UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,

Petitioner,

v.

HOLOGIC, INC.,

Patent Owner.

Case IPR2016-00868
Patent 6,872,183

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

PATENT OWNER'S NOTICE OF APPEAL

By Electronic Filing
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

By Hand Delivery
Office of the General Counsel
U.S. Patent & Trademark Office
Madison Building East, 10B20
600 Dulany Street
Alexandria, Virginia 22314-5793

By Electronic Filing
Circuit Executive and Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439

To the Director of the United States Patent and Trademark Office:

Pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. § 90.2(a), Patent Owner Hologic, Inc. ("Appellant") hereby provides this Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board ("PTAB") in IPR2016-00868, concerning the *inter partes* review of U.S. Patent No. 6,872,183 ("the '183 patent"), and from all underlying orders, decisions, rulings, and opinions. The issues on appeal include, without limitation, the following: (i) the PTAB's determination of unpatentability of claims 1-15 of the '183 patent under 35 U.S.C. § 103, (ii) the PTAB's determination of unpatentability of substitute claims 16-23 presented in Appellant's Motion to Amend over the prior art of record, and (iii) the PTAB's

decision denying Appellant's Motion to Exclude Evidence. A copy of the PTAB's Final Written Decision is attached as Exhibit 1.

The PTAB issued its Final Written Decision on December 15, 2017. This notice is therefore timely filed within sixty-three (63) days of the PTAB's decision as prescribed by 35 U.S.C. § 142 and 37 C.F.R. § 90.3(a)(1).

Pursuant to 37 C.F.R. § 90.2(a)(1), a copy of this Notice of Appeal is being filed with the PTAB. Pursuant to Federal Circuit Rule 15(a)(1), a copy of this Notice of Appeal is also being filed with the Clerk of the United States Court of Appeals for the Federal Circuit, along with the necessary fees.

Appellant does not believe that any fees are due to the United States Patent and Trademark Office with this Notice of Appeal. However, if any such fees are due, the Director is authorized to charge the fees to Deposit Account No. 50-2387.

Dated: February 9, 2018

Respectfully submitted,

/Jennifer A. Sklenar/

Jennifer A. Sklenar (Reg. No. 40,205)
ARNOLD & PORTER KAYE SCHOLER LLP
777 S. Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Email: Jennifer.Sklenar@apks.com
Tel: (213) 243-4000
Fax: (213) 243-4199

Attorney for Patent Owner Hologic, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing PATENT OWNER'S NOTICE OF APPEAL was served on February 9, 2018 to the following Counsel for Petitioner via e-mail:

Michael T. Rosato, Lead Counsel
Matthew A. Argenti
Steven W. Parmelee
WILSON SONSINI GOODRICH & ROSATI
701 5th Avenue, Suite 5100
Seattle, WA 98104-7036
mrosato@wsgr.com
margenti@wsgr.com
sparmelee@wsgr.com

Attorneys for Petitioner Minerva Surgical, Inc.

/Jennifer A. Sklenar/
Jennifer A. Sklenar (Reg. No. 40,205)
ARNOLD & PORTER KAYE SCHOLER LLP
777 S. Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Email: Jennifer.Sklenar@apks.com
Tel: (213) 243-4000
Fax: (213) 243-4199

Exhibit 1

Trials@uspto.gov
571-272-7822

Paper No. 63
Entered December 15, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MINERVA SURGICAL, INC.,
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HOLOGIC, INC.,
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IPR2016-00868
Patent 6,872,183 B2

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

PETRAVICK, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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."). We instituted *inter partes* review (Paper 10, "Inst. Dec.") on the following grounds:

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

Patent Owner, Hologic, Inc., filed a Patent Owner's Response (Paper 22, "PO Resp."), and Petitioner filed a Reply to the Patent Owner's Response (Paper 32, "Pet. Reply").

[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).
[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).

Patent Owner also filed a Motion for Observations on Cross-Examination (Paper 43), and Petitioner filed a Response to Motion for Observation on Cross-Examination (Paper 44).

Patent Owner further filed a Motion to Exclude Evidence (Paper 48, "MTE"). Petitioner filed an Opposition to the Motion to Exclude Evidence (Paper 50, "MTE Opp."), and Patent Owner filed a Reply in Support of the Motion to Exclude Evidence (Paper 51, "MTE Reply").

Patent Owner additionally filed a Motion to Amend (Paper 24, "MTA"). Petitioner filed an Opposition to the Motion to Amend (Paper 33, "MTA Opp."), and Patent Owner filed a Reply in Support of the Motion to Amend (Paper 38 "MTA Reply").

