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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MINERVA SURGICAL, INC.,
Petitioner,

v.

HOLOGIC, INC.,
Patent Owner.

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IPR2016-00868
Patent 6,872,183 B2

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Before MEREDITH C. PETRAVICK, MITCHELL G. WEATHERLY and TIMOTHY J. GOODSON, *Administrative Patent Judges.*

PETRAVICK, *Administrative Patent Judge.*

# DECISION
Instituting *Inter Partes* Review
*37 C.F.R. § 42.108*

# I. INTRODUCTION

## *Background*

Minerva Surgical, Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–15 of U.S. Patent No. 6,872,183 B2 (Ex. 1001, "the '183 patent"). Paper 3 ("Pet."). Hologic, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

We have authority to institute an *inter partes* review under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

We determine that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. For the reasons described below, we institute an *inter partes* review of claims 1–15.

## *Patent Owner's Motion to Accept E-mail Submission Of Preliminary Response*

As an initial matter, we turn to Patent Owner's Motion to Accept Email Submission of the Preliminary Response. The deadline for filing the Preliminary Response was July 14, 2016. Paper 7, 1. On July 14, 2016, Patent Owner attempted to, but was unable to file the Preliminary Response due to errors in the new PTAB E2E filing system. *Id.* at 1–2. Patent Owner contacted the administrative staff at the Patent Trial and Appeal Board ("Board") and was advised to file the Preliminary Response via email to trials@uspto.gov. *Id.* at 2.

On July 14, 2016, Petitioner submitted the Preliminary Response and accompanying exhibits to the trials@uspto.gov and served the documents on the Petitioner. *Id.* at 2, Ex. 3001. Patent Owner additionally submitted a Motion to Accept Email Submission requesting acceptance of the e-mail submission, as required by 37 C.F.R. § 42.6 (b)(2)(i)(A). Paper 7. Petitioner did not oppose the Motion. Ex. 3001, 1.

On July 18, 2016, the Board notified Patent Owner via reply e-mail that the submission was accepted and would be uploaded into the PTAB E2E system on Patent Owner's behalf. *Id.* Thus, the filing date of the Preliminary Response and the accompanying exhibits is shown as July 18, 2016 in the PTAB E2E system.

Given these circumstances, Patent Owner's Motion to Accept Email Submission is granted, and the Preliminary Response and accompanying exhibits are considered to have been timely filed on July 14, 2016.

*Related Proceedings*

The parties indicate that the '183 patent is at issue in *Hologic, Inc. v. Minerva Surgical, Inc.*, Case No. 1:15-cv-01031-SLR, in the U.S. District Court for the District of Delaware. Pet. 18, Paper 6, 2.

*The '183 Patent*

The '183 patent is titled "System and Method for Detecting Perforations in a Body Cavity" and issued on March 29, 2005, from an application filed on May 24, 2004. Ex. 1001, (22), (45), (54). The '183 patent claims priority through a chain of continuation applications to a provisional application filed on November 10, 1999. *Id.* at (60), (63).

The ’183 patent discloses that certain medical procedures are carried out within a body cavity without direct endoscopic visualization. *Id.* at 1:34–35. For example, ablation of the endometrial layer of the uterus involves insertion of an elongated ablation device without the use of a hysteroscope. *Id.* at 1:35–38. If the uterus has a perforation, the ablation device could inadvertently pass through the perforation into the bowl causing injury. *Id.* at 1: 38–41. Thus, there is a need to detect the presence of perforations in a body cavity.

The ’183 patent discloses a method of detecting perforations in a body cavity by pressurizing the cavity and detecting whether the body cavity can maintain the pressurized condition. *Id.* at 1:14–17. A liquid or gas fluid is used to pressurize the cavity, and a pressure sensing system monitors whether the pressure is sustained for a predetermined test period. *Id.* at 1:50–57. If the pressure is not sustained, a physician is alerted to check for perforations. *Id.* at 1:54–57, 2:37–44.

The ’183 patent’s perforation detection system may be part of a Radio Frequency (“RF”) ablation system or other alternative systems or may be used independently of a larger treatment system. *Id.* at 2:13–20. For example, alternative systems include “thermal ablation devices in which heated liquid is circulated through a balloon positioned within the body cavity.” *Id.* at 3:1–5.

In a preferred embodiment, the system may include a pre-test lockout feature that prevents RF power delivery to the ablation system unless perforation detection has been performed and no perforations were detected. *Id.* at 1:58–62, 2:45–58.

*Illustrative Claims*

Claims 1 and 9 of the '183 patent are independent. Claims 2–8 depend from claim 1. Claims 11–15 depend from claim 9. Claims 1 and 9, reproduced below, are illustrative of the '183 patent.

> 1. 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.
>
> 9. A method of detecting a perforation in a uterus, comprising the steps of:
> passing an inflation medium into the uterus;
> monitoring for the presence of a perforation in the uterus using a pressure sensor;
> if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device; and
> if a perforation is detected during the monitoring step, preventing ablation of the uterus.

*Asserted Grounds of Unpatentability*

Petitioner asserts the following grounds of unpatentability:

| No. | Ground | Claim(s) | Prior Art |
|---|---|---|---|
| 1 | § 103 | 1, 4, 6, 7, 9, 11–13, and 15 | Masterson[1] and Bolduc[2] |
| 2 | § 103 | 2, 3, and 14 | Masterson, Bolduc, and Isaacson[3] |

[1] U.S. Patent No. 5,891, 094 (issued April 6, 1999) (Ex. 1006).
[2] U.S. Patent No. 3,871,374 (issued on Mar. 18, 1975) (Ex. 1008).
[3] Int'l Patent Application WO 97/24074 (published July 10, 1997) (Ex. 1007).

| No. | Ground | Claim(s) | Prior Art |
|---|---|---|---|
| 3 | § 103 | 5 | Masterson, Bolduc, and Himmelstein[4] |
| 4 | § 103 | 8 and 10 | Masterson, Bolduc, and Benaron[5] |
| 5 | § 103 | 1–4, 6, 7, 9, and 11–15 | Isaacson and Goldrath[6] |
| 6 | § 103 | 5 | Isaacson, Goldrath, and Himmelstein |
| 7 | § 103 | 8 and 10 | Isaacson, Goldrath, and Benaron |

Petitioner proffers a Declaration of John Anthony Pearce, Ph.D. (Ex. 1002) to support its analysis regarding patentability in the Petition.

