloon assembly has a soft, relaxed sleeve member that is expanded to a predetermined pressure to substantially fully displace the uterine cavity. The pressure within the chamber surrounded by the sleeve member will not be attained if the walls of the uterus are weak, diseased or ruptured . . . ." 1:62-2:1. "The actuator assembly 79 functions to apply a predetermined fluid pressure to the sleeve member to substantially displace the uterine cavity with the sleeve member and initially monitor the integrity of the uterus." 5:42-50. "The spring 89 has a calibrated force, preferably 7 to 7½ psi. . . ." 6:15-16. "When the pressure is at the desired level, i.e., 7 to 7½ psi, the member 84 will move from its extended position into the member 81 to a contracted or 'in' position. This movement will align pin 98 with hole 101." 7:26-32. "In the event that there is a leak in the fluid system of the sleeve member 44 or that the walls of the uterus are weak, diseased, or ruptured . . . the actuator assembly 79 will not lock into the control mechanism 102. The impaired uterus will not develop a reaction pressure . . . sufficient to overcome the compression

	characteristics of spring 89 . . . thereby provid[ing] an indication of deficiency in the strength of the uterine wall." 7:41-55. *See also* **Bolduc** FIGS. 1, 5-7, 9; Ex. 1002 ¶¶ 69-78.

Masterson discloses that the ablation device "includes a pressure sensor 31 that is disposed to monitor the intrauterine pressure when device 10 is the in the patient." Ex. 1006 at 11:8-10; *see also* Ex. 1002 ¶ 69. Masterson describes monitoring the fluid so that "the care giver may be alerted to the possibility of a leak that is occurring within the hollow body organ." Ex. 1006 at 17:41-46; *see also* Ex. 1002 ¶ 71. Dr. Pearce explains that a POSA would have understood that Masterson's pressure sensor, which is "electrically connected to a controller" configured with alarms to indicate "abnormal operating conditions" such as an "over or under pressure" situation, would detect a perforation in the uterus, since there would be a drop in intrauterine pressure as fluid leaks through the perforation. Ex. 1006 at 11:8-15, 18:51-59; Ex. 1002 ¶ 70. The claimed subject matter would, at a minimum, have been apparent to a POSA reviewing Masterson with an understanding of the basic principles of leakage in a pressurized container. *See, e.g.*, Section I.C; *see also* Ex. 1002 ¶ 71.

To the extent Masterson does not expressly disclose detecting uterine perforations based on pressure measurement, this feature is also taught by Bolduc. Ex. 1002 ¶ 72. Bolduc discloses a device with a "sleeve member that is expanded to a predetermined pressure to substantially fully displace the uterine cavity." Ex. 1008 at 1:62-64; FIG. 1; Ex. 1002 ¶ 72. Bolduc teaches that the predetermined pressure will not be achieved "if the walls of the uterus are weak, diseased or ruptured," *i.e.*, perforated. Ex. 1008 at 1:64-2:1; Ex. 1002 ¶ 72. As explained by

Dr. Pearce, Bolduc describes that a uterine perforation is detected using a pressure sensor—specifically a pressure-calibrated spring—where compression of the spring indicates whether a desired intrauterine pressure level has been achieved. Ex. 1002 ¶¶ 73-75; Ex. 1008 at 5:42-50, 6:15-18, FIGS. 1, 5, 7. If the uterus is perforated, the pressure within the sleeve member will not be "sufficient to overcome the compression characteristics of spring 89 . . . thereby provid[ing] an indication of deficiency in the strength of the uterine wall." Ex. 1008 at 7:41-55; Ex. 1002 ¶ 74. Therefore, Bolduc discloses a fluid pressure-based approach to detecting uterine perforations. Ex 1002 ¶ 76.

As explained by Dr. Pearce and discussed in more detail with respect to rationale to combine, a POSA would have used the Masterson pressure sensor to monitor for uterine perforations and leaks, particularly in view of the pressure-based uterine perforation monitoring described in Bolduc. Ex. 1002 ¶ 77. Accordingly, the combination of Masterson and Bolduc discloses the elements of limitation 1.3. *Id.* ¶ 78.

The combination of Masterson and Bolduc discloses **limitation 1.4**:

'183 Patent	**Masterson and Bolduc**
[1.4] treating the interior of the uterus using the ablation device.	**Masterson discloses:** "The invention provides methods and devices for heating a thermally (and usually electrically) conductive medium within a hollow body organ, such as the uterus, to necrose or ablate the mucosa or endothelial lining." 3:48-51. *See also* Ex. 1002 ¶¶ 79-80.

Masterson discloses "heating a thermally (and usually electrically) conductive medium within a hollow body organ, such as the uterus, to necrose or ablate the mucosa or endothelial lining." Ex. 1006 at 3:48-51; *see also* Ex. 1002 ¶

79. Accordingly, the combination of Masterson and Bolduc discloses the elements of limitation 1.4. Ex. 1002 ¶ 80.

Accordingly, each and every element of claim 1 is taught and suggested by the combination of Masterson and Bolduc. Ex. 1002 ¶ 80.

ii. Independent Claim 9

As Dr. Pearce explains, independent claim 9 is rendered obvious by the combination of Masterson and Bolduc for reasons similar to those discussed above for claim 1. Ex. 1002 ¶¶ 93-101. These claims contain requirements substantively similar to those in claim 1, and the few differences presented are discussed below.

To the extent that the **claim 9 preamble** is limiting, this language is disclosed by the combination of Masterson and Bolduc:

'183 Patent	Masterson and Bolduc
9. A method of detecting a perforation in a uterus, comprising the steps of:	**Masterson** at 3:48-51, 11:8-15, 17:44-46; 18:51-59. **Bolduc** at 1:62-2:1, 5:42-50, 6:15-16, 7:26-32, 7:41-55, FIGS. 1, 5-7, 9. *See also* Ex. 1002 ¶ 93; discussion of claim 1 preamble, limitation 1.3.

As discussed above with respect to the preamble and limitation 1.3 of claim 1, Masterson discloses a method of detecting leakage in a uterus, such as would occur due to a perforation, while Bolduc discloses a method of detecting perforations in a uterus. Ex. 1002 ¶ 93. Accordingly, Masterson and Bolduc disclose the elements of the preamble of claim 9. *Id.*

The combination of Masterson and Bolduc discloses **limitation 9.1**:

'183 Patent	Masterson and Bolduc
[9.1] passing an inflation medium into the uterus;	**Masterson** at 9:43-45, 14:26-29. **Bolduc** at 4:47-50, 7:16-21. *See* Ex. 1002 ¶ 94; *see also* discussion of claim 1, limitation 1.2.

As discussed above with respect to limitation 1.2 of claim 1, Masterson discloses flowing an inflation medium into the uterus, which is one way of passing such a medium into the uterus. Ex. 1002 ¶ 94. Accordingly, Masterson and Bolduc disclose the elements of limitation 9.1. *Id.*

The combination of Masterson and Bolduc discloses **limitation 9.2**:

'183 Patent	**Masterson and Bolduc**
[9.2] monitoring for the presence of a perforation in the uterus using a pressure sensor;	**Masterson** at 11:8-15, 17:41-46; 18:51-59. **Bolduc** at 1:62-2:1, 5:42-50, 6:15-16, 7:26-32, 7:41-55, FIGS. 1, 5-7, 9. *See also* Ex. 1002 ¶ 95; discussion of claim 1, limitation 1.3.

As discussed above with respect to limitation 1.3 of claim 1, Masterson and Bolduc disclose "monitoring for the presence of a perforation in the uterus using a pressure sensor." Ex. 1002 ¶ 95. Accordingly, Masterson and Bolduc disclose the elements of limitation 9.2. *Id.*

The combination of Masterson and Bolduc discloses **limitation 9.3**:

'183 Patent	**Masterson and Bolduc**
[9.3] if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and	**Masterson discloses:** "Further, controller 170 maybe provided with a variety of alarms to indicate abnormal operating conditions, such as . . . over or under pressure, . . . and the like. In the event that certain conditions are detected, controller 170 is configured to cease operation of device 162 to provide increased safety to the patient." 18:51-59; *see also* 3:48-51, 17:41-46. **Bolduc discloses:** "In the event the uterine walls have sufficient strength, the member 84 will move relative to member 81 of the actuator assembly 79 and pin 98 will move into registration with the hole 101. . . . Pin 98 locks the actuator assembly 79 to the body 103, preventing further movement of actuator assembly 79 into cylinder 73." 7:63-8:18. "Referring to FIG. 7, as soon as the dispensing of the drug material 67 from the container 63 is completed, the operator applies a force to the actuator assembly 79 to progressively expand the sleeve member 44. As shown in FIG. 3, sleeve

	member 44 moves outward to fill the entire uterine cavity. As the sleeve member 44 expands, it forces or pushes the drug material up into the canals 33 and 34 of the Fallopian tubes 23 and 24, respectively. The sleeve member 44 is expanded to its initial expanded position, as shown in FIG. 1. The actuator 79, being locked to the control mechanism by the pin 98, limits the movement of the actuator into the cylinder 73." 8:31-44. *See also* Ex. 1002 ¶¶ 84, 86-90, 96-98; discussion of claim 1, limitations 1.3 and 1.4.

As discussed above with respect to limitations 1.3 and 1.4, Masterson and Bolduc disclose pressure-based monitoring for perforations and ablation of a uterus using an ablation device. Ex. 1002 ¶ 96. A doctor using an ablation device would logically permit the procedure to continue after checking for a compromise in uterine wall integrity and finding none. *Id.* Masterson also describes preventing the ablation device from operating if the pressure monitor detects a problem. *See* Ex. 1006 at 18:57-59 ("In the event that certain conditions are detected, controller 170 is configured to cease operation of device 162 to provide increased safety to the patient"); *see also* Ex. 1002 ¶ 84, 86. Dr. Pearce explains that a POSA would understand that, conversely, the ablation device would be permitted to continue operating if no such problems are detected – *e.g.*, the fail-safe would not be triggered. Ex. 1002 ¶ 96.