An oral hearing was held on June 21, 2017. A transcript of the hearing is included in the record. Paper 55 ("Tr.").

On October 4, 2017, just two days before the statutory one-year period for issuing a final written decision was set to expire (*see* 35 U.S.C. § 316(a)(11)), the Federal Circuit issued an *en banc* decision in *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017). The Chief Administrative Patent Judge determined that good cause existed to extend the statutory one-year period (Paper 56), and pursuant to 35 U.S.C. § 316(a)(11) and 37 C.F.R. § 42.100(c), the time period for issuing a final written decision was extended by up to six months (Paper 57).

Pursuant to our authorization (Paper 58), Patent Owner filed a supplemental brief (Paper 60, "PO Supp. Br.") and Petitioner filed a supplemental brief (Paper 59, "Pet. Supp. Br.") providing arguments supplementing their prior briefing on Patent Owner's Motion to Amend.

After consideration of the parties' arguments and evidence, and for the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–15 of the '183 patent are unpatentable. Based on the entirety of record before us, we also determine that a preponderance of the evidence establishes that substitute claims 16–23 presented in the Motion to Amend are unpatentable over the prior art of record. We also deny Patent Owner's Motion to Exclude Evidence.

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. 8, 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 bowel,

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.

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.

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); *see also 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).

Order of Steps — Claim 1

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

In its Preliminary Response, Patent Owner argued with regards to claim 1 that "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." Paper 9, 7. We found Patent Owner's argument unpersuasive in our Institution Decision and determined that claim 1 does not "require[] that the monitoring step must occur before the treating step." Inst. Dec. 7–11. Patent Owner does not raise this argument again, with respect to claim 1, in its Patent Owner's Response, and we discern no reason to alter our prior determination. *See generally* PO Resp. 9–11. Accordingly, for the reasons expressed in our Institution Decision, claim 1 does not require that the monitoring step must occur before the treating step. *See* Inst. Dec. 7–11.

Order of Steps — Claim 7

Claim 7 depends from claim 1 and further recites a step of "preventing performance of the treating step until *after* the monitoring step has been carried out." *Id.* at 8:31–33 (emphasis added).

Patent Owner argues that the only reasonable interpretation of the language of claim 7 is that "the ablation cannot begin until after the monitoring step has been completed." PO Resp. 9. Petitioner responds that "[t]he order of steps in claim 7 is undisputed." Pet. Reply 8. Thus, there is no dispute as to the order of steps of claim 7, and the undisputed construction is supported by the plain language of the claim. We agree with the parties that the plain language, which recites "after," requires that ablation cannot begin until after the monitoring step has been completed.

Order of Steps — Claim 9

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:

> Under the broadest reasonable construction of claim 9, the step of monitoring for the presence of perforations in the uterus must be completed ***before*** the step of treating the uterus using an ablation device. Otherwise the ablation would not have been "prevented" if a perforation were detected.

PO Resp. 9–11. According to Patent Owner, "starting and then stopping an ablation is not the same as 'preventing' ablation." *Id.* at 10. Patent Owner argues that this is consistent with the fundamental purpose of the perforation detection method of the '183 patent, which "is to ensure patient safety by monitoring for perforations ***before*** ablation is performed." *Id.* at 10 (citing Ex. 1001, 1:38–46, 1:54–57, 6:28–30, 6:51–55, 7:12–20, 7:27–29).

Petitioner disagrees. Pet. Reply 8–9. Petitioner argues that, unlike claim 7, the language of claim 9 does not require preventing ablation until *after* monitoring step has been carried out. *Id.* at 8. Petitioner argues "claim 9 would have completely different meaning if PO had chosen to require 'preventing ablation of the uterus from beginning' versus 'preventing ablation of the uterus from continuing.' PO chose neither, and it is improper to read one of those options into the claim." *Id.*

"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, 1359 (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 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. The language of claim 9, however, 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. *See Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.").

We are also 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. 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* PO Resp. 10. We are not persuaded, however, because Patent Owner’s argument does not account for other disclosures of the ’183 patent. As Petitioner points out, the ’183 patent states that “the physician can start or stop the perforation test at any time in the sequence.” Pet. Reply 9 (citing Ex. 1001, 7:54–55); *see also* Ex. 1001, 8:34–35 (claim 8 reciting a step of “suspending performance of the treating step if a perforation is detected in the monitoring step”). Further, the ’183 patent indicates 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).