## II. ANALYSIS

### *Claim Interpretation*

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as they would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

[4] U.S. Patent No. 4,542,643 (issued Sept. 24, 1985) (Ex. 1009).
[5] U.S. Patent No. 5,786,658 (issued Jul. 28, 1998) (Ex. 1010).
[6] U.S. Patent No. 5,503,626 (issued Apr. 2, 1996) (Ex. 1013).

*Order of Steps*

Claim 1 recites a step of "monitoring for the presence of perforations in the uterus using a pressure sensor" ("the monitoring step") and a step of "treating the interior of the uterus using the ablation device" ("the treating step"). Ex. 1001, 8:13–15.

Claim 9 recites the monitoring step and two conditional steps — "if no perforation is detected during the monitoring step, permitting ablation of the uterus using an ablation device" ("the permitting ablation step" and "if a perforation is detected during the monitoring step, preventing ablation of the uterus" ("the preventing ablation step"). *Id*. at 8:42–48.

Patent Owner argues that "[u]nder the broadest reasonable construction . . ., the step of monitoring for the presence of perforations in the uterus must occur ***before*** the step of treating the uterus using an ablation device." Prelim. Resp. 7. According to Patent Owner, the fundamental purpose of the perforation detection method of the '183 patent "is to ensure patient safety by monitoring for perforations ***before*** ablation is performed" and it would be contrary to this fundamental purpose if the monitoring step occurred after the treatment step. *Id.* at 7–8 (citing Ex. 1001, Abstract, 1:38–46, 1:54–57, 6:28–30, 6:51–55, 7:12–20, 7:27–29). Additionally, Patent Owner argues that claim 9 requires the monitoring step to occur before the treating step because claim 9 recites what happens if the result of the monitoring step is that no perforation is detected (i.e., permitting ablation) or if the result of the monitoring step is that a perforation is detected (i.e., preventing ablation). *Id.* at 9.

Petitioner does not explicitly propose a construction addressing the order of the monitoring and treating steps. Petitioner, however, does imply

that the claims allow for the monitoring step to be performed simultaneously with the treatment step. For example, Petitioner argues that Masterson meets the monitoring and treating step because Masterson discloses monitoring the pressure during an ablation treatment and discloses stopping or continuing the ablation treatment based on a detected pressure condition. *See e.g.*, Pet. 19 ("the ablation device would be permitted to continue operating if no such problems are detected").

"Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one. . . . However, such a result can ensue when the method steps implicitly require that they be performed in the order written." *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 59 (Fed. Cir. 2001). To determine if "the steps of a method claim that do not otherwise recite an order, must nonetheless be performed in the order in which they are written," we first

> look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written. . . . If not, we next look to the rest of the specification to determine whether *it* "directly or implicitly requires such a narrow construction." . . . If not, the sequence in which such steps are written is not a requirement.

*Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369–70 (Fed. Cir. 2003) (quoting *Interactive Gift Express, Inc.*, 256 F.3d at 1343) (internal citations omitted).

Claim 1 recites the monitoring step and then recites the treating step, but does not actually recite that the steps must occur in the order written. The language of claim 1 neither grammatically nor logically requires that the monitoring and treating steps be performed in the order written. In other words, the language of claim 1 does not require that the monitoring step

occur before the treating step or preclude the monitoring step from occurring simultaneously with the treating step.

The Specification of the ’183 patent also does not directly or implicitly require that the monitoring step must occur only before the treating step. Patent Owner argues for its narrow reading of claim 1 based upon the Background of the Invention section of the ’183 patent, which discloses a need to detect perforations prior to treatment and the description of preferred embodiments in which the monitoring step occurs before the treating step. *See* Prelim. Resp. 7–8. We are not persuaded, however, because Patent Owner’s argument does not account for other disclosures of the ’183 patent, which indicate that the perforation detection system can be used with alternative devices or independently of a treatment system. *See* Ex. 1001, 2:17–20, 2:66–3:9, 7:63–8:1. The ’183 patent, itself, informs us that

> although the system is described with reference to a particular embodiment, many other configurations are suitable for implementing the teachings of the invention. Those having ordinary skill in the art will certainly understand from the embodiment disclosed herein that many modifications are possible without departing from the teachings hereof. All such modifications are intended to be encompassed within the following claims.

Ex. 1001, 8:2–8. Thus, we are not persuaded that the Specification of the ’183 patent directly or implicitly requires that the monitoring step must occur only before the treating step. We will not import an order of steps from the Specification into the claim. *See Altiris, Inc.*, 318 F.3d at 1370 (embodiments disclosed in the specification are not determinative of the meaning of disputed claim terms).

Similar to claim 1, claim 9 recites the monitoring step and then recites the preventing ablation step or permitting ablation step. Logically the language of claim 9 requires that the monitoring at least begin before the preventing of ablation or permitting of ablation, because the preventing or permitting is conditioned on the result of the monitoring step.

Patent Owner implies that the preventing ablation step or permitting ablation step must be the preventing of the *initiation* of ablation. *See* Prelim. Resp. 7–8. Thus, according to Patent Owner, the monitoring step must be completed before the initiation of the ablation. *Id.* The language of claim 9 does not recite preventing or permitting *initiation* of ablation based on the results of the monitoring step. It does not preclude the monitoring step from occurring simultaneously with the ablation or the preventing ablation step or permitting ablation step from encompassing preventing or permitting ablation to continue after it has begun. For the same reasons as discussed above, we are not persuaded that the Specification of the '183 patent directly or implicitly requires that the monitoring step must occur before the initiation of ablation or the preventing or permitting ablation steps must prevent or permit initiation of ablation. We, thus, are not persuaded by Patent Owner that the monitoring step must occur only before the initiation of the ablation.