The claim feature is additionally found in the teachings of Bolduc. Ex. 1002 ¶¶ 87-90, 97. Bolduc describes carrying out a treatment step if the pressure monitoring step is completed without detection of a perforation. *Id.* Specifically, Bolduc explains that "[i]n the event the uterine walls have sufficient strength," the device moves from the monitoring configuration to the treatment configuration. Ex. 1006 at 7:63-8:8 (describing locking function of pin 98). As explained by Dr.

Pearce, the treatment procedure described in Bolduc would not work properly if the pin 98 is not initially locked, and therefore Bolduc describes a treatment step that can only occur if the pressure testing step is successfully completed. *Id*; *see also* Ex. 1006 at 8:31-44 (describing role of pin 98 in setting "initial expanded position" of sleeve member 44 and subsequent re-inflation during treatment); Ex. 1002 ¶¶ 87-90, 97.

As explained by Dr. Pearce and discussed in more detail below with respect to rationale to combine, an ablation device as in Masterson would benefit from a safety mechanism based on detecting the presence of a perforation in the uterus, and pressure-based safety mechanisms are expressly suggested in the Masterson reference itself. Ex. 1002 ¶ 97. Accordingly, the combination of Masterson and Bolduc discloses the elements of limitation 9.3. *Id.* ¶ 98.

The combination of Masterson and Bolduc discloses **limitation 9.4**:

'183 Patent	**Masterson and Bolduc**
[9.4] if a perforation is detected during the monitoring step, preventing ablation of the uterus.	**Masterson discloses:** "Further, controller 170 maybe provided with a variety of alarms to indicate abnormal operating conditions, such as . . . over or under pressure, . . . and the like. In the event that certain conditions are detected, controller 170 is configured to cease operation of device 162 to provide increased safety to the patient." 18:51-59; *see also* 3:48-51, 17:41-46. **Bolduc discloses:** "In the event that there is a leak in the fluid system of the sleeve member 44 or that the walls of the uterus are weak, diseased, or ruptured they will not have sufficient strength to confine the sleeve member 44, the actuator assembly 79 will not lock into the control mechanism 102. The impaired uterus will not develop a reaction pressure that will establish a pressure of the fluid in chamber 48 sufficient to overcome the compression characteristics of spring 89. Accordingly, pin 98 will not move into registration with hole 101. When the operator releases the pressure on the actuator assembly 79, the

	actuator assembly 79 will move back to its initial position, as shown in FIG. 4, and thereby provide an indication of deficiency in the strength of the uterine wall." 7:41-55; *see also* 5:54-61, 7:63-8:8 *See also* Ex. 1002 ¶¶ 84, 86-90, 99-101; discussion of claim 1, limitations 1.3 and 1.4; claim 9, limitation 9.3.

As discussed above with respect to limitation 9.3 of claim 9, Masterson describes ablation of a uterus using an ablation device and preventing the ablation device from operating if the pressure monitor detects a problem. Ex. 1002 ¶ 99. Specifically, Masterson describes "a variety of alarms to indicate abnormal operating conditions, such as . . . over or under pressure," Ex. 1006 at 18:51-57. An alarm indicating an "under pressure" condition would alert the user to the presence of a perforation in the uterus, since such a perforation would result in a loss of pressure as fluid escapes from the uterus. Ex. 1002 ¶¶ 84, 86, 99. Masterson further explains that "[i]n the event that certain conditions are detected, controller 170 is configured to cease operation of device 162 to provide increased safety to the patient." Ex. 1006 at 18:57-59. Therefore, Masterson discloses preventing ablation of the uterus (*i.e.*, ceasing operation) if a perforation is detected during monitoring. Ex. 1002 ¶¶ 86, 99.

Although Masterson fully discloses the elements of this limitation, Dr. Pearce notes that Bolduc similarly describes preventing performance of a treatment step if a perforation is detected. Ex. 1002 ¶ 100. Bolduc explains if the monitoring step fails due to the uterus being "weak, diseased, or ruptured," the device will be unable to transition to the treatment configuration: "The impaired uterus will not develop a reaction pressure . . . sufficient to overcome the compression characteristics of spring 89. Accordingly, pin 98 will not move into registration

with hole 101." *See* Ex. 1008 at 7:41-55; *see also* Ex. 1002 ¶¶ 87-90, 100. As discussed above with respect to limitation 9.3 of claim 9, Bolduc's treatment procedure would not work properly if the pin 98 is not initially locked, *i.e.*, if the perforation monitoring procedure using sleeve 44 is not performed prior to introducing the drug. Ex. 1002 ¶ 87-90, 100. Therefore, Bolduc also discloses preventing treatment of the uterus if a perforation is detected during the monitoring step. *Id.*.

Masterson and Bolduc disclose the elements of limitation 9.4. *Id.* ¶ 101. Accordingly, each and every element of claim 9 is taught and suggested by the combination of Masterson and Bolduc. *Id.* ¶ 101.

iii. Dependent Claims

The additional elements of claims 4, 6, and 7, which depend from claim 1, and claims 11-13 and 15, which depend from claim 9, are also taught or suggested by the combination of Masterson and Bolduc.

Claims 4 and 15: Claim 4 adds the requirement that "the treating step includes delivering thermal energy to the tissue." Similarly, claim 15 adds the requirement that "the ablation device is a thermal ablation device."

Masterson discloses treating the uterus by delivering thermal energy to the tissue, specifically, "heating a thermally conductive fluid within an internal body organ to thermally ablate or necrose the body organ." Ex. 1006 at Abstract; *see also id.* at 1:15-20, 6:10-13, 10:51-52; Ex. 1002 ¶¶ 81, 111. Accordingly, claims 4 and 15 would have been obvious in view of Masterson and Bolduc. Ex 1002 ¶¶ 82, 112.

Claims 6 and 11: Claim 6 adds the requirement of "if a perforation is detected in the monitoring step, providing feedback alerting a user to the presence of a perforation in the uterus." Claim 11 is identical to claim 6 except that it recites "activating a notification signal" rather than "providing feedback."

As discussed above with respect to claim 1 and 9 (*e.g.*, pp. 14-16, 18), Masterson and Bolduc disclose monitoring pressure within the uterus to detect a perforation. Ex. 1002 ¶¶ 83, 102. Masterson further discloses providing feedback and/or a notification signal to a user if the pressure monitoring detects an issue. *Id.* ¶ 84, 102; Ex 1006 at 17:41-46 ("[T]he care giver may be alerted to the possibility of a leak that is occurring within the hollow body organ"). The system described in Masterson "may be provided with a variety of alarms to indicate abnormal operating conditions," including "over or under pressure." *See id.* at 18:51-57. Such an alarm indicating an "under pressure" condition would provide feedback/a notification signal alerting the user to the presence of a perforation in the uterus. Ex. 1002 ¶¶ 84, 102. Accordingly, claims 6 and 11 would have been obvious in view of Masterson and Bolduc. *Id.* ¶¶ 85, 103.

Claim 7: Claim 7 recites "preventing performance of the treating step until after the monitoring step has been carried out."

As discussed above with respect to limitations 9.3 and 9.4 of claim 9, Masterson discloses preventing treatment if a perforation in the uterus is detected. *See*, *e.g.*, Ex. 1006 at 18:57-59; Ex. 1002 ¶ 86. To the extent that Masterson does not explicitly describe prevention of a treatment step until after the monitoring step has been carried out, this element is disclosed by Bolduc. Ex. 1002 ¶ 87. When

discussing the detection of "weak, diseased, or ruptured uterus walls," Bolduc explains that "monitoring of the integrity of the uterus walls is done before the drug material is introduced." Ex 1008 at 5:54-61. In other words, Bolduc discloses that the pressure monitoring step is carried out prior to the treatment step. Ex. 1002 ¶ 87. As previously discussed with respect to limitations 9.3 and 9.4 of claim 9, the Bolduc device will be unable to transition to the treatment configuration if the monitoring step fails. *See* Ex. 1008 at 7:41-55, 8:31-44; Ex. 1002 ¶¶ 88-90. Therefore, Bolduc discloses preventing performance of the treating step until after the monitoring step has been carried out. Accordingly, claim 7 would have been obvious in view of Masterson and Bolduc. *Id.* ¶¶ 91-92.

Claim 12: Claim 12 requires that "the inflation medium is introduced using a medical device separate from the ablation device."

A POSA reviewing the references would understand that components separate from the ablation device could be utilized independently or in conjunction with the ablation device in introducing inflation medium. Ex. 1002 ¶ 104. Masterson, for example, discloses a system 160 where reservoir 176 and flow control 180 are separate from ablation device 162, but coupled about flow line 178. Ex. 1006 at 17:32-50, FIG. 16. The separate reservoir assembly is used in conjunction with the ablation device in introducing inflation medium. *Id.* The '183 patent specification mentions an embodiment where components are separate and an embodiment where components are independently provided. Ex. 1001at 3:5-l; *see also* Ex. 1002 ¶ 104.

Additionally, as discussed above, Bolduc discloses a medical device for detecting a uterine perforation prior to treatment. Ex. 1002 ¶ 105. Dr. Pearce explains that a POSA would have viewed the combined teachings of the references as teaching sequential application of separate devices as a treatment approach, allowing a user to first confirm that a uterus has no perforations and subsequently treat the uterus via ablation with a separate device. *Id*. If the perforation detection method of Bolduc was performed prior to the ablation treatment described in Masterson, inflation medium would be introduced into the uterus via the Bolduc balloon followed by using the thermally conductive fluid of Masterson for ablation. *See* Ex. 1008 at 7:16-21 ("The fluid, as air, in cylinder 73 flows via tube 74 and passage 43 in tube 41 into the chamber 48 surrounded by sleeve member 44. . . the sleeve member 44 is expanded until it fills the entire uterine cavity 32"); *see also* Ex. 1002 ¶ 106. Performing separate detection and ablation steps might add complexity, but would benefit safety with confirmation that the uterus is sound prior to direct introduction of the Masterson fluid for ablation. Ex. 1002 ¶ 106. Masterson's disclosure of pressure monitoring during treatment would still provide benefit in continuously monitoring whether a perforation might occur during the treatment stage. *Id.* Accordingly, claim 12 would have been obvious in view of Masterson and Bolduc. *Id.* ¶ 107.