Patent Owner proffers extrinsic evidence to show that the word "preventing" requires preventing the initiation of the ablating. PO Resp. 10 (citing Ex. 2011, Ex. 2016, Ex. 2007 ¶ 68; Ex. 2030, 68:13–20). First, Patent Owner proffers dictionary definitions of the word "preventing" and implies that the meaning of "preventing" is different from "ceasing" or "halting." PO Rep. 10 (citing Ex. 2011, Ex. 2016). One of the dictionaries defines "prevent" as "to keep (some-one) from doing something; impede," and indicates that "verbs that mean to stop or hinder something from happening, especially by advanced planning or action" are synonyms. Ex. 2011, 5; *see also* Ex. 2016, 3 (providing a similar definition). The dictionary definitions, thus, do not support Patent Owner's argument.

Patent Owner also points to testimony of Petitioner's declarant, Dr. Pearce. PO Resp. 10 (citing Ex. 2030, 68:13–20). Dr. Pearce testifies that his understanding of what preventing means is "it would be impossible to apply the heat source, whatever it is, if a perforation is detected." Dr. Pearce's testimony also does not support Patent Owner's argument because it does not require preventing of *initiation* of ablating.

Patent Owner, further, points to the testimony of its declarant, Dr. Martin. PO Resp. 10 (citing Ex. 2007 ¶ 68). Dr. Martin testifies that "[a] person of ordinary skill in the art would have known that an ablation that has been 'prevented' has not yet begun." Ex. 2007 ¶ 68. Dr. Martin bases his testimony on portions of the Specification of the '183 patent and dictionary

definitions cited by Patent Owner. *Id.* at ¶¶ 67–69. Dr. Martin's testimony is unpersuasive because, for the same reasons as discussed above, it does not account for other disclosures in the '183 patent and definitions in the proffered dictionaries that run counter to Petitioner's argument.

Considering all the parties' arguments and evidence, we are not persuaded by Patent Owner that 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 claim 9 precludes monitoring simultaneously with ablation.

"perforation"

The claims recite a "perforation." For example, claim 1 recites "a perforation in the uterus" and claim 9 recites "[a] method of detecting a perforation in a uterus." Ex. 1001, 8:13–14, 8:39–40.

Petitioner argues that "perforation" refers "to damage to the wall of the uterus, such as a rupture caused by accident or disease." Pet. 11; *see also* Pet. Reply 5–7. Patent Owner argues that '"perforation' should be construed to mean 'an abnormal hole in the wall of the uterus.'" PO Resp. 7. In addition, Patent Owner argues that a rupture is not a perforation. *See e.g., id.* at 7.

We are persuaded by Patent Owner that the broadest reasonable construction in light of the Specification of the '183 patent of "perforation" is an abnormal hole in the wall of the uterus. Patent Owner's construction is consistent with the Specification of the '183 patent, which discloses that "the presence of a perforation in the uterus could result in inadvertent passage of the ablation device through the perforation and out of the uterus and bowel."

Ex. 1001, 1:38–41. Patent Owner's construction is also consistent with dictionary definitions proffered by both Petitioner and Patent Owner. *See* Ex. 1012, 3; Ex. 2002, 3; Ex. 2003, 3; Ex. 2004, 3. For example, The New Oxford American Dictionary defines "perforation" as "an aperture passing through or into something." Ex. 2003, 3. Webster's Medical Desk Dictionary defines perforation as "the penetration of a body part through accident or disease" and defines the related term "perforate" as "to make a hole through." Ex. 1012, 3.

We, however, are not persuaded by Patent Owner that perforations cannot encompass ruptures. Patent Owner relies upon the testimony of Dr. Martin to support its argument. PO Resp. 8 (citing Ex. 2007 ¶¶ 56–58). Dr. Martin's testimony that a rupture is not a perforation is based on a construction of "perforation" that is narrower than the construction proposed by Patent Owner. *See* Ex. 2007 ¶¶ 56–58; Ex. 1016, 42:13–43:15. For example, Dr. Martin testifies that a perforation is "relatively small compared to the uterus" and "that perforations are holes ranging in size from less than 1 mm in diameter to 15 mm in diameter." Ex. 2007 ¶¶ 54, 57. Patent Owner's proposed construction does not require a certain size of the hole. Further, as Petitioner points out, the '183 patent suggests that perforations can be larger — "the system is capable of detecting perforations *exceeding* the range of sizes of devices normally inserted into body cavities (from say 15 mm down to less than 1 mm diameter)." Pet. Reply 6 (quoting Ex. 1001 7:46–49 (emphasis added)). In addition, Dr. Martin's testimony is inconsistent with another definition from Webster's Medical Desk Dictionary, which defines "perforations" as "a rupture in a body part caused

esp. by accident or disease." Ex. 1012, 3. Patent Owner's argument that perforations cannot encompass ruptures, thus, is unpersuasive.