At this point in the proceeding and on this record, we are not persuaded by Patent Owner that claim 1 or claim 9 should be construed to require that the step of monitoring for the presence of perforations in the uterus must occur before initiation of ablation of the uterus, nor are we persuaded that these claims preclude monitoring simultaneously with ablation.

*"inflation medium" and "perforation"*

Petitioner proposes constructions for the claim terms "inflation medium" and "perforation." Pet. 10–11. Patent Owner disagrees with Petitioner's proposed constructions and argues that explicit construction is unnecessary to resolve the issues presented in the Petitioner. Prelim. Resp. 6. We determine that no explicit claim construction is required for these claims terms for purposes of this Decision. *See, e.g.*, *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'").

*Obviousness*

Section 103 forbids issuance of a claim when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103. The ultimate determination of obviousness under § 103 is a question of law based on underlying factual findings. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1996)). These underlying factual considerations consist of: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of non-obviousness such as "commercial success, long felt but unsolved needs, failure of others,

etc."[7] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham*, 338 U.S. at 17–18).

*Ground One — Masterson and Bolduc*

Petitioner contends that claims 1, 4, 6, 7, 9, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. Pet. 11–29. In addition to the cited references themselves, Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 50–62. Patent Owner disputes that the claims are unpatentable over Masterson and Bolduc. Prelim. Resp. 14–19, 20–25, 30–35.

For the reasons discussed below, we determine that Petitioner shows a reasonable likelihood that claims 1, 4, 6, 7, 9, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc.

*Overview of Masterson*

Masterson is titled "System for Direct Heating of Fluid Solution in a Hollow Body Organ and Methods" and issued on April 6, 1999. Ex. 1006, [45], [54]. Masterson discloses "methods and devices for thermally ablating hollow body organs, such as the uterus, by heating a thermally conductive fluid disposed within the organ." *Id.* at 1:17–20.

Masterson discloses an ablation method in which a thermally conductive fluid is heated within the uterus to destroy the lining of the uterus. *Id.* at 9:35–37. The fluid is also electrically conductive and an RF current is used to heat the fluid. *Id.* at 9:38–40.

[7] At this stage in the proceedings, the record contains no evidence or arguments concerning secondary considerations.

Figure 16 of Masterson is reproduced below.

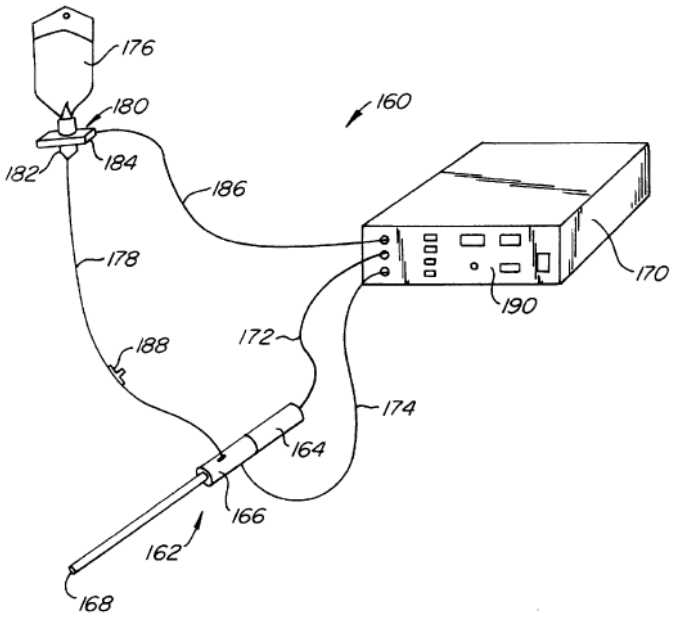


FIG. 16.

Figure 16 depicts Masterson's system. Distal end 168 of device 162 is inserted into the uterus. To fill the uterus, fluid flows from fluid reservoir 176, through device 162, and out of distal end 168 of device 162 into the uterus. *Id.* at 14:7–44. Masterson discloses that it is desirable that the intrauterine pressure be maintained during the procedure, and, optionally provides flow control sensor 180 to monitor and control the flow of fluid into the uterus. *See id.* at 14:37–39, 17:41–50, 17:41–44. "By detecting a flow of liquid from fluid reservoir 176, . . . the care giver may be alerted to a possible leak somewhere within system 160 or within the patient," including within the uterus. *Id.* at 17:44–50; *see also id.* at 7:36–30, 14:34–37 (also disclosing monitoring fluid flow for leaks). "Controller 170 may then be programmed to stop operation of thermal ablation device 162 when a

threshold amount of liquid has passed through drip chamber 182." *Id.* at 17:56–60.

Additionally, Masterson discloses a pressure sensor that monitors intrauterine pressure when the device is within a patient. *Id.* at 11:8–15. Masterson states:

> [C]ontroller 170 may be 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.

*Id.* at 18:51–59.

*Overview of Bolduc*

Bolduc is titled "Dispensing Instrument" and issued on March 18, 1975. Ex. 1008, [54], [45]. Bolduc discloses a system for dispensing a fluid into the canals of the Fallopian tubes. *Id.* at Abstract. Bolduc discloses "monitoring the integrity of the walls of the uterus and fluid pressure system of the instrument before the material is introduced into the uterine cavity." *Id.* at 2:38–42.

Figure 1 of Bolduc is reproduced below.