Claim 13: Claim 13 adds the requirement that "the inflation medium is introduced using the ablation device."

As noted above, Masterson discloses a system 160 where reservoir 176 and flow control 180 are separate from ablation device 162, but coupled about flow

line 178. The separate reservoir assembly is used in conjunction with the ablation device in introducing inflation medium. Masterson also describes its "thermal ablation device 10" as including "an elongate body 12 having a proximal end 14 and a distal end 16." Ex. 1006 at 10:52-54. The elongate body includes "a fluid inflow port 24 and a fluid outflow port 26 through which fluids may be introduced and withdrawn, respectively, to and from the uterus." *Id*. at 10:66-11:2; *see also* Ex. 1002 ¶¶ 108-109. The inflation medium of Masterson is introduced "using" both the reservoir assembly and the ablation device 162. Accordingly, claim 13 would have been obvious in view of Masterson and Bolduc. Ex. 1002 ¶ 110.

iv. Rationale to Combine

As discussed above and in Dr. Pearce's declaration, a POSA at the relevant time period would have understood that the endometrial ablation methods of Masterson would have detected a perforation in the uterus as a cause of fluid leakage. Ex. 1002 ¶¶ 57-58. Masterson specifically teaches monitoring the uterus for fluid leakage, as would occur if the uterus were perforated. Ex. 1006 at 17:41-46; Ex. 1002 ¶ 58. Masterson also discloses a pressure sensor for detecting abnormal low pressure conditions in the uterus, as well as a corresponding alerting functionality in response to low or abnormal pressure situations. Ex. 1006 at 11:8-10, 18:51-69. A POSA at the time would be familiar with the concept that a pressurized container leaking fluid exhibits pressure loss.[1] As such, a POSA at

[1] As Dr. Pearce explains, this concept would be readily apparent to a person of ordinary skill in the art. Ex. 1002 ¶ 58; *see also id*. ¶¶ 29-32. To the extent

the time would understand that fluid leakage from the uterus through the perforations would cause a loss of pressure detected by the sensor, which would trigger an abnormal conditions alert as set forth in Masterson. Ex. 1006 11:8-10, 18:51-69; Ex. 1002 ¶ 58; *see also* Section I.C., *supra*.

A person of ordinary skill is not one that disregards fundamental technical concepts or common sense, but is deemed to have "good reason to pursue the technical options within his or her technical grasp." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1732 (2007). Thus, to the extent Masterson does not anticipate the claims of the '183 patent, a POSA would view those claims as being obvious over Masterson in view of basic knowledge regarding pressurized container behavior.

Additionally, a skilled artisan would have recognized that a pressure sensor in an ablation device as in Masterson could be used to detect uterine perforations in view of Bolduc, which expressly discloses that ruptures (perforations) in the uterine wall would compromise pressurization of the uterus. Ex. 1008 at 7:41-55; Ex. 1002 ¶ 59. Dr. Pearce explains that a POSA would reasonably have incorporated pressure-based perforation monitoring, as disclosed by Bolduc, in an ablation device such as disclosed in Masterson in order to maximize the usefulness of Masterson's pressure sensor and thereby improve the safety of the ablation

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explicit substantiation is beneficial, see Ex. 1009 at 1:10-13 ("A common method of determining fluid leakage characteristics of a container is to measure pressure decay following pressurizing of the container with a suitable fluid").

device. Ex. 1002 ¶ 59. In fact, such a combination could have been accomplished without any modification to Masterson's device and method. *Id.* Masterson already discloses detecting "the possibility of a leak that is occurring within the hollow body organ" (*i.e.*, the uterus), and Bolduc merely confirms that such leaks could be caused by a perforation in the uterus such as a rupture in the uterine wall. *See* Ex. 1006 at 17:41-46; Ex. 1008 at 7:41-55; *see also* Ex. 1002 ¶ 59. Additionally, Masterson already discloses a pressure sensor capable of detecting abnormalities in intrauterine pressure that would indicate the presence of a perforation. *See* Ex. 1006 at 11:8-10; Ex. 1002 ¶ 59.

Furthermore, a POSA would have recognized that Masterson's endometrial ablation method would benefit from a safety mechanism that prevents treatment if the pressure test fails, as disclosed by Bolduc. Ex. 1002 ¶¶ 56, 60. As discussed above, Masterson itself discloses preventing treatment if the pressure sensor signals the controller that a low-pressure condition is detected. Ex. 1006 at 18:51-59. Bolduc further describes allowing treatment only if a pressure-monitoring step is passed. Ex. 1008 at 7:41-55, 8:31-44. Dr. Pearce explains that prevention of the ablation treatment described in Masterson could have been achieved by a POSA, for example, by simply delaying application of heating energy to the thermally conductive fluid until after the pressure monitoring step had been carried out to confirm the uterus walls were intact. Ex. 1002 ¶ 60. This would have required minimal, if any, modification to Masterson's system, because activation of the heating electrodes is not a prerequisite to performing Masterson's pressure detection step. *Id.*; *see also* Ex. 1006 at 13:66-14:44; Ex. 1002 ¶ 60. A POSA

would have recognized a benefit in delaying treatment until after perforation testing so as to ensure that treatment was not performed on a perforated uterus unable to contain heated ablation fluid, thus improving safety and efficacy. Ex. 1002 ¶ 60.

Moreover, Masterson and Bolduc are similarly directed to devices for transcervically accessing the uterus, and both disclose introducing an inflation medium into the uterus and monitoring intrauterine pressure. *See, e.g.,* Ex. 1006 at 3:48-51, 11:8-10, 14:26-29; Ex. 1008 at1:51-53, 6:15-18, 7:16-21; *see also* Ex. 1002 ¶ 61. In considering reasonable modifications to an ablation device as in Masterson, a POSA of medical device design would logically have looked to similar surgical instruments for guidance in applying known prior art approaches. Ex. 1002 ¶ 61. Therefore, a POSA would have been motivated to combine the teachings of Masterson and Bolduc to obtain an obvious and predictable combination of complementary features. *Id.* ¶ 62.

B. [Ground 2] Claims 2, 3, and 14 are Obvious under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson

Isaacson, published July 10, 1997, qualifies as a prior art printed publication under 35 U.S.C. § 102(b). As explained in Dr. Pearce's declaration and described in further detail below, claims 2, 3, and 14 of the '183 patent would have been obvious in view of Masterson, Bolduc, and Isaacson. Ex. 1002 ¶¶ 113-127.

Claim 2, which depends from claim 1, adds the requirement that "the treating step includes delivering electrical energy to the tissue." Claim 3, which depends from claim 2, further requires that "the electrical energy is RF energy."

Similarly, claim 14, which depends from claim 9, requires that "the ablation device is an RF ablation device."

Masterson recognizes the use of electrical energy as an ablation technique. Ex. 1006 at 3:1-4 (describing background prior art including electrical ablation apparatus), 3:48-51; *see also* Ex. 1002 ¶ 118. Dr Pearce notes that Masterson discloses the use of RF energy in its ablation method. *See* Ex. 1006 at 3:66-4:5 ("radio frequency current passes between the electrodes and through the thermally conductive fluid"); *see also* Ex. 1002 ¶ 118. Masterson discloses the use of fluid that is both thermally and electrically conductive. Ex. 1006 at 3:48-50, 4:9-11. While the primary ablative effect per Masterson is thermal, electrical energy could be delivered to the tissue with the use of an electrically conductive fluid as described. Ex. 1002 ¶ 118. Furthermore, Isaacson expressly identifies its ablative effect with regard to electric energy delivered to the tissue, in which an "electrical current is applied to cut 182 or treat the identified site." Ex. 1007 at 14:30-33, 17:3-4; *see also* Ex. 1002 ¶¶ 119-121. With respect to the electrical energy specifically being RF as recited claims 3 and 14, Masterson discloses applying RF energy an indicated above – and Isaacson further describes an electrosurgery system in which "[a] RF signal is delivered to electrode from generator unit 82 and applied to tissue 84." Ex. 1007 at 14:30-33; Ex. 1002 ¶¶ 122-127.

The obviousness of this combination is underscored by the numerous similarities between the teachings of these references. *Id.* ¶ 115. Isaacson, like Masterson and Bolduc, discloses a method and device for treating a uterus that incorporates a pressure monitor to detect whether the uterus is damaged or leaking.

Id. For example, Isaacson discloses "[p]ressure transducers to monitor the pressure of the fluid" in the uterus and states that "the possibility of a uterine perforation can be detected by these means." Ex. 1007 at 13:31-34, 14:24-29. Additionally, Isaacson and Masterson are similarly directed to ablation devices utilizing RF energy. *See, e.g., id.* at 14:30-33; Ex. 1006 at 4:2-4; *see also* Ex. 1002 ¶ 115. A POSA would have looked to analogous instruments when making improvements to an existing device. Ex. 1002 ¶ 115.

Dr. Pearce states that the pressure-monitoring ablation methods disclosed in Masterson would deliver RF electrical energy to the uterine tissue through its electrically conductive distension fluid. *Id.* ¶ 116. The '183 patent itself does not draw a bright line distinction between RF ablation and thermal ablation. *See, e.g.*, Ex. 1001 at 3:9-18. Regardless of whether the primary purpose of Masterson's RF energy is to heat the ablation fluid, the fluid could also conduct RF energy to the uterine tissue. Ex. 1002 ¶ 116. In addition, Isaacson confirms that RF electrical energy applied to the tissue has a therapeutic effect in endometrial ablation and would be desirable in the context of the '183 patent claims. *Id.* Accordingly, a person of ordinary skill in the art would have recognized the benefit in applying electrical energy to the uterine tissue through a conductive fluid, as disclosed in Masterson, as a mode of therapeutic ablation treatment. *Id.*

Therefore, a POSA would have found claims 2, 3 and 14 obvious over Masterson, Bolduc, and Isaacson. *Id.* ¶¶ 117, 121, 125, 127.