We are not persuaded by Petitioner that "perforations" should be construed as "damage to the wall of the uterus." Pet. 11. Petitioner's proposed construction is unreasonably broad to the extent that it broadly encompasses all types of damage to the wall of the uterus, such as adhesions. *See* Ex. 2007 ¶ 56.

Given the above, we determine that the broadest reasonable interpretation, in light of the Specification of the '183 patent, of "perforation" is an abnormal hole in the wall of the uterus, which can encompass a "rupture."

"inflation medium" and "pressure sensor"

Petitioner and Patent Owner propose constructions for the claim term "inflation medium" (Pet. 10–11; PO Resp. 7) and "pressure sensor" (PO Resp. 8; Pet. Reply 7). We determine that no explicit claim construction is required for these claims terms. *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." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham*, 338 U.S. at 17–18).

Level of Ordinary Skill

Petitioner and Patent Owner dispute the level of ordinary skill in the art. Petitioner contends that:

> 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 device.

Pet. 7–8. Patent Owner argues that "Petitioner's proposed level of ordinary skill in the art is erroneous to the extent that it does not explicitly require experience with devices used in the uterus." PO Resp. 11.

"Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi*

Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007) (quoting *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)).

Here, Patent Owner argues that "the level of ordinary skill in the art must include experience with uterine devices" because the claims are limited to a method of monitoring for perforations in the uterus, the asserted references and the '183 patent are specifically directed to pressurized fluid inside the uterus, and the types of problems encountered in the art are associated with pressurized fluids in the uterus (e.g., "intravasation of fluid into the patient's blood stream"). *Id.* at 12.

Patent Owner's arguments are not persuasive. As Petitioner points out, Patent Owner's arguments are "at odds with the '183 patent." Pet. Reply 2–3. The '183 patent, which is titled "System and Method for Detecting Perforations in a Body Cavity," explicitly discloses that the invention is applicable to body cavities generally and indicates that the problem with perforations is not unique to ablation of the uterus. *See* Ex. 1001, (54), 1:12–14, 1:25–28, 2:12–20. The '183 patent states that "[a]lthough the for[e]going description is with reference to a perforation detection system having a device usable to ablate tissue within a uterus, the present invention is applicable to perforation detection within other body cavities . . . ." *Id.* at 7:63–65. Likewise, Masterson discloses that its device can be used "for thermally ablating hollow body organs, such as the uterus." Ex. 1006, 1:15–20. Patent Owner alleges that the claimed invention solves a number of other problems encountered in the art are associated with pressurized fluids in the uterus, such as intravasation. PO Resp. 12–13. We are persuaded, however, by Petitioner that these problems do not require the level of ordinary skill in the art to include experience with uterine ablation

devices, as opposed to general ablation devices. *See* Pet. Reply 2–3 (citing Ex. 2030, 47:15–48:14, Ex. 1016, 40:19–23, Ex. 2030, 101:12–15).

Given this, we are persuaded by Petitioner that a person having ordinary skill in the art includes 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." Pet. 7–8.

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; Pet. Reply 9–24. In addition to the cited references themselves, Petitioner cites to the Declaration of Dr. Pearce for support (Ex. 1002)[7] and the Declaration of Dr. Mirabile (Ex. 1018). Patent Owner disputes that the claims are unpatentable over Masterson and Bolduc. PO Resp. 16–36. Patent Owner cites to the Declaration of Dr. Martin for support (Ex. 2007) and to the Declaration of Dr. Evantash for support (Ex. 2008).

[7] Patent Owner argues that we should give Dr. Pearce's testimony little or no weight because he does not have expertise with endometrial ablation devices, as opposed to other ablation devices. *See* PO Resp. 13–16. Essentially, this is the same argument Patent Owner makes in its Motion to Exclude. *See* MTE 2–8. For the same reasons as discussed with below with respect to the Motion to Exclude, Patent Owner's argument is unpersuasive. We are also persuaded by Petitioner's arguments (Pet. Reply 3–4) that Dr. Pearce is qualified to testify as an expert.

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.

Figure 16 of Masterson is reproduced below.