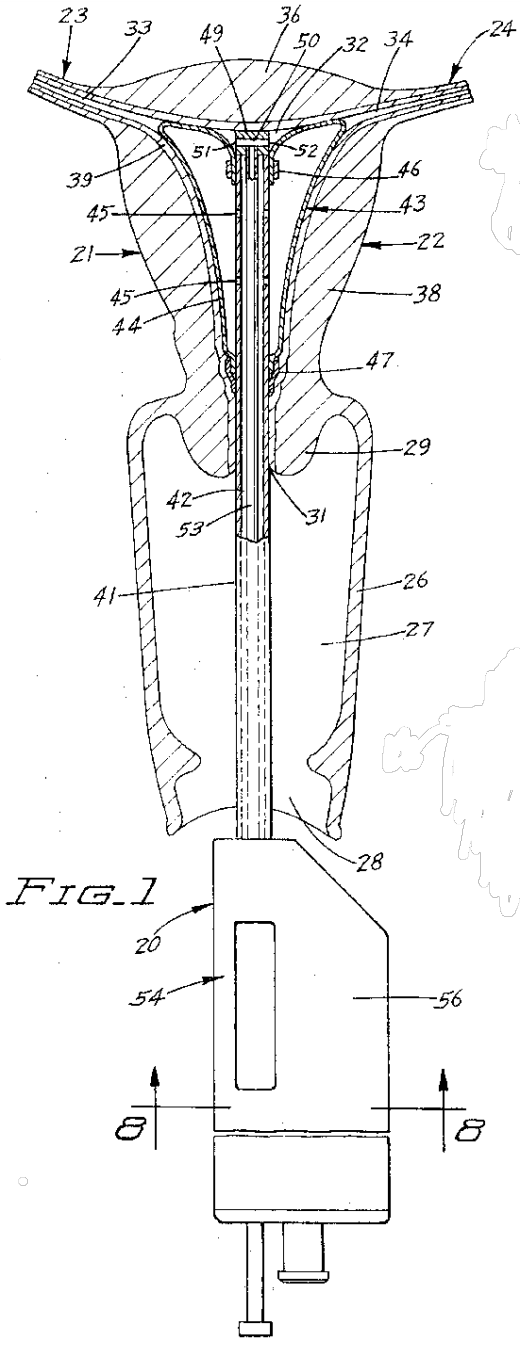


Figure 1 of Bolduc depicts the dispensing device in place in the uterus. Bolduc discloses sleeve member 44, made from a soft and relaxed flexible and elastic material. *Id.* at 4:41–44. When the device is inserted into the uterus, air is forced into sleeve member 44 by actuator 97 to pressurize

sleeve member 44 to a predetermined pressure and to displace the uterine cavity. *Id.* at 5:46–50.

> The pressure applied to the sleeve member 44 will increase if the walls of the uterus have sufficient strength to resist expansion of the sleeve member 44. Weak, diseased or ruptured uterus walls and enlarged uteri are detected by the instrument as the sleeve member 44 will not be subjected to the predetermined fluid pressure since these uterus walls cannot contain the sleeve member. This checking or monitoring of the integrity of the uterus walls is done before the drug material is introduced into the uterine cavity.

*Id.* at 5:47–61.

Additionally, Bolduc discloses that its device has a control mechanism for preventing the dispensing a fluid into the canals of the Fallopian tubes, in the event that the walls of the uterus are weak, diseased or ruptured. *Id.* at 6:39–7:63. The control mechanism produces an audio click to signal to the operator that the uterus has a size and strength to accommodate the expanded sleeve member 44. *Id.* at 7:63–8:3. No audio click is produced if the uterus walls are weak or if there is a leak in the fluid system. *Id.* at 8:3–6. A further indication of weak uterus walls is that an actuator assembly will move back to its initial position. *Id.* at 7:51–58.

*Independent Claims 1 and 9*

Petitioner contends that claims 1 and 9 are unpatentable over Masterson and Bolduc. Pet. 12–22. Petitioner contends that Masterson teaches all of the steps of claims 1 and 9. *See id.* at 12–22. In particular, Petitioner contends that Masterson discloses monitoring for the presence of a perforation in the uterus using a pressure sensor because Masterson discloses pressure sensor 31 that monitors intrauterine pressure when device 10 is in the patient and discloses that controller 170 has an alarm that indicates

abnormal conditions, such as over and under pressure. *Id.* at 14–15, 18–19. Petitioner states "[t]o the extent Masterson does not expressly disclose detecting uterine perforations based on pressure measurement, this feature is also taught by Bolduc." *Id.* at 15. According to Petitioner, Bolduc teaches detecting a uterine perforation using a pressure sensor. *Id.* at 15–16, 19–20. Petitioner argues that it would have been obvious to one of ordinary skill in the art given the disclosures of Bolduc and Masterson, that Masterson's alarm indicating under pressure condition in the uterus would detect undesirable perforations in the uterus. *Id.* at 27–28. Petitioner reasons that one of ordinary skill in the art "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 device." Pet. 27–28.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows a reasonable likelihood that claims 1 and 9 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc.

Patent Owner argues that 1) neither Masterson nor Bolduc disclose the monitoring step, 2) that the combination of Masterson and Bolduc does not disclose the monitoring step occurring before the treating step, and 3) that Petitioner fails to provide a sufficient rationale to combine Masterson and Bolduc in the manner recited by the claims. Prelim. Resp. 20–25, 31–35.

First, Patent Owner argues that neither Masterson nor Bolduc discloses monitoring for the presence of a perforation in the uterus using a pressure sensor. Patent Owner argues that "pressure sensor 31 . . . is

described only in connection with monitoring and controlling the pressure in the uterus; Masterson does not describe using a pressure sensor to detect leaks." *Id.* at 21. According to Patent Owner, to detect leaks, Masterson discloses using a flow sensor to monitor the volume of fluid passing into the uterus at a generally constant pressure. *Id.* at 21, 23. Patent Owner further argues that because Masterson discloses that leaked fluid is continuously replenished, the pressure in Masterson will remain generally constant, and thus leaks do not result in significant pressure decreases. *Id.* at 21–22.

Patent Owner's argument is unpersuasive because it does not account for Masterson's explicit disclosure of detecting abnormal operating conditions, such as under pressure. As Petitioner points out, Masterson discloses that controller 170 has an alarm that indicates abnormal conditions, such as over and under pressure. Ex. 1006, 18:51–59. Thus, contrary to Patent Owner's argument, Masterson discloses that pressure decreases (i.e., under pressure conditions) can occur and represent an abnormal condition justifying cessation of the procedure. Masterson discloses that intrauterine pressure is monitored by pressure sensor 31 when device 10 is in the patient. *Id.* at 11:8–15. Monitoring for abnormal pressure conditions is akin to how perforations are monitored in the '183 patent. The '183 discloses monitoring for perforation by using a pressure sensor to detect under pressure. *See* Ex. 1001, 2:35–46, 5:30–36. In any event, Bolduc discloses that failing to maintain a predetermined pressure is an indication of ruptures of the uterus. Ex. 1008, 5:47–61; *see also* Ex. 1002 ¶¶ 84, 86, 99 (testimony of Dr. Pearce that perforations of the uterus would result in loss of pressure).