C. [Ground 3] Claim 5 is Obvious under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein

Himmelstein, issued September 24, 1985, qualifies as a prior art printed publication under 35 U.S.C. § 102(b). As explained in Dr. Pearce's declaration and described in further detail below, claim 5 of the '183 patent would have been obvious in view of Masterson, Bolduc, and Himmelstein. Ex. 1002 ¶¶ 128-141.

Claim 5, which depends from claim 1, adds the requirement that "the flowing step includes: passing an inflation medium through the ablation device and into the uterus" and "the monitoring step includes monitoring a pressure within the uterus for a predetermined period of time."

With respect to the first limitation of claim 5, which requires passing an inflation medium through the ablation device and into the uterus, this feature is disclosed by Masterson, as discussed above with respect to claim 9, limitation 9.1, and claim 13. Ex. 1002 ¶ 134; Ex. 1006 at 3:3-4, 9:43-45, 10:66-11:2.

With respect to the second limitation of claim 5, which requires monitoring a pressure within the uterus for a predetermined period of time, to the extent that Masterson and Bolduc do not expressly disclose performing their pressure monitoring steps for a predetermined amount of time, this aspect is taught by Himmelstein. Ex. 1002 ¶¶ 135-137. Dr. Pearce explains that, like Masterson and Bolduc, Himmelstein discloses a method of testing for leakage of fluid from an enclosed space by monitoring pressure. *See* Ex. 1009 at 1:10-13 ("A common method of determining fluid leakage characteristics of a container is to measure pressure decay following pressurizing of the container with a suitable fluid"); *see also* Ex. 1002 ¶ 138. Himmelstein teaches that its pressure monitoring method

involves stabilizing the pressure "for a preselected period of time," followed by a second monitoring step that runs for "a second preselected period of time," after which "the pressure within the container is again measured to determine any decrease therein resulting from leakage." Ex. 1009 at 1:29-37; *see also* Ex. 1002 ¶¶ 138-141.

Dr. Pearce explains that a POSA would have had good reason to incorporate monitoring pressure for a predetermined amount of time as taught by Himmelstein. *Id.* ¶¶ 130-131. From a mechanical standpoint, it would have been readily apparent to a POSA that a perforation in a container (or similarly, an enclosed cavity such as the uterus), would result in a loss of pressure over time due to fluid leakage. *Id.* This is evidenced by Himmelstein, which discloses that decay-based pressure testing methods were already known and commonly used more than a decade before the presumed priority date of the '183 patent. *Id.* A POSA would have looked to old and well-established pressure-based testing methods such as those disclosed by Himmelstein when considering improvements to the pressure-based testing ablation method disclosed by the combination of Masterson and Bolduc. *Id.* As explained by Dr. Pearce, applying a pressure test that runs for a predetermined amount of time, such as disclosed in Himmelstein, would allow the user to ensure that the uterus is capable of maintaining its integrity for a set period of time prior to treatment, as opposed to simply measuring the pressure in the uterus at any given moment, increasing the safety and reliability of the treatment method. *Id.* ¶ 132. Accordingly, claim 5 would have been obvious over the combination of Masterson, Bolduc, and Himmelstein. Ex. 1002 ¶¶ 133, 141.

D. [Ground 4] Claims 8 and 10 are Obvious under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron

Benaron, issued July 28, 1998, qualifies as a prior art printed publication under 35 U.S.C. § 102(b). As explained in Dr. Pearce's declaration and described in further detail below, claims 8 and 10 of the '183 patent would have been obvious in view of Masterson, Bolduc, and Benaron. Ex. 1002 ¶¶ 142-157.

Claim 8, which depends from claim 1, adds the requirement of "suspending performance of the treatment step if a perforation is detected in the monitoring step; detecting an override signal from a user input device; and permitting treatment of the uterus using the ablation device following detection of the override signal." Similarly, claim 10, which depends from claim 9, adds the requirement of "if a perforation is detected during the monitoring step, detecting an override signal from a user input device and permitting treatment of the uterus using the ablation device following detection of the override signal."

With respect to the first limitation of claim 8, which requires suspending performance of the treatment step if a perforation is detected, this feature is disclosed by Masterson. Ex. 1002 ¶ 148. As discussed above in Ground 1, Masterson discloses that "the care giver may be alerted to the possibility of a leak" in the uterus, and if such an "under pressure" condition (*i.e.*, a perforation) is detected "controller 170 is configured to cease operation of device 162 to provide increased safety to the patient." Ex. 1006 at 18:51-59; *see also* Ex. 1002 ¶ 148.

Although Masterson alone fully discloses all the elements of this limitation, Benaron similarly teaches use of an "analyzer" that can "monitor the operating state of tool 30 during operation," "provide suitable alarms and warnings," and

"produce an interlock control signal" that automatically ceases operation of the tool under certain conditions. *See* Ex. 1010 at 11:59-64; *see also* Ex. 1002 ¶¶ 149-150. This functionality is consistent with the teachings of Masterson, which discloses alerting and safeguard functionalities. Ex. 1006 at 18:48-59; *see also* Ex. 1002 ¶ 148.

With respect to the remaining limitations of claim 8, and claim 10 in its entirety, which require detecting an override signal from a user input device, whereby treatment is permitted, Benaron states that "the feedback/interlock feature can be overridden and/or disabled by the surgeon as a matter of choice." Ex. 1010 at 12:5-7; *see also id.* at 28:9-11; Ex. 1002 ¶¶ 151, 154. A POSA would therefore have understood Benaron to disclose a user input device enabling a user to input a input signal that would override the safety interlock. Ex. 1010 at 9:43-53 (an "interlock control signal may be used to disable or enable the tool"); *see also* Ex. 1002 ¶¶ 151-157.

As explained by Dr. Pearce, it would have been obvious to a POSA that the method disclosed by the combination of Masterson and Bolduc would benefit from a user override as taught by Benaron. *Id.* ¶¶ 144-145. Benaron, like both Masterson and Bolduc, describes a device that can be used during treatment of the uterus. *See* Ex. 1010 at 4:6-14 (discussing identification of "endometrial tissue (lining of the uterus)"); *see also* Ex. 1002 ¶ 145. Dr. Pearce testifies that applying a user override, as disclosed in Benaron, to a pressure-monitoring ablation treatment as disclosed in Masterson would provide the user operating the device

greater control over patient treatment, which would be desirable given that the user would typically be a highly skilled medical professional. *Id.* ¶ 146.

Accordingly, claims 8 and 10 of the '183 patent would have been obvious in view of Masterson, Bolduc, and Benaron. *Id.* ¶¶ 147, 156, 157.

E. [Ground 5] Claims 1-4, 6, 7, 9, and 11-15 are Obvious under 35 U.S.C. § 103 over Isaacson and Goldrath

Goldrath, issued April 2, 1996, is qualified as a prior art printed publication under 35 U.S.C. § 102(b). As described below, claims 1-4, 6, 7, 9, and 11-15 of the '183 patent would have been obvious in view of Isaacson and Goldrath. Ex. 1002 ¶¶ 158-160.

Isaacson discloses an electrosurgical device for surgical procedures within the uterine cavity. Ex. 1007 at 2:18-21. Consistent with conventional ablation procedures at the time (*see* Section I.C., *supra*), Isaacson describes introducing an isotonic fluid into the uterus. Ex. 1007 at 3:3-4. The device includes pressure transducers attached to the fluid inlet and outlet ports are used to measure the fluid pressure within the uterine cavity. *Id.* at 13:31-34. Isaacson further discloses detecting uterine perforations. *See id.* at 14:24-29; *see also* Ex. 1002 ¶ 161.

As explained by Dr. Pearce, Isaacson on its own arguably discloses, and certainly renders obvious, the claimed method of using a pressure sensor to monitor for the presence of a perforation in the uterus. Ex. 1002 ¶ 162. As discussed in Section I.C. above, fluid leakage through the perforation would compromise the uterus's ability to maintain pressure, and a POSA would have understood that perforation detection was a necessary consequence of the pressure-

sensing method described in Isaacson. *Id.* To the extent that pressure-based perforation monitoring is not expressly described in Isaacson, that would have been a readily apparent use for Isaacson's intrauterine pressure sensor in view of knowledge in the art (*e.g.*, knowledge that a leaking container exhibits pressure decay) or in view of the prior art teachings as in Goldrath. *Id.* ¶ 163. Goldrath expressly discloses measuring fluid pressure to detect whether fluid is escaping from the uterus into the patient's body, as would occur if the uterus were perforated. *See, e.g.*, Ex. 1013 at 2:53-60, 4:13-16, 6:33-35; *see also id.* at 2:9-12, 3:58-60; Ex. 1002 ¶ 163.

Additionally, Isaacson discloses a safety circuit that prevents treatment if the electrodes are not immersed in fluid, as would occur if the uterus were perforated and unable to retain the fluid. Ex. 1007 at 4:29-35; 22:19-26. Accordingly, Isaacson on its own arguably discloses, or at least renders obvious, the step of preventing treatment of the uterus if a perforation is detected found in independent claim 9. Ex. 1002 ¶ 164. To the extent Isaacson does not expressly disclose that its safety circuit prevents treatment based on the existence of a perforation, this would also have been readily apparent in view of knowledge of prior art teachings as in Goldrath. *Id.* Goldrath teaches the use of an electronic controller that prevents treatment if an abnormal pressure condition is detected, as would occur due to uterine perforation. Ex. 1013 at 2:57-65, 4:8-16; 5:44-46, 6:33-35; Ex. 1002 ¶ 164. In view of these teachings, a POSA would have understood that a safety circuit as disclosed in Isaacson could reasonably be used to prevent treatment if a pressure sensor detected a perforation in the uterus, and that such a use would have

added an additional level of safety beyond the electrode immersion detection discussed in Isaacson. Ex. 1002 ¶ 164.