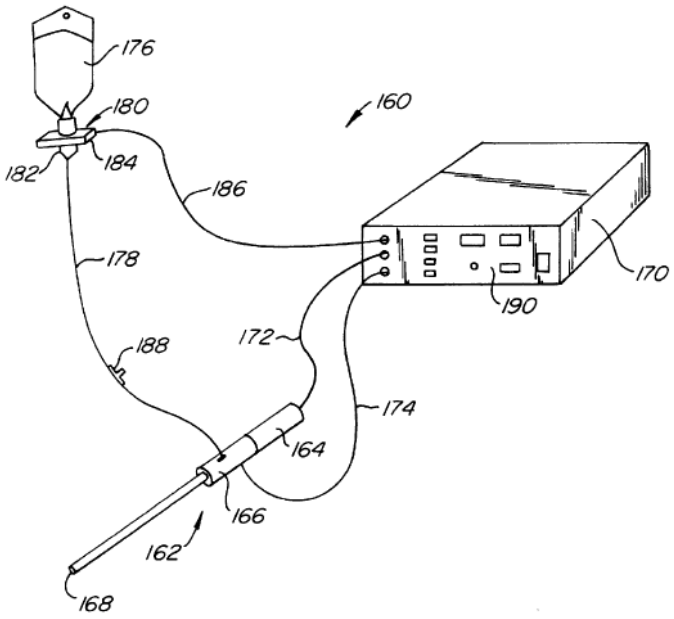


FIG. 16.

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 positioned 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.

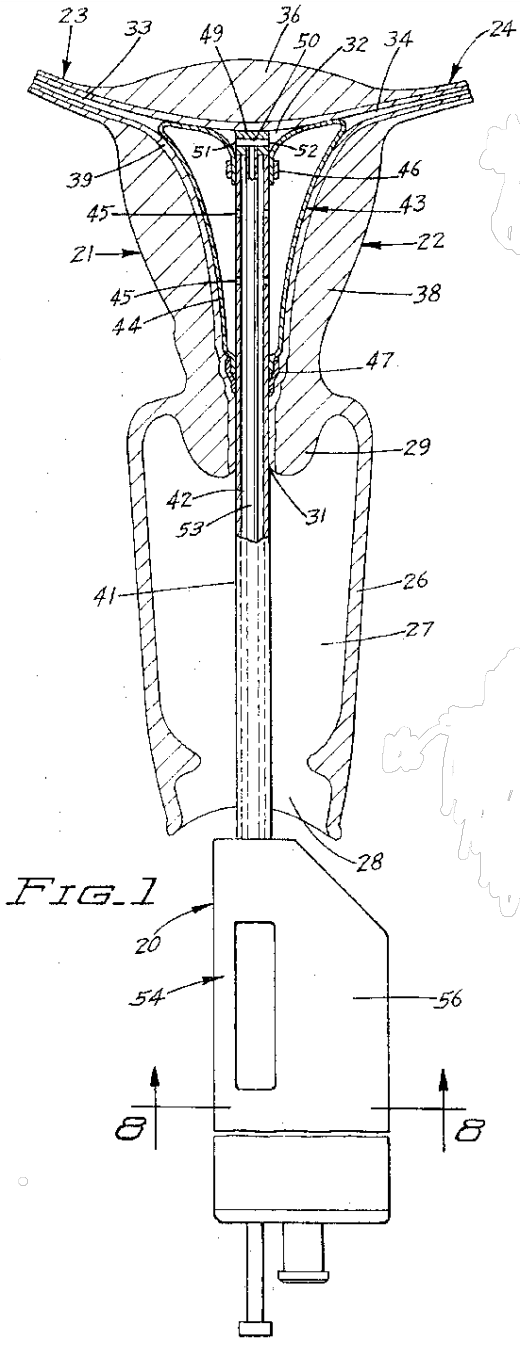


Figure 1 of Bolduc depicts the dispensing device in place in the uterus. Bolduc discloses sleeve member 44, made from a soft and relaxed flexible and elastic material. *Id.* at 4:41–44. When the device is inserted into the uterus, air is forced into sleeve member 44 by actuator 97 to pressurize

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.