Second, Patent Owner argues that the combination of Masterson and Bolduc does not disclose the monitoring step occurring before the initiation

of the treating or ablation. Prelim. Resp. 23–25. This argument is not commensurate with the scope of claim 1 or claim 9. As discussed above, neither claim 1 nor claim 9 requires that the monitoring step occurs before the initiation of the treating or ablation. We, thus, find Patent Owner's second argument unpersuasive on the record currently before us.

Third, Patent Owner argues that Petitioner fails to provide a sufficient rationale to combine Masterson and Bolduc in the manner recited by the claims. Pet. 31–35. Patent Owner's argument is unpersuasive. Petitioner reasons that one of ordinary skill in the art "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 device." Pet. 27–28. Petitioner's reasoning is supported by the testimony of Dr. Pearce. *See* Ex. 1002 ¶ 59. On this record, we are persuaded that Petitioner's evidence and analysis is sufficient to establish that it would have been obvious to a person of ordinary skill in the art to use Masterson's pressure sensor and controller that detects abnormal conditions, such as under pressure conditions, to monitor for perforations in the uterus.

*Dependent Claims 4, 6, 7, 11–13, and 15*

Petitioner contends that claims 4, 6, 7, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. Pet. 22–26. Patent Owner argues these claims are patentable for the same reasons it argues that claims 1 and 9 are patentable. Prelim. Resp. 30–31.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine that Petitioner shows a

reasonable likelihood that claims 4, 6, 7, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. For the reasons discussed above with respect to the patentability of claims 1 and 9 over Masterson and Bolduc, we find Patent Owner's argument unpersuasive.

*Ground Two — Masterson, Bolduc, and Isaacson*

Petitioner contends that claims 2, 3, and 14 are unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson. Pet. 29–31. Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 113–127. Patent Owner disputes that the claims are unpatentable over Masterson, Bolduc, and Isaacson. Prelim. Resp. 26–28.

For the reasons discussed below, we determine that Petitioner shows a reasonable likelihood that claim 14 is unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson, but fails to shows a reasonable likelihood that claims 2 and 3 are unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson.

*Claims 2 and 3*

Claim 2 depends from claim 1 and additionally requires that "the treating step includes delivering electrical energy to the tissue." Claim 3 depends from claim 2 and additionally requires that "the electrical energy is RF energy."

According to Petitioner, Masterson discloses that its fluid is electrically conductive, as well as thermally conductive. Pet. 30 (citing Ex. 1006, 3:48–50, 4:9–11). Petitioner argues that "[w]hile 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." Pet. 30

(citing Ex. 1002 ¶ 118). Petitioner further argues that Isaacson teaches applying RF electrical energy to tissue during ablation. *Id.* at 30–31. Given these disclosures, Petitioner asserts that "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.* at 31.

Patent Owner disputes that Masterson discloses applying electrical or RF energy to the tissue. Prelim. Resp. 26–28. Patent Owner also argues that Petitioner fails to explain how Masterson could be modified to deliver electrical, rather than thermal, energy to the tissue. *Id.* at 27–28.

We are persuaded by Patent Owner that Petitioner fails to meet its burden of showing it would have been obvious to a person of ordinary skill in the art to modify Masterson to apply electrical energy to the uterine tissue through the fluid. Masterson discloses supplying RF current to electrodes 46, 48, located in a heating chamber in the distal end of device 162. Ex. 10006, 11:54–56. The electrodes then pass current through the fluid within a heating chamber, to heat the fluid between the electrodes. *Id.* at 11:58–60. Masterson states:

> The tubing of the elongated body . . . at the distal tip . . . is preferably constructed of a dialectic material so that the electrodes 46, 48 are electrically isolated from the patient. This protects the patient from unintended contact with the electrodes which may result in electric burns and fouling of the electrodes.

*Id.* at 11:61–66. Masterson discloses that heated fluid then flows out of the heating chamber into the uterus (*id.* at 12:28–29), but does not disclose that the fluid carries electrical energy directly to the tissue of the uterus. Petitioner's argument fails to account for these disclosure of Masterson,

which suggest that electrical energy should not be applied directly to the tissue.

Further, neither Petitioner nor Dr. Pearce provide a sufficient explanation as to why one of ordinary skill in the art would make the proposed modification in light of the teachings of Masterson, Bolduc, and Isaacson. Isaacson does not cure the deficiency of Masterson because Isaacson also does not teach using an electrically conductive fluid to apply electrical energy to tissue. As discussed in detail below, Isaacson discloses applying electrodes directly to the tissue. See *e.g.*, Ex. 1007, 11:21–28. Petitioner provides no other explanation sufficient to establish that the proposed modification to Masterson would have been obvious.

*Claim 14*

Claim 14 depends from claim 9 and additionally requires that "the ablation device is an RF ablation device." As Petitioner points out, Masterson's system uses RF energy in its ablation method. Pet. 30 (citing Ex. 1006, 3:66–4:5). On this record and at this point in the proceeding, Petitioner's evidence is sufficient to show a reasonable likelihood that claim 14 is unpatentable over Masterson and Bolduc.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine Petitioner shows a reasonable likelihood that claim 14 is unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson, but fails to shows a reasonable likelihood that claims 2 and 3 are unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson.

*Ground Three – Masterson, Bolduc, and Himmelstein*

Claim 5 depends from claim 1 and additionally recites that "the monitoring step includes monitoring a pressure within the uterus for a predetermined amount of time."

Petitioner contends that claim 5 is unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein. Pet. 32–33. Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 128–141. Patent Owner disputes that the claims are unpatentable over Masterson, Bolduc, and Himmelstein. Prelim. Resp. 28–30.