The discussion below further illustrates that each and every element of claims 1-4, 6, 7, 9, and 11-15 of the '183 patent would have been obvious to a POSA in view of Isaacson and Goldrath. The particular citations listed are intended to be illustrative, not exhaustive. A detailed discussion of rationale to combine follows the discussion of the individual claims. *See* Section VI.E.iv, *infra*.

i. Independent Claim 1

Assuming that the **claim 1 preamble** is limiting, this language is disclosed by the combination of Isaacson and Goldrath:

'183 Patent	Isaacson and Goldrath
1. A method of ablating a uterus, comprising the steps of:	**Isaacson discloses:** **"**The present invention relates to an intralumen or intracavity electrosurgical device . . . for surgical procedures within the uterine cavity." 2:18-21. "The system is used specifically to treat . . . those needing endometrial ablation or resection." 3:23-26. **Goldrath discloses:** "U.S. Patent No. 5,242,390 discloses a method and apparatus for thermally ablating the lining of the uterus." 1:21-23; *see also* 2:19-21, 2:42-43, 4:41-44. *See also* Ex. 1002 ¶¶ 173-175.

Isaacson discloses a method of ablating a uterus: "The present invention relates to an intralumen or intracavity electrosurgical device . . . for surgical procedures within the uterine cavity." Ex. 1007 at 2:18-21; *see also id*. at 3:23-26 (discussing "endometrial ablation."). Similarly, Goldrath discloses improvements to a prior art system for "ablating the lining of the uterus." Ex. 1013 at 1:21-23,

2:19-21, 2:42-43; Ex 1002 ¶¶ 173-174. Accordingly, the combination of Isaacson and Goldrath discloses the elements of the preamble of claim 1. Ex. 1002 ¶ 175.

The combination of Isaacson and Goldrath discloses **limitation 1.1**:

'183 Patent	Isaacson and Goldrath
[1.1] inserting an ablation device into a uterus;	**Isaacson discloses:** "After insertion of the hysteroscope into the uterus, the electrode system at the distal end of the device is positioned relative to a surgical site in the uterus." 3:18-20. "After adequate cervical dilation . . . the resectoscope is inserted 170, an isotonic distension fluid such as saline or Ringer's lactate is inserted 172." 16: 27-31*; see also* FIG. 5. **Goldrath discloses:** "The patented [prior art] apparatus comprises a hysteroscope having a proximal portion for insertion into the uterus through the vagina." 1:23-25; *see also* 4:41-44, FIG. 1. *See also* Ex. 1002 ¶¶ 176-178.

Isaacson discloses inserting an ablation device into a uterus, specifically "insertion of the hysteroscope into the uterus" including an "electrode system" for ablation. Ex. 1007 at 3:18-20; *see also id.* at 16:27-31; FIG. 5. Similarly, Goldrath discloses improvements to an ablation apparatus utilizing "a hysteroscope having a proximal portion for insertion into the uterus through the vagina." Ex. 1013 at 1:23-25. Accordingly, the combination of Isaacson and Goldrath discloses the elements of limitation 1.1. Ex. 1002 ¶¶ 176-178.

The combination of Isaacson and Goldrath discloses **limitation 1.2**:

'183 Patent	Isaacson and Goldrath
[1.2] flowing an inflation medium into the uterus;	**Isaacson discloses:** "The method includes inserting an isotonic fluid into the uterus of the patient." 3:3-4. "After adequate cervical dilation . . . the resectoscope is inserted 170, an isotonic distension fluid such as saline or Ringer's lactate is inserted 172." 16: 27-31*; see also* FIG. 5. **Goldrath discloses:** "Such procedures often require the continuous introduction of large amounts of fluid into the uterine cavity so as to expand the

	size thereof." 4:44-46; *see also* 1:39-54. *See also* Ex. 1002 ¶¶ 179-180.

Isaacson discloses flowing an inflation medium into the uterus: "The method includes inserting an isotonic fluid into the uterus." Ex. 1007 at 3:3-4; *see also id.* 16:27-31; FIG. 5; Ex. 1002 ¶ 179. Goldrath likewise discloses "introduction of large amounts of fluid into the uterine cavity so as to expand the size thereof." Ex. 1013 at 4:44-46; *see also id.* at 1:39-54; Ex. 1002 ¶ 179. Accordingly, the combination of the prior art discloses the elements of limitation 1.2. *Id.* ¶ 180.

The combination of Isaacson and Goldrath discloses **limitation 1.3**:

'183 Patent	**Isaacson and Goldrath**
[1.3] monitoring for the presence of a perforation in the uterus using a pressure sensor; and	**Isaacson discloses:** "Pressure transducers to monitor the pressure of the fluid are attached at the inlet port 46 and outlet port 47. The pressure within the uterine cavity can be calculated based on the differential between the two transducers." 13:31-34. "[T]he possibility of a uterine perforation can be detected by these means." 14:24-29. **Goldrath discloses:** "[T]he invention included first and second fluid conduits for . . . delivering and drawing away first and second streams of physiologically compatible fluid into and out of the uterine cavity of a patient. The system includes means for measuring the magnitude of said first and second streams (by 'magnitude' is meant . . . pressure, . . . or any other measurable quality that reflects the quantity of fluid being introduced), and for . . . determining a value indicative of whether the magnitude of the second stream differs from the magnitude of the first stream. Means may be provided for terminating the flow of said first stream when the measured differential exceeds a preset value . . . thus indicating the patient is absorbing too much fluid." 2:48-65; *see also* 4:15-16. "[W]hile the system has been described with reference to devices for measuring weight, volume and flow rate, it is possible that it may utilize other types of measuring devices which measure other quantifiable physical parameters, such as, for example, fluid pressure." 6:31-35; *see also* 3:57-60. *See also* Ex. 1002 ¶¶ 181-185.

Isaacson discloses use of a pressure sensor to monitor intrauterine pressure: "Pressure transducers to monitor the pressure of the fluid are attached at the inlet port 46 and outlet port 47. The pressure within the uterine cavity can be calculated based on the differential between the two transducers." Ex. 1007 at 13:31-34; *see also* Ex. 1002 ¶ 181. Dr. Pearce explains that a POSA would have understood that Isaacson's pressure sensors would detect a perforation in the uterus, since there would be a drop in intrauterine pressure as fluid escapes through the perforation. Ex. 1002 ¶ 182. Indeed, Isaacson discloses monitoring for "the possibility of a uterine perforation." Ex. 1007 at 14:24-29; *see also* Ex. 1002 ¶ 182. The claimed subject matter would, at a minimum, have been apparent to a POSA reviewing Masterson with an understanding of the basic principles of leakage in a pressurized container. *See, e.g.*, Section I.C; Ex. 1002 ¶ 182.

To the extent that Isaacson does not expressly disclose using its pressure transducers to detect perforations, this would have been readily apparent in view of Goldrath. Ex. 1002 ¶ 183. Goldrath discloses an ablation system that measures the differential in "fluid pressure" between "first and second streams of physiologically compatible fluid into and out of the uterine cavity of a patient" so that "the surgeon knows that the patient is absorbing too much fluid and can terminate the procedure." Ex. 1013 at 2:48-65, 4:15-16, 6:31-35. Additionally, like Isaacson, Goldrath also teaches that one risk of an ablation procedure is "damage or rupture to the uterus." *Id*. at 3:57-60. Therefore, Goldrath discloses a pressure-based approach to detecting whether fluid is escaping into the body during treatment, as would occur if the uterus was perforated. Ex 1002 ¶ 183.

As explained by Dr. Pearce and discussed in more detail with respect to rationale to combine, a POSA would have used the Isaacson pressure sensor to monitor for uterine perforations and leaks, particularly in view of the pressure-based detection of excess fluid absorption described in Goldrath, to improve treatment safety. Ex. 1002 ¶ 184. Accordingly, the combination of Isaacson and Goldrath discloses the elements of limitation 1.3. *Id.* ¶ 185.

The combination of Isaacson and Goldrath discloses **limitation 1.4**:

'183 Patent	**Isaacson and Goldrath**
[1.4] treating the interior of the uterus using the ablation device.	**Isaacson discloses:** "The present invention relates to an intralumen or intracavity electrosurgical device . . . for surgical procedures within the uterine cavity." 2:18-21. "The system is used specifically to treat . . . those needing endometrial ablation." 3:23-26; *see also* 3:18-22. **Goldrath discloses:** "The method of the patent as described therein includes . . . delivering and introducing to the uterine cavity aqueous carbohydrate solution . . . heated to an endometrial tissue coagulating temperature. . . and thereby cause uniform and complete destruction of the endometrium." 1:39-59; *see also* 1:21-23. *See also* Ex. 1002 ¶¶ 186-188.

Isaacson discloses treating the interior of the uterus using the ablation device. For example, Isaacson describes an "electrosurgical device … for surgical procedures within the uterine cavity," and "[t]he system is used specifically to treat. . . those needing endometrial ablation." Ex. 1007 at 2:18-21, 3:23-26; *see also id.* at 3:18-22; Ex. 1002 ¶ 186. Similarly, Goldrath discusses a prior art ablation method utilizing a fluid "heated to an endometrial tissue coagulating temperature" that is applied to the interior of the uterus to cause "destruction of the

endometrium." Ex. 1013 at 1:39-59; Ex. 1002 ¶ 187. Accordingly, the combination of prior art discloses the elements of limitation 1.4. Ex. 1002 ¶ 188.

Accordingly, each and every element of claim 1 is taught and suggested by the combination of Isaacson and Goldrath. *Id.*

ii. Independent Claim 9

As Dr. Pearce explains, independent claim 9 is rendered obvious by the combination of Isaacson and Goldrath for reasons similar to those discussed above for claim 1. Ex. 1002 ¶¶ 205-213. These claims contain requirements substantively similar to those in claim 1, and the few differences presented are discussed below.

To the extent that the **claim 9 preamble** is limiting, this language is disclosed by the combination of Isaacson and Goldrath:

'183 Patent	Isaacson and Goldrath
9. A method of detecting a perforation in a uterus, comprising the steps of:	**Isaacson** at 2:18-21, 3:23-26, 13:31-34, 14:24-29. **Goldrath** at 1:21-23, 2:19-21, 2:42-43, 2:48-60, 3:47-60, 4:15-16, 4:41-44, 6:31-35. *See also* Ex. 1002 ¶ 205; discussion of claim 1 preamble, limitation 1.3.