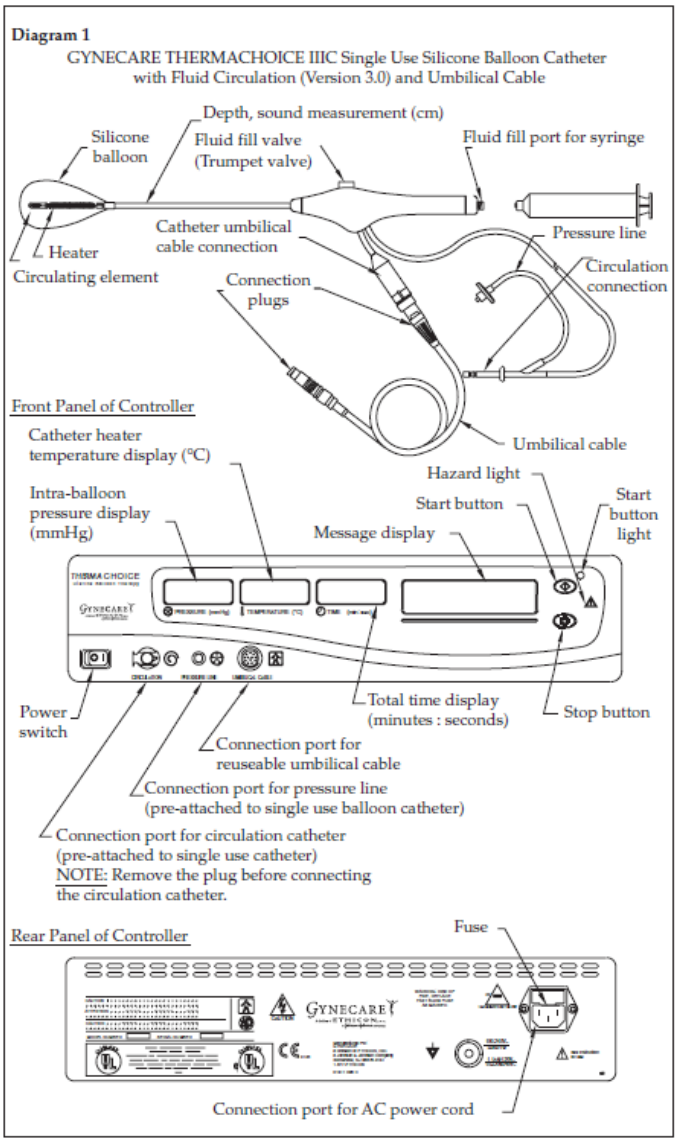
Id. at 5:47–61.

Additionally, Bolduc discloses that its device has a control mechanism for preventing 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 uterine walls is that an actuator assembly will move back to its initial position. *Id.* at 7:51–58.

Overview of ThermaChoice® Manual

As discussed below, Petitioner and Patent Owner refer to the ThermaChoice® Manual to support their arguments regarding the conventional wisdom at the time of the invention of the ’183 patent. *See e.g.*, Pet. Reply 17 (citing Ex. 1019, 20); MTA Opp. 10–11 (citing Ex. 1019, 20–23); MTA Reply 10–11. Given this, an overview of the ThermaChoice® Manual is helpful.

The ThermaChoice® Manual discloses an ablating device and method of using the ablating device. Ex. 1019. Diagram 1 of the ThermaChoice® Manual is reproduce below. Ex. 1019, 2.



The diagram depicts the ThermaChoice® ablation system, which includes a silicon balloon applicator head that expands in the uterus. *See id.* at 19–20. During use, the silicon balloon is inserted into the uterus and expanded by

filling it with gas. *See id*. at 19–20, 3.5–3.7. The ThermaChoice® device has a pressure sensor (*see id*. at 22–23), and the ThermaChoice® Manual states:

> *If pressure cannot be stabilized at 160–180 mmHg for 30–45 seconds with 30 ml of fluid, this may indicate uterine perforation*. Remove the balloon catheter. If a balloon leak is present, replace the catheter and continue with the procedure. If no balloon leak is found, perform appropriate diagnostic measure to evaluate for perforation before proceeding. If perforation cannot be ruled out, abandon the procedure.

(Ex. 1019, 20 (emphasis added); *see also* Ex. 1021, 8). "When a steady pressure . . . is maintained," the user can start ablative treatment. *Id.* at 21.

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 the steps of claims 1 and 9. *See id.* at 12–22 (explaining with specificity how Masterson and Bolduc teach the limitations of claims 1 and 9). 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 (citing Ex. 1006, 11:8–15, 18:51–59). 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." Pet. 15. According to Petitioner, Bolduc teaches detecting a uterine perforation using a pressure sensor. *Id.* at 15–16, 19–20 (citing Ex. 1008, 1:62–2:1, 5:42–50, 7:41–55). 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 an 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; *see* Ex. 1006, 17:41–55; Ex. 1008, 5:47–61

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments and evidence, discussed below, we determine that the Petitioner shows by a preponderance of the evidence that claims 1 and 9 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. As can be seen from our summary of Masterson and Bolduc, above, and as the Petition points out, the combination of Masterson and Bolduc teaches each limitation of claims 1 and 9. *See* Pet. 12–22. Further, we agree with Petitioner that one of ordinary skill in the art would have been motivated to combine Masterson and Bolduc to improve the safety of the ablation device. *See* Pet. 27–28 (citing Ex. 1006, 17:41–55; Ex. 1008, 5:47–61); Pet. Reply 19 (citing Ex. 1016, 83:18–23). In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

Patent Owner argues that 1) neither Masterson nor Bolduc disclose the monitoring step, 2), with respect to claim 9 only, 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. PO Resp. 23–30, 33–36.