Petitioner argues that "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." Pet. 32. According to Petitioner, Himmelstein discloses a method of testing for leakage of fluid from an enclosed space by monitoring pressure and discloses testing for a preselected period of time. *Id.* at 32–33 (citing Ex. 1009, 1:10–13, 1:29–37). Petitioner contends that

> 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.

Pet. 33.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows a reasonable likelihood that claim 5 is unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein.

Patent Owner disputes that the proposed modification would have been obvious because Himmelstein does not disclose using its device for a medical purpose. Prelim Resp. 29. Patent Owner also argues that because Masterson discloses that leaked fluid is continuously replenished, the pressure in Masterson will remain generally constant, and thus leaks do not result in significant pressure decreases. *Id.*

Patent Owner's arguments are unpersuasive. Himmelstein's failure to disclose that its device is used for a medical purpose is not dispositive of obviousness. *See KSR*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one."). As Petitioner points out, all of Masterson, Bolduc, and Himmelstein relate to method of testing for leaking fluids. *See* Pet. 32.

As discussed above with regards to claims 1 and 9, contrary to Patent Owner's argument, Masterson's explicitly discloses detecting abnormal operating conditions, such as under pressure. As Petitioner points out, Masterson discloses that controller 170 has an alarm that indicates abnormal conditions, such as over and under pressure. Ex. 1006, 18:51–59. Thus, Masterson discloses that pressure decreases (i.e., under pressure conditions) can occur. Further, Bolduc discloses that failing to maintain a predetermined pressure is an indication of ruptures of the uterus. Ex. 1008, 5:47–61; *see also* Ex. 1002 ¶¶ 84, 86, 99 (testimony of Dr. Pearce that perforations of the uterus would result in loss of pressure).

*Ground Four — Masterson, Bolduc, and Benaron*

Petitioner contends that claims 8 and 10 are unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron. Pet. 34–36. Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 142–157. Patent Owner argues these claims are patentable for the same reasons it argues that claims 1 and 9 are patentable. Prelim. Resp. 30–31.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine the Petitioner shows a reasonable likelihood that claims 8 and 10 are unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron. For the reasons discussed above with respect to the patentability of claims 1 and 9 over Masterson and Bolduc, we find Patent Owner's argument unpersuasive.

*Ground Five – Isaacson and Goldrath*

Petitioner contends that claims 1, 4, 6, 7, 9, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. Pet. 36–56. Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 160–226. Patent Owner disputes that the claims are unpatentable over Masterson and Bolduc. Prelim. Resp. 39–48.

For the reasons discussed below, we determine that Petitioner shows a reasonable likelihood that claims 1, 4, 6, 7, 9, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath.

*Overview of Isaacson*

Isaacson is titled "Apparatus and Method for Electrosurgery" and was published on July 10, 1997. Ex. 1007, (54), (43). Isaacson discloses a device that can be used for "correction of congenital uterine defects and

endometrial ablation." *Id.* at 1:15–19. Isaacson's electrosurgical device can be used in the uterine cavity. *Id.* at 2:18–21. The electrosurgical device has an electrode assembly that is used to remove tissue and that is powered by a RF energy source. *Id.* at 7:10–8:11.

The electrosurgical device provides a fluid flow to the surgical site during cutting. *Id.* at 13:11–26. Isaacson discloses that

> [t]he fluid flow rate can depend upon a number of variables including the inflow pressure, the tubing diameter, the outflow diameter, the mean arterial pressure of the patient, and the amount of bleeding or degradation. 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. Alternatively, pressure transducer can be directly placed in the uterus with the device.

*Id.* at 13:27–14:2. Isaacson further discloses that

> by monitoring the volume and flow rate of the fluid discharged from the uterus and comparing such discharge volume with the monitored volume and flow rate of the isotonic fluid charge to the uterus, the possibility of a uterine perforation can be detected by these means.

*Id.* at 14:25–29.

In one embodiment, Isaacson discloses a safety circuit, which prevents delivery of current to the electrodes is the electrodes are not immersed in the fluid. *Id.* at 4:29–5:2, 22:29–26.

*Overview of Goldrath*

Goldrath is titled "Fluid Delivery System for Hysteroscopic Surgery" and issued on April 2, 1996. Ex. 1013, [45], [54]. Goldrath discloses a system for delivering fluid to the uterus during hysteroscopic procedures,

where the amount of fluid is closely monitored. *Id.* at 42–47. Goldrath states:

> The system includes means for measuring the magnitude of said first and second streams (by "magnitude" is meant flow rate, pressure, volume, weight, or any other measurable quality that reflects the quantity of fluid being introduced), and for sending first and second electrical signals indicative thereof. The system also includes a controller for receiving said first and second signals 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 values; e.g., the amount of fluid leaving the uterus is less than the amount entering by more than a selected value, thus indicating the patient is absorbing too much fluid.

*Id.* at 2:52–67; *see also id.* at 6:31–35 (also disclosing measuring pressure as an alternative to volume and flow rate).

*Claims 1 and 9*

Petitioner contends that claims 1 and 9 are unpatentable over Isaacson and Goldrath. Pet. 36–47. Petitioner contends that Isaacson teaches all steps of claims 1 and 9. *See id.* at 38–47. In particular, Petitioner contends that Isaacson discloses monitoring for the presence of a perforation in the uterus by calculating the pressure within the uterine cavity based on the differential between the pressure of the fluid at an inlet port and an outlet port. Pet. 40–42 (citing Ex. 1007, 13:31–34). Isaacson also discloses that uterine perforations can be detected by monitoring the volume and flow rate of the fluid discharge from the uterus. Ex. 1007, 14:25–29. Petitioner states "[t]o 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." Pet. 41. According to Petitioner, Goldrath discloses measuring the differential in fluid pressure between first and second streams of fluid into and out of the uterine cavity so that a surgeon knows if a patient is absorbing too much fluid and can terminate the procedure. *Id.* at 41–42 (citing Ex. 1013, 2:48–65, 4:15–16, 6:31–35). Petitioner argues that it would have been obvious to one of ordinary skill in the art, given the disclosures of Isaacson and Goldrath, to use Isaacson's pressure sensor to monitor for uterine perforations, to improve treatment safety. *Id.* at 42, 52–54.