As discussed above with respect to the preamble and limitation 1.3 of claim 1, Isaacson discloses monitoring pressure in a uterus and detecting uterine perforations, while Goldrath discloses pressure-based detection of fluid loss from the uterus in conjunction with ablation treatment, such as would occur if the uterus was perforated. Ex. 1002 ¶ 205. Accordingly, Isaacson and Goldrath discloses the elements of the preamble of claim 9. *Id.*

The combination of Isaacson and Goldrath discloses **limitation 9.1**:

'183 Patent	Isaacson and Goldrath

[9.1] passing an inflation medium into the uterus;	**Isaacson** at 3:3-4, 16:27-31, FIG. 5. **Goldrath** at 1:39-54, 4:44-46. *See also* Ex. 1002 ¶ 206; discussion of claim 1, limitation 1.2.

As discussed above with respect to limitation 1.2 of claim 1, Isaacson discloses flowing an inflation medium into the uterus, which is one way of passing such a medium into the uterus. *Id.* ¶ 206. Goldrath likewise discloses expanding or inflating the uterine cavity with fluid. *Id.* Accordingly, the prior art discloses the elements of limitation 9.1. *Id.*

The combination of Isaacson and Goldrath discloses **limitation 9.2**:

’183 Patent	Isaacson and Goldrath
[9.2] monitoring for the presence of a perforation in the uterus using a pressure sensor;	**Isaacson** at 13:31-34, 14:24-29. **Goldrath** at 2:48-60, 3:47-60, 4:15-16, 6:31-35,. *See also* Ex. 1002 ¶ 207; discussion of claim 1, limitation 1.3.

As discussed above with respect to limitation 1.3 of claim 1, Isaacson and Goldrath disclose “monitoring for the presence of a perforation in the uterus using a pressure sensor.” Ex. 1002 ¶ 207. Accordingly, Isaacson and Goldrath discloses the elements of limitation 9.2. *Id.*

The combination of Isaacson and Goldrath discloses **limitation 9.3**:

’183 Patent	Isaacson and Goldrath
[9.3] if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and	**Isaacson discloses:** “Second generator 162 is part of a safety circuit 160 that applies a separate signal across electrodes 152, 154 to detect whether the distal section is immersed in solution. Detector 164 senses whether there is a circuit through the solution at the distal section 106 so that treatment can be rendered safely. The detector generates a second signal that enables the user to actuate generator 158 and proceed with treatment.” 22:19-26; *see also* 4:29-5:2. **Goldrath discloses:** “The system also includes a controller for . . . determining a value indicative of whether the magnitude of the second stream differs from the magnitude of the first stream. Means may be provided for terminating the flow of said first stream when the measured differential exceeds a preset value.” 2:57-65; *see also* 4:8-16.

	"If the preset value is exceeded, the controller sends a signal to the valve 20 to stop the flow of fluid." 5:44-46; *see also* 6:33-36. *See also* Ex. 1002 ¶¶ 201-202, 208-211; discussion of claim 1, limitation 1.4.

As discussed above with respect to limitations 1.3 and 1.4, Isaacson and Goldrath disclose pressure-based monitoring for perforations and ablation of a uterus using an ablation device. Ex. 1002 ¶ 208. This combination further teaches or suggests carrying out a treatment step if the pressure monitoring step is completed without detection of a perforation. *Id.* ¶ 201-202, 208. Specifically, Isaacson discloses a "safety circuit" that prevents activation of the generator powering the electrosurgical device unless the system detects that the electrodes inside the uterus are immersed in the isotonic distension fluid. Ex. 1007 at 22:19-26, 4:29-5:2. Dr. Pearce explains that such a system would prevent the generator powering the ablation treatment from activating if the uterus were perforated such that it could not contain fluid sufficient to immerse the electrodes, and conversely such a system would permit the ablation treatment if no perforation was detected and the electrodes were immersed. Ex. 1002 ¶¶ 201, 208. A doctor using an ablation device would logically permit the procedure to continue after checking for a compromise in uterine wall integrity and finding none. *Id.* ¶ 208.

The claim feature is additionally found in Goldrath, which teaches the use of an electronic controller that prevents treatment if an abnormal pressure condition is detected. Ex. 1013 at 2:57-65, 4:8-16; 5:44-46, 6:33-35; Ex. 1002 ¶ 202, 209. Specifically, Goldrath describes a "controller" that calculates whether the detected pressure differential "exceeds a preset value," and "[i]f the preset value is exceeded, the controller sends a signal to the valve 20 to stop the flow of fluid, and

thereby prevent treatment from proceeding. Ex. 1013 at 2:57-65, 5:44-46; *see also id.* at 4:8-16, 6:33-36; Ex. 1002 ¶¶ 202, 209. Conversely, if the controller does not detect a pressure abnormality, the procedure is not terminated and ablation treatment is permitted. Ex. 1002 ¶ 209. Dr. Pearce explains that a safety circuit as disclosed in Isaacson could be used to prevent treatment if a pressure monitor detected a perforation in the uterus, as suggested by Goldrath. *Id.* ¶ 210. As explained by Dr. Pearce and discussed in more detail below with respect to rationale to combine, this would add an additional level of safety beyond the electrode immersion detection discussed in Isaacson. *Id.* Accordingly, the combination of prior art discloses the elements of limitation 9.3. *Id.* ¶ 211.

The combination of Isaacson and Goldrath discloses **limitation 9.4**:

'183 Patent	**Isaacson and Goldrath**
[9.4] if a perforation is detected during the monitoring step, preventing ablation of the uterus.	**Isaacson discloses:** "Second generator 162 is part of a safety circuit 160 that applies a separate signal across electrodes 152, 154 to detect whether the distal section is immersed in solution. Detector 164 senses whether there is a circuit through the solution at the distal section 106 so that treatment can be rendered safely. The detector generates a second signal that enables the user to actuate generator 158 and proceed with treatment." 22:19-26; *see also* 4:29-5:2. **Goldrath discloses:** "The system also includes a controller for . . . determining a value indicative of whether the magnitude of the second stream differs from the magnitude of the first stream. Means may be provided for terminating the flow of said first stream when the measured differential exceeds a preset value." 2:57-65; *see also* 4:8-16. "If the preset value is exceeded, the controller sends a signal to the valve 20 to stop the flow of fluid." 5:44-46; *see also* 6:33-36. *See also* Ex. 1002 ¶¶ 201-202, 212-213; discussion of claim 1, limitation 1.4; claim 9, limitation 9.3.

As discussed above with respect to limitation 9.3, Isaacson and Goldrath disclose preventing uterine ablation if a perforation is detected during the

monitoring step. Ex. 1007 at 22:19-26 (describing "safety circuit" that enables the user to "proceed with treatment"), 4:29-5:2; Ex. 1013 at 2:57-65 (describing a "controller" that can "terminat[e] the flow" of fluid), 5:44-46, 4:8-16, 6:33-36; *see also* Ex. 1002 ¶¶ 201-202, 212. Thus, the prior art discloses the elements of limitation 9.4. *Id.* ¶ 213.

Accordingly, each and every element of claim 9 is taught and suggested by Isaacson and Goldrath. *Id.* ¶ 213.

iii. Dependent Claims

The additional elements of claims 2, 3, 6, and 7, which depend from claim 1, and claims 11-14, which depend from claim 9, are also taught or suggested by the combination of Isaacson and Goldrath.

Claims 2, 3, and 14: Claim 2 adds the requirement that "the treating step includes delivering electrical energy to the tissue." Claim 3 further requires that "the electrical energy is RF energy." Similarly, claim 14 requires that "the ablation device is an RF ablation device."

With respect to claim 2, Isaacson discloses treating the uterus by delivering electrical energy to the tissue. For example, Isaacson describes a "system used to conduct electrosurgery with the probe 80," in which an "[a]n electrical current is applied to cut 182 or treat the identified site." Ex. 1007 at 17:3-4; *see also* Ex. 1002 ¶ 189. With respect to claims 3 and 14, Isaacson specifically describes a device that applies RF energy to the uterine issue to provide ablation treatment: "A RF signal is delivered to electrode from generator unit 82 and applied to tissue 84." Ex. 1007 at 14:30-33; *see also* Ex. 1002 ¶¶ 191, 223. Accordingly, claims 2,

3, and 14 would have been obvious in view of Isaacson and Goldrath. Ex. 1002 ¶¶ 190, 192, 223.

Claims 4 and 15: Claim 4 adds the requirement that "the treating step includes delivering thermal energy to the tissue." Similarly, claim 15 adds the requirement that "the ablation device is a thermal ablation device."

Isaacson recognizes that thermal energy may be used to ablate tissue. *See* Ex. 1007 at 3:23 ("The tissue is cut or heated with the electrode"); *see also* Ex. 1002 ¶ 193. While Isaacson's primary ablative effect is electrical, thermal energy would be delivered not only through the application of RF energy to the uterine tissue but also through the heating of the isotonic distension fluid used to disperse heat from the area of localized treatment. Ex. 1007 at 7:34-8:1 ("The bipolar conduction process results in the localized heating of tissue."); *see also id.* at 13:10-12, Ex. 1002 ¶ 193. This is very similar to the ablation procedure described in the '183 patent. *Id.*; *see also* Ex. 1001 at 3:9-18. In addition, Goldrath expressly discloses delivering thermal energy to ablate the tissue, describing a prior art method and apparatus for "thermally ablating the lining of the uterus," whereby a distension fluid is "heated to an endometrial tissue coagulating temperature" and "expose[d] to the entire endometrial surface" resulting in "destruction of the endometrium." Ex. 1013 at 1:21-23, 1:39-59; Ex. 1002 ¶¶ 194, 224.