First, Patent Owner argues that neither Masterson nor Bolduc discloses monitoring for the presence of a perforation in the uterus using a pressure sensor. *Id.* at 16–19, 23–25. 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. *See, e.g.*, *id.* at 18. 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. *See*, *e.g.*, *id.* at 19–20. Patent Owner contends that Masterson's system, thus, is incapable of monitoring for the presence of a perforation in the uterus using a pressure sensor. *See, e.g.*, *id.* at 17 ("Masterson repeatedly and expressly stresses the importance of a generally constant pressure").

We agree with Patent Owner that Masterson discloses that it is desirable to maintain constant uterine pressure during normal operating conditions. For example, Masterson describes that leaked fluid is replenished, "damping pressure variations that may occur within the uterus." Ex. 1001, 10:44–50. We do not agree, however, with Patent Owner that a perforation in the uterus, an abnormal condition, would not cause an under pressure condition in the uterus. Dr. Martin's testimony indicates that the uterine pressure in Masterson will vary under abnormal conditions. *See* Ex. 1016, 51:23–52:1; *see also* Ex. 2007 ¶ 99 ("Masterson's system, although designed to remain at a constant pressure, can be under pressurized . . . for many reasons"). Dr. Pearce's testimony also indicates that the uterine pressure will vary. Ex. 1002 ¶ 54, Ex. 2030 81:7–23. Indeed, Masterson

explicitly discloses that abnormal conditions, such as over and under pressure, can occur. Ex. 1006, 18:51–59. Masterson explicitly describes detecting these conditions and ceasing operation of its device. *Id.*

Patent Owner's argument implies that the monitoring must be *only* for a decrease in intrauterine pressure that is caused by a perforation. 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 be caused by a perforation but may alternatively be caused by malfunctions in the equipment. For example, the '183 patent 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. Dr. Martin's testimony indicates Masterson's under pressure could be caused by many reasons, including a perforation in the uterus. *See* Ex. 1016, 51:23–52:1, 54:8–23, 55:5–10; Ex. 2030 81:7–23 (testimony of Dr. Pearce). Bolduc also discloses that failing to maintain a predetermined pressure is an indication of ruptures of the uterus. Ex. 1008, 5:47–61.

Second, Patent Owner argues, with respect to claim 9 only, that the combination of Masterson and Bolduc does not disclose the monitoring step occurring before the treating step. PO Resp. 27–30. Patent Owner's argument is unpersuasive because it is not commensurate with the scope of claim 9. As discussed above, claim 9 does not require that the monitoring step be completed before the ablation begins.

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

claims. PO Resp. 33–36. 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 Masterson, itself, which describes detecting abnormal conditions, including over and under pressure, and ceasing operation "to provide increased safety to the patient." Ex. 1006, 18:57–59. Petitioner's reasoning is also supported by Bolduc, which describes prior to performing a procedure, monitoring for weak, diseased or *ruptured* walls of the uterus using pressure. *See* Ex. 1008, 1:65–2:3, 7:41–55, 8:31–44.

Patent Owner also argues that it would not have been obvious to combine Masterson and Bolduc because neither individually teaches the claimed methods. For example, Patent Owner disputes that Bolduc teaches monitoring for perforations because ruptures are not perforations. PO Resp. 35. As discussed above, however, we determine that the broadest reasonable interpretation of perforation does not exclude ruptures. Patent Owner also disputes that Bolduc teaches a pressure sensor. *Id.* at 25. As Petitioner points out, however, it is undisputed that Masterson teaches a pressure sensor (Pet. Reply 14 (citing PO Resp. 25, 26; Ex. 1016, 51:23–53:3)). In any event, we agree with Petitioner that Bolduc's pressure-calibrated spring is a pressure sensor, even under Patent Owner's proposed construction. *See* Pet. Reply 14 (citing Ex. 1016, 72:4–8); *see also* Ex. 1008, 6:15–18 (describing a spring calibrated to a certain pressure). Patent Owner's arguments are unpersuasive. "Non-obviousness cannot be established by

attacking reference individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Further, Patent Owner argues that alleged incompatibilities in Masterson's and Bolduc's systems demonstrate patentability. PO Resp. 33–36. Patent Owner's arguments are unpersuasive. The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. *In re Keller*, 642 F.2d 413, 425, (CCPA 1981); *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012).