Petitioner also relies upon Goldrath to teach the permitting ablation step and preventing ablation step of claim 9. *Id.* at 45. According to Petitioner, Goldrath teaches the use of an electronic controller that prevents treatment if an abnormal pressure condition is detected. *Id.* (citing Ex. 1013, 2:57–65, 4:8–16, 5:44–46, 6:33–35). Petitioner argues that adding a safety mechanism that prevents treatment if the pressure test fails, would improve safety and efficacy. *Id.* at 45–46, 54–56.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows a reasonable likelihood that claims 1 and 9 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath.

Patent Owner argues that: 1) neither Isaacson nor Goldrath discloses monitoring for the presence of perforations in the uterus using a pressure sensor; 2) neither Isaacson nor Goldrath discloses the preventing ablation step and permitting ablation step of claim 9; and 3) Petitioner fails to provide a sufficient rationale to combine Isaacson and Goldrath in the manner recited by the claims. Prelim. Resp. 35–49, 56–61.

First, Patent Owner argues that neither Isaacson nor Goldrath discloses monitoring for the presence of perforations in the uterus using a pressure sensor. *Id.* at 39–43. Patent Owner argues that Petitioner's analysis is based upon an "assumption that a leak would cause a decrease in fluid volume and, correspondingly, a decrease in fluid pressure," which is only true "in closed systems where fluid can only flow out of the uterus via a leak." *Id.* at 40. Patent Owner further argues that even if Isaacson detects a decrease in intrauterine pressure, this would not necessarily mean the presence of a perforation. *Id.* at 41.

Patent Owner's argument is unpersuasive because it attacks the references individually when the Petitioner relies upon a combination of Isaacson and Goldrath to meet the monitoring step. *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981) ("One cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references") (citation omitted).

Further, at this point in the proceeding, Patent Owner's argument that leaks cause decreases in pressure only in closed systems is unsupported by evidence. Mere attorney arguments and conclusory statements that are unsupported by factual evidence have little probative value. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997); *see also In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). In contrast to Patent Owner's statement, Goldrath's disclosure indicates that the magnitude of the streams can be determined by measuring pressure. *See* Ex. 1013, 2:52–62; 6:31–35.

Additionally, we are not persuaded by Patent Owner that the combination of Isaacson and Goldrath fails to meet the monitoring step because Isaacson's detection of a decrease in intrauterine pressure would not

necessarily mean the presence of a perforation. Prelim. Resp. 41. Patent Owner's argument is not commensurate with the scope of the claim. We do not read the monitoring step as requiring monitoring for a decrease in intrauterine pressure that can be caused *only* by a perforation. We read the monitoring step as encompassing monitoring for decrease in intrauterine pressure that may possibly be caused by a perforation but may also be caused by malfunctions in the equipment. For example, the '183 patent discloses that a decrease in pressure that may be caused by a kinked tubing or other problem leading to a false test result. Ex. 1001, 7:44–46.

Second, Patent Owner argues that neither Isaacson nor Goldrath discloses the preventing ablation step and permitting ablation step of claim 9. Prelim. Resp. 43–48. Patent Owner's argument again is unpersuasive because it attacks the references individually when the Petitioner relies upon a combination of Isaacson and Goldrath to meet the preventing and permitting step. *See Keller*, 642 F.2d at 426 ("One cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references") (citation omitted).

Patent Owner argues that the combination of Isaacson and Goldrath does not disclose the monitoring step occurring before the preventing or permitting of initiation of ablation. Prelim. Resp. 45. This argument is not commensurate with the scope of claim 1 or claim 9. As discussed above, claim 9 does not require that the monitoring step occurs only before the preventing or permitting of initiation of ablation. We, thus, find Patent Owner's second argument unpersuasive on the record currently before us.

Third, Patent Owner argues that Petitioner fails to provide a sufficient rationale to combine Isaacson and Goldrath in the manner recited by the

claims. Prelim. Resp. 51–56. Patent Owner's argument is unpersuasive. Petitioner reasons that it would have been obvious to one of ordinary skill in the art, given the disclosures of Isaacson and Goldrath, to use Isaacson's pressure sensor to monitor for uterine perforations to improve treatment safety. Pet. 42, 52–54. Petitioner also reasons that adding a safety mechanism that prevents treatment if the pressure test fails would improve safety and efficacy. *Id.* at 45–46, 54–56. Petitioner's reasoning is supported by the testimony of Dr. Pearce. *See* Ex. 1002 ¶¶ 169, 210. On this record, we are persuaded that Petitioner's evidence and analysis is sufficient to establish a reasonable likelihood that it would have been obvious to a person of ordinary skill in the art to combine Isaacson and Goldrath in the manner proposed by Petitioner.

*Dependent Claims 2, 3, 7, and 12–14*

Petitioner contends that claims 2, 3, 7, and 12–14 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. Pet. 47–52. Patent Owner argues these claims are patentable for the same reasons it argues that claims 1 and 9 are patentable. Prelim. Resp. 56.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine that Petitioner shows a reasonable likelihood that claims 2, 3, 7, and 12–14 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. For the reasons discussed above with respect to the patentability of claims 1 and 9 over Isaacson and Goldrath, we find Patent Owner's argument unpersuasive.

*Claims 4 and 15*

Claim 4 depends from claim 1 and additionally recites that "the treating step includes delivering thermal energy to the tissue." Claim 15

depends from claim 9 and additionally recites that "the ablation device is a thermal ablation device."

Petitioner contends that claims 4 and 15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. Pet. 48–49. Petitioner states "[w]hile 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." *Id.* at 48 (citing Ex. 1007, 7:34–8:1, 13:10–12). According to Patent Owner, Isaacson's fluid is not capable of reaching a temperature capable of thermally ablating the uterus. Prelim. Resp. 28–30.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine the Petitioner shows a reasonable likelihood that claims 4 and 15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. As Petitioner points out, Isaacson discloses localized heating of tissue adjacent to the electrode assembly. Ex. 1007, 7:34–8:1, 13:10–12.