As explained by Dr. Pearce and discussed in more detail below with respect to rationale to combine, a POSA would have recognized that the pressure-monitoring RF ablation methods disclosed in Isaacson would deliver thermal

energy to the uterine tissue, and would further have recognized that doing so would be therapeutically beneficial as discussed in Goldrath. Ex. 1002 ¶¶ 170-172, 195, 225. Accordingly, a POSA would have recognized the benefit in applying thermal energy to the uterine tissue, as disclosed in Isaacson, as a mode of therapeutic ablation treatment. *Id.* Accordingly, claims 4 and 15 would have been obvious in view of Isaacson and Goldrath. Ex. 1002 ¶¶ 196, 226.

Claims 6 and 11: Claim 6 adds the requirement of "if a perforation is detected in the monitoring step, providing feedback alerting a user to the presence of a perforation in the uterus." Claim 11 is identical to claim 6 except that it recites "activating a notification signal" rather than "providing feedback."

As discussed above with respect to claims 1 and 9 (*e.g.*, pp. 40-42, 44), the combination of Isaacson and Goldrath discloses monitoring pressure within a uterus to detect a uterine perforation. Ex. 1002 ¶¶ 197, 214. Dr. Pearce testifies that the teachings of Isaacson render obvious providing feedback alerting a user to a detected uterine perforation, since otherwise the perforation detection would serve no purpose. *Id.* However, to the extent that this element is not expressly described by Isaacson, Goldrath discloses providing such feedback. Ex. 1002 ¶¶ 198, 214. For example, Goldrath explains that the controller discussed above with respect to limitations 9.3 and 9.4 is capable of "automatically stopping the flow of fluid into the uterus" if an abnormal pressure condition is detected. Ex. 1013 at 4:8-21. Goldrath also explains that, based on the controller's calculation of the pressure differential, "the surgeon knows that the patient is absorbing to much fluid." *Id.* Goldrath therefore describes providing feedback alerting the user to a

pressure abnormality, such as would result from a perforation in the uterus. Ex. 1002 ¶¶ 198-199, 214. Accordingly, claims 6 and 11 would have been obvious in view of Isaacson and Goldrath. *Id.* ¶¶ 200, 215.

Claim 7: Claim 7 recites "preventing performance of the treating step until after the monitoring step has been carried out."

As discussed above with respect to limitations 9.3 and 9.4 of claim 9, the combination of Isaacson and Goldrath discloses preventing the treatment of the uterus if a perforation in the uterus is detected. *See* Ex. 1002 ¶¶ 201-203. In particular, Isaacson discloses a "safety circuit" that requires the distal end of the ablation device to be immersed in isotonic distension fluid in the uterus before the generator powering the ablation treatment can be actuated. Ex. 1007 at 4:29-5:2, 22:19-26. This safety circuit prevents performance of the ablation treatment, which requires activation of the generator, until after it detects that the uterus is capable of retaining a sufficient quantity of distension fluid, a condition that would not be met in the event of a uterine perforation. Ex. 1002 ¶ 201. Accordingly, in view of this aspect of Isaacson as well as Isaacson's pressure-monitoring disclosure and the pressure-based treatment prevention taught by Goldrath, a POSA would have used a safety circuit such as the one disclosed in Isaacson to prevent treatment until after a pressure monitoring step has been carried out. *Id.* ¶¶ 202-203. Accordingly, claim 7 would have been obvious in view of Isaacson and Goldrath. *Id.* ¶ 204.

Claim 12: Claim 12 requires that "the inflation medium is introduced using a medical device separate from the ablation device."

A POSA reviewing the references would understand that components separate from the ablation device could be utilized independently or in conjunction with the ablation device in introducing the inflation medium. Ex. 1002 ¶ 216. For example, Isaacson discloses a fluid reservoir 34 and valve or pump mechanism that are separate from ablation device 10 but coupled to conduit 46. *See, e.g.*, Ex. 1007 at 8:7-15; 16:11-13 ("The fluid source 34 may communicate with a value or pump mechanism (not shown)."); FIG. 1A; Ex. 1002 ¶ 216. The '183 patent specification mentions an embodiment where components are separate and an embodiment where components are independently provided. Ex. 1001 3:5-9.

Additionally, Goldrath discloses a "system for delivering fluid during hysteroscopic surgery." Ex. 1013 at Abstract. Goldrath expressly states that its fluid delivery system may be used in conjunction with other devices for uterine surgery: "the circulation system of the present invention is equally applicable for use with other types of hysteroscopes and interuterine cannulas." *Id.* at 4:49-52. Goldrath, therefore, teaches that its fluid delivery system is not integral to the specific ablation device disclosed and may be separate from it. Ex. 1002 ¶ 217.

In view of the combined teachings of these references, a POSA would reasonably have used a separate device for delivering inflation medium when treating the uterus with an ablation device. Ex. 1002 ¶ 218. Dr. Pearce explains that use of separate devices for fluid delivery and ablation therapy would enable inflation of the uterus with fluid prior to introducing the ablation device. *Id.* This would allow the user to perform other operations requiring uterine distension before ablating the uterus, such as using an endoscope to visually inspect the uterus

in order to improve safety. *Id.* Indeed, Goldrath specifically describes examining the interior of a fluid-distended uterus with a hysteroscope prior to initiating ablation. *See* Ex. 1013 1:39-59; 2:3-8; 4:44-46. Accordingly, claim 12 would have been obvious in view of Isaacson and Goldrath. Ex. 1002 ¶ 219.

Claim 13: Claim 13 depends from claim 9 and adds the requirement that "the inflation medium is introduced using the ablation device."

As noted above, Isaacson discloses a fluid reservoir 34 and valve or pump mechanism that are separate from ablation device 10 but coupled to conduit 46. *See, e.g.*, Ex. 1007 at 8:7-15; 16:11-13; Fig 1A. The separate reservoir and vale or pump are used in conjunction with the ablation device in introducing inflation medium. Ex. 1002 ¶ 220.

Isaacson also describes its "hysteroscopic electrosurgical device" as including "probe 12 having proximal end 14 and distal end 16." Ex. 1007 at 6:25-27. "A first fluid channel 29 is formed within inner sheath 19 for allowing isotonic fluid to flow to an aperture at the distal end of the probe 12," *i.e.*, into the uterus. *Id*. at 7:2-5; *see also* Ex. 1002 ¶ 221. The inflation medium of Isaacson is introduced "using" both the reservoir/valve/pump assembly and the ablation device 10. Accordingly, claim 13 would have been obvious in view of Isaacson and Goldrath. Ex. 1002 ¶ 222.

iv. Rationale to Combine

As discussed above and in Dr. Pearce's declaration, a POSA at the relevant time period would have understood that the endometrial ablation methods of Isaacson would have detected a perforation in the uterus when determining the

intrauterine pressure. Isaacson specifically describes detecting uterine perforations as part of its endometrial ablation method, and also discloses a pressure sensor for monitoring intrauterine pressure. *See* Ex. 1007 at 13:31-34, 14:25-29; Ex. 1002 ¶ 166. A POSA at the time would be familiar with the concept that a pressurized container leaking fluid exhibits pressure loss.[2] As such, a POSA at the time would understand that Isaacson's pressure sensor performs this function, since it is a basic physical principle that fluid leakage from the uterus through the perforations would cause a loss of pressure that would be detected by the sensor. Ex. 1002 ¶ 166*; see also* Section I.C., *supra.*

A person of ordinary skill is not one that disregards fundamental technical concepts or common sense, but is deemed to have "good reason to pursue the technical options within his or her technical grasp." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1732 (2007). Thus, to the extent Isaacson does not anticipate the claims of the '183 patent, a POSA would view those claims as being obvious over Isaacson in view of basic knowledge regarding pressurized container behavior.

Additionally, a skilled artisan would have recognized that a pressure sensor in an ablation device as in Isaacson could be used for perforation detection in view

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[2] As Dr. Pearce explains, this concept would be readily apparent to a person of ordinary skill in the art. Ex. 1002 ¶ 166; *see also id.* ¶¶ 29-32. To the extent explicit substantiation is beneficial, see Ex. 1009 at 1:10-13 ("A common method of determining fluid leakage characteristics of a container is to measure pressure decay following pressurizing of the container with a suitable fluid").

of Goldrath, since Goldrath expressly describes using pressure measurements to detect whether "the amount of fluid leaving the uterus is less than the amount entering," as would occur if fluid were escaping through the perforations. Ex. 1013 at 2:48-65; *see also id.* at 2:9-19, 6:31-315; Ex. 1002 ¶ 167. Dr. Pearce explains that a POSA would have had good reasons to combine the teachings of Isaacson and Goldrath in this manner in order to maximize the usefulness of Isaacson's pressure sensor and thereby improve the safety of the ablation device. Ex. 1002 ¶ 168. In fact, such a combination could have been accomplished without any modification to Isaacson's device and method, because Isaacson already expressly discloses a pressure sensor and detecting uterine perforations. *Id.*

Additionally, a POSA would have recognized that Isaacson's endometrial ablation method would benefit from a safety mechanism that prevents treatment if the pressure test fails, such as disclosed by the combination of Isaacson and Goldrath. Ex. 1002 ¶ 169. In fact, Isaacson itself teaches the use of a "safety circuit" that prevents activation of the generator powering the ablation treatment if the electrodes in the uterus are not immersed in fluid, *e.g.*, due to fluid escaping through uterine perforations. Ex. 1007 at 4:29-5:2, 22:19-26; *see also* Ex. 1002 ¶ 169. While Isaacson does not expressly disclose the use of its pressure sensors in its safety circuit, Goldrath discloses preventing treatment if a controller detects an abnormal fluid pressure condition. Ex. 1013 at, *e.g.*, 2:57-65, 5:44-46.