Patent Owner's argument is unpersuasive because it is not commensurate with the scope of the claims. Neither claim 4 nor claim 15 requires that the amount of thermal energy delivered to the tissue be such that it is capable of thermally ablating the uterus.

*Claims 6 and 11*

Claim 6 depends from claim 1 and additionally recites "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 depends from claim 9 and additionally recites "if a perforation is detected during the

monitoring step, activating a notification signal alerting the user to the presence of a perforation in the uterus."

Petitioner contends that claims 6 and 11 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. Pet. 48–49. Petitioner argues that providing feedback would have been obvious in light of Isaacson's teaching of detecting a perforation, because "otherwise the perforation detection would serve no purpose." *Id*. at 49 (citing Ex. 1002 ¶¶ 197, 214). Petitioner further argues that "[t]o the extent that this element is not expressly described by Isaacson, Goldrath discloses providing such feedback." Pet. 49. According to Petitioner, Goldrath provides feedback by stopping the flow of fluid into a uterus and discloses that this is how a surgeon knows that a patient is absorbing too much fluid. Ex. 1013, 4:8–21.

Patent Owner argues that neither Isaacson nor Goldrath discloses providing feedback or a notification signal that alerts the user to the presence of a perforation in the uterus because Goldrath discloses alerting when a patient is absorbing too much fluid, which could be for any number of reasons. Prelim. Resp. 54–55.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine the Petitioner shows a reasonable likelihood that claims 6 and 11 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath.

Patent Owner's argument again is unpersuasive because it attacks the references individually when the Petitioner relies upon a combination of Isaacson and Goldrath to meet the monitoring step. *See Keller*, 642 F.2d at 426 ("One cannot show non-obviousness by attacking references

individually where, as here, the rejections are based on combinations of references") (citation omitted).

Further, as discussed above with regards to claims 1 and 9, Patent Owner's argument is not commensurate with the scope of the claim. We do not read the claims as requiring monitoring for a decrease in intrauterine pressure that can be caused *only* by a perforation in the uterus. We read the monitoring step as encompassing monitoring for a decrease in intrauterine pressure that may possibly be caused by a perforation. This reading is consistent with the '183 patent, which discloses that a decrease in pressure may be caused by a kinked tubing or other problem leading to a false test result. Ex. 1001, 7:44–46.

*Ground Six – Isaacson, Goldrath, and Himmelstein*

Petitioner contends that claim 5 is unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein. Pet. 56–58. Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 227–242. Patent Owner disputes that the claims are unpatentable over Isaacson, Goldrath, and Himmelstein. Prelim. Resp. 51–53.

Petitioner argues that "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." Pet. 57. Petitioner argues that Himmelstein discloses a method of testing for leakage of fluid from an enclosed space by monitoring pressure and discloses testing for a preselected period of time. *Id.* at 57–58 (citing Ex. 1009, 1:10–13, 1:29–37). Petitioner contends that

> 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.

Pet. 58.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows a reasonable likelihood that claim 5 is unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein.

Patent Owner disputes that the proposed modification would have been obvious. Prelim. Resp. 51–53. Patent Owner argues that Isaacson and Goldrath disclose an open fluid-circulation system and that leaks in an open system may result in decrease fluid volume, but not necessarily in fluid pressure. *Id.* at 53. Petitioner further argues that Petitioner has not provide a sufficient rationale to combine Isaacson, Goldrath, and Himmelstein. *Id.*

Patent Owner's arguments are unpersuasive. As discussed above with regard to claims 1 and 9, at this point in the proceeding, Patent Owner's argument that leaks cause decreases in pressure only in closed systems is unsupported by evidence. Mere attorney arguments and conclusory statements that are unsupported by factual evidence have little probative value. *Geisler*, 116 F.3d at 1470; *see also De Blauwe,* 736 F.2d at 705.

We are also not persuaded by Patent Owner that Petitioner has not provide a sufficient rationale to combine Isaacson, Goldrath, and Himmelstein. Petitioner reasons that the combination would allow the user to ensure that the uterus is capable of maintaining its integrity for a set period of time prior to treatment, thus increasing safety and reliability of the

treatment method. Pet. 58. Petitioner's reasoning is supported by the testimony of Dr. Pearce. *See* Ex. 1002 ¶ 231. On this record, we are persuaded that Petitioner's evidence and analysis is sufficient to establish a reasonable likelihood that it would have been obvious to a person of ordinary skill in the art to combine Isaacson, Goldrath, and Himmelstein in the manner proposed by Petitioner.

*Ground Seven – Isaacson, Goldrath, and Benaron*

Petitioner contends that claims 8 and 10 are unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron. Pet. 58–60. Petitioner cites to the Declaration of Dr. Pearce for support. Ex. 1002 ¶¶ 243–259.

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine the Petitioner shows a reasonable likelihood that claims 8 and 10 are unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron. For the reasons discussed above with respect to the patentability of claims 1 and 9 over Isaacson and Goldrath, we find Patent Owner's argument unpersuasive.

## III. CONCLUSION

On this record, we determine that Petitioner demonstrates a reasonable likelihood of prevailing on the grounds of:

claims 1, 4, 6, 7, 9, 11–13, and 15 being unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc;

claim 14 being unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson;

claim 5 being unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein;

claims 8 and 10 being unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron;

claims 1–4, 6, 7, 9, and 11–15 being unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath;

claim 5 being unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein; and

claims 8 and 10 under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron.

The Board has not yet made a final determination as to the patentability of any of the challenged claims.

## IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Accept Email Submission (Paper 7) is granted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '183 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds of:

claims 1, 4, 6, 7, 9, 11–13, and 15 being unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc;

claim 14 being unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson;

claim 5 being unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein;

claims 8 and 10 being unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron;

claims 1–4, 6, 7, 9, and 11–15 being unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath;

claim 5 being unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein; and

claims 8 and 10 under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron.

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