Dr. Pearce explains that prevention of the ablation treatment described in Isaacson could have been achieved by a POSA, for example, by simply delaying

application of electrical energy to the uterine tissue until after the pressure monitoring step had been carried out to confirm the uterus was intact. Ex. 1002 ¶ 169. This would require minimal modification to Isaacson's system, because activation of the ablation electrodes is not a prerequisite to performing Isaacson's pressure detection step. *Id.*; *see also* Ex 1007 at 16:27-17:26. Dr. Pearce explains that a POSA would have recognized that a pressure sensor could be incorporated into a safety circuit as disclosed by Isaacson, and that such a circuit could be configured to terminate or prevent treatment if an abnormal condition is detected, as demonstrated by the controller disclosed in Goldrath. Ex. 1002 ¶ 169. A POSA would have recognized a benefit in delaying treatment until after perforation testing so as to ensure that the ablation treatment was not performed on a perforated uterus unable to contain fluid, thus improving safety and efficacy. *Id.*

A POSA would further have recognized that the pressure-monitoring RF ablation methods disclosed in Isaacson would deliver thermal energy to the uterine tissue. Ex. 1002 ¶ 170. The '183 patent does not draw a bright line distinction between RF ablation and thermal ablation. *See, e.g.*, Ex. 1001 at 3:9-18; Ex. 1002 ¶ 170. Regardless of the extent that the thermal effect of Isaacson's ablation procedure is controlled, that reference does disclose delivery of thermal energy to the uterine tissue. In addition, Goldrath confirms that thermal energy applied to the tissue, including via the distension fluid, has a therapeutic effect in endometrial ablation and would be desirable in the context of the '183 patent claims. Ex. 1002 ¶ 170. Accordingly a POSA would have recognized the benefit in applying

thermal energy to the uterine tissue, as disclosed in Isaacson, as a mode of therapeutic ablation treatment. *Id.*

Moreover, Isaacson and Goldrath are similarly directed to fluid-based ablation devices for treating the uterus, and both recognize the need to monitor fluid pressure in conjunction with the treatment. *See, e.g.,* Ex. 1007 at 2:18-21, 13:31-34, 16:26-31; Ex. 1013 at 1:21-23, 2:19-21, 2:42-60, 6:31-35; *see also* Ex. 1002 ¶ 171. It would have been readily apparent to a POSA to consider analogous instruments when making improvements to an existing device. Ex. 1002 ¶ 171. Therefore, a POSA would have had good reasons to combine the teachings of Isaacson and Goldrath, as explained above, to obtain an obvious and predictable combination of complementary features. *Id.* ¶ 172.

F. [Ground 6] Claim 5 is Obvious under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein

As explained in Dr. Pearce's declaration and described in further detail below, claim 5 of the '183 patent would have been obvious in view of Isaacson, Goldrath, and Himmelstein. Ex. 1002 ¶¶ 227-242.

Claim 5, which depends from claim 1, adds the requirement that "the flowing step includes: passing an inflation medium through the ablation device and into the uterus" and "the monitoring step includes monitoring a pressure within the uterus for a predetermined period of time."

With respect to the first limitation of claim 5, which requires passing an inflation medium through the ablation device and into the uterus, Isaacson describes an isotonic distension fluid (*i.e.*, a fluid that distends or inflates the uterus)

that is passed into the uterus through the ablation device. Ex. 1002 ¶¶ 233-235; *see also* Ex. 1007 at 3:3-4, 16:27-1, FIG. 5. Specifically, Isaacson discloses a "hysteroscopic, electrosurgical device 10" having a "first fluid channel . . . for allowing isotonic fluid to flow to an aperture" in the device and into the uterus. *Id.* at 6:25-27, 7:2-5; *see also* Ex. 1002 ¶ 234.

With respect to the second limitation of claim 5, which requires monitoring a pressure within the uterus for a predetermined period of time, to the extent that Isaacson and Goldrath do not expressly disclose performing their pressure monitoring steps for a predetermined amount of time, this aspect is taught by Himmelstein. Ex. 1002 ¶¶ 236-238. Like Isaacson and Goldrath, Himmelstein discloses a method of testing for leakage of fluid by monitoring pressure. *See* Ex. 1009 at 1:10-13 ("A common method of determining fluid leakage characteristics of a container is to measure pressure decay following pressurizing of the container with a suitable fluid"). Himmelstein teaches that its pressure monitoring method involves stabilizing the pressure "for a preselected period of time," followed by a second step that runs for a "second preselected period of time," after which "the pressure within the container is again measured to determine any decrease therein resulting from leakage." Ex. 1009 at 1:29-37; *see also* Ex. 1002 ¶¶ 239-240.

Dr. Pearce explains that a POSA would have had good reasons to incorporate monitoring pressure for a predetermined amount of time as taught by Himmelstein. *Id.* ¶¶ 229-232, 241. From a mechanical standpoint, it would have been readily apparent to a POSA that a perforation in a container (or similarly, an enclosed cavity such as the uterus), would result in a loss of pressure over time due

to fluid leakage. *Id.*¶ 230 This is evidenced by Himmelstein, which discloses that decay-based pressure testing methods were already known and commonly used more than a decade before the presumed priority date of the '183 patent. *Id.* A POSA would have looked to old and well-established pressure-based testing methods such as those disclosed by Himmelstein when considering improvements to the pressure-based testing ablation method disclosed by the combination of Isaacson and Goldrath. *Id.*

As explained by Dr. Pearce, applying the pressure test that runs for a predetermined amount of time, as disclosed in Himmelstein, would allow the user to ensure that the uterus is capable of maintaining its integrity for a set period of time prior to treatment, as opposed to simply measuring the pressure in the uterus at any given moment, increasing the safety and reliability of the treatment method. *Id* ¶ 231. Accordingly, claim 5 would have been obvious over the combination of Isaacson, Goldrath, and Himmelstein. *Id*. ¶ 242.

G. [Ground 7] Claims 8 and 10 are Obvious under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron

As explained in Dr. Pearce's declaration and described in further detail below, claims 8 and 10 of the '183 patent would have been obvious in view of Isaacson, Goldrath, and Benaron. Ex. 1002 ¶ 243-259.

Claim 8, which depends from claim 1, adds the requirement of "suspending performance of the treatment step if a perforation is detected in the monitoring step; detecting an override signal from a user input device; and permitting treatment of the uterus using the ablation device following detection of the

override signal." Similarly, claim 10, which depends from claim 9, adds the requirement of "if a perforation is detected during the monitoring step, detecting an override signal from a user input device and permitting treatment of the uterus using the ablation device following detection of the override signal."

With respect to the first limitation of claim 8, which requires suspending performance of the treatment step if a perforation is detected, this feature is disclosed by Goldrath. Ex. 1002 ¶¶ 249, 252. As discussed above with respect to Ground 5, Goldrath discloses that the controller for its fluid pressure monitoring operation "sends a signal to the valve 20 to stop the flow of fluid" upon detection of a pressure abnormality such as would be caused by a uterine perforation. Ex. 1013 at 5:44-46; *see also id*. at 6:4-6; Ex. 1002 ¶ 249. Benaron likewise teaches suspension of a treatment step. Ex. 1002 ¶¶ 250-252. Dr. Pearce explains that Benaron teaches use of an "analyzer" that can "monitor the operating state of tool 30 during operation," "provide suitable alarms and warnings," and "produce an interlock control signal" that automatically ceases operation of its surgical tool under certain conditions. *See* Ex. 1010 at 11:59-64; *see also* Ex. 1002 ¶ 250.

With respect to the remaining limitations of claim 8 and claim 10 in its entirety, which require detecting an override signal from a user input device, whereby treatment is permitted, Benaron states that "the feedback/interlock feature can be overridden and/or disabled by the surgeon as a matter of choice." Ex. 1010 at 12:5-7; *see also id.* at 28:9-11; Ex. 1002 ¶¶ 244, 253. Dr. Pearce testifies that a POSA would therefore have understood Benaron to disclose a user input device enabling the surgeon to enter an input signal that would override the safety

interlock. Ex. 1002 ¶¶ 253, 256; *see also* Ex. 1010 at 9:43-53 (describing an "interlock control signal [that] may be used to disable or enable the tool").

As explained by Dr. Pearce, it would have been obvious to a POSA that the method disclosed by the combination of Isaacson and Goldrath would benefit from a user override as taught by Benaron. *Id. ¶¶* 245-248, 254. Benaron, like both Isaacson and Goldrath, describes a device that can be used during treatment of the uterus. *See* Ex. 1010 at 4:6-14 (discussing identification of "endometrial tissue (lining of the uterus)"); *see also* Ex. 1002 ¶ 246. Dr. Pearce testifies that applying a user override, as disclosed in Benaron, to a pressure-monitoring ablation treatment, as taught by Isaacson, would provide the user operating the device greater control over patient treatment, which would be desirable given that the user would typically be a highly skilled medical professional. *Id.* ¶ 247. Accordingly, claims 8 and 10 would have been obvious in view of Isaacson, Goldrath, and Benaron. Ex. 1002 ¶¶ 258, 259.

VII. CONCLUSION

For the reasons set forth above, claims 1-15 of the '183 patent are unpatentable, and an *inter partes* review of these claims should be instituted.

Respectfully submitted,

Dated: April 11, 2016

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

VIII. 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.

IX. APPENDIX – LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 6,872,183 to Sampson *et al.*
1002	Declaration of John Anthony Pearce, Ph.D.
1003	John Anthony Pearce *curriculum vitae*
1004	File History of U.S. Patent No. 6,872,183 to Sampson *et al.*
1005	U.S. Patent No. 6,813,520 to Truckai *et al.*
1006	U.S. Patent No. 5,891,094 to Masterson *et al.*
1007	PCT Application No. WO 97/24074 to Isaacson *et al.*
1008	U.S. Patent No. 3,871,374 to Bolduc *et al.*
1009	U.S. Patent No. 4,542,643 to Himmelstein
1010	U.S. Patent No. 5,785,658 to Benaron *et al.*
1011	Complaint for Patent Infringement, Hologic, Inc. et al. v. Minerva Surgical, Inc., 15-cv-01031-SLR (November 6, 2015)
1012	*Perforation*, Webster's Medical Dictionary
1013	U.S. Patent No. 5,503,626 to Goldrath
1014	R. Quiñones-Guerrero, *Liquid Distention Media*, HYSTEROSCOPY, H. van der Pas et al. (eds.) (1983)

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), this is to certify that I caused to be served a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,872,183 (and accompanying Exhibits 1001 through 1014) by overnight courier (Federal Express or UPS), on this 11th day of April, 2016, on the Patent Owner at the correspondence address of the Patent Owner as follows:

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