Dependent Claims 4, 6, 11–13, and 15

Petitioner contends that claims 4, 6, 11–13, and 15 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. Pet. 22–26. Patent Owner argues that these claims are patentable for the same reasons as it argued with respect to claims 1 and 9. PO Resp. 30–36. Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's evidence and argument, we determine that Petitioner shows by a preponderance of the evidence that claims 4, 6, 11–13 and 15 are unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. *See* Pet. 22–26 (explaining with specificity how Masterson and Bolduc teach the limitations of claims 4, 6, 11–13, and 15). 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.

Dependent Claim 7

Claim 7 depends from claim 1 and recites "preventing performance of the treating step until after the monitoring step has been carried out." Ex. 1001, 8:30–32. As discussed above, the parties do not dispute that claim 7 requires that ablation cannot begin until after the monitoring step has been completed.

As for claim 1 and 9, Petitioner contends that claim 7 is unpatentable over Masterson and Bolduc. Pet. 23–24. Petitioner asserts that "[t]o 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." *Id.* (citing Ex. 1008, 5:54–61, 7:41–55, 8:31–44). 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." *See* Pet. 27–28 (citing Ex. 1006, 17:41–55; Ex. 1008, 5:47–61); Pet. Reply 19 (citing Ex. 1016, 83:18–23).

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments and evidence, discussed below, we determine the Petitioner shows by a preponderance of the evidence that claim 7 is unpatentable under 35 U.S.C. § 103 over Masterson and Bolduc. *See id.* at 23–24 (explaining with specificity how Masterson and Bolduc teach the limitation of claim 7). It reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

First, Patent Owner argues that these claims are patentable for the same reasons as it argued with respect to claims 1 and 9. PO Resp. 32. 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.

Second, Patent Owner argues that combining Masterson and Bolduc would not have been obvious because 1) the combination would go against conventional wisdom and 2) there is no reasons to add an additional step when Masterson already provides for leak detection. PO Resp. 32–33; *see also id.* at 27–30. Patent Owner argues that "[l]engthening the Masterson procedure by preventing ablation until a leak monitoring step has been completed would go against conventional wisdom to keep the procedure as short as possible and would increase the patient's risk from intravasation and anesthesia." PO Resp. 33 (citing Ex. 2007 ¶¶ 28–108; Ex. 2008 ¶ 21.); *see also* PO Resp. 28–30. Patent Owner asserts that "commercial endometrial ablations systems in the late-1990s and early-2000s, *e.g.*, those that used a heated balloon or heated fluid, were not capable of monitoring for perforations before ablating tissue." *Id.* at 29.

Patent Owner's argument is unpersuasive. As Petitioner points out, Patent Owner misrepresents the conventional wisdom or state of the art. *See* Pet. Reply 16–18 (citing Ex. 1018). Dr. Mirabile's testimony indicates that, despite other risk, such as longer duration, "a physician performing endometrial ablation procedures in November 1999 would gladly have extended the duration of the procedure if the ultimate result was a safer treatment for the patient." *See* Ex. 1018 ¶ 12. Dr. Mirabile further testifies that "a system already existed prior to November 1999 . . . involved a step of

detecting a uterine perforation prior to ablating the uterus." *Id.* ¶ 17. Dr. Mirabile points to the ThermaChoice® Manual (Ex. 1019), which discloses an endometrial ablation system using a balloon. *Id.* ¶¶ 17–21. The ThermaChoice® Manual states:

> *If pressure cannot be stabilized at 160–180 mmHg for 30–45 second with 30 ml of fluid, this may indicate uterine perforation.* Remove the balloon catheter. If a balloon leak is present, replace the catheter and continue with the procedure. If no balloon leak is found, perform appropriate diagnostic measure to evaluate for perforation before proceeding. If perforation cannot be ruled out, abandon the procedure.

Ex. 1019, 2 (emphasis added); *see also* Ex. 1021, 8. Given Dr. Mirabile's testimony and its underlying support, we are not persuaded by Patent Owner's argument that modifying Masterson to monitor for perforations prior to ablating would have gone against the conventional wisdom or state of the art.

Patent Owner argues that the ThermaChoice® Manual is not evidence of the conventional wisdom or state of the art with regards to perforation detection because "the balloon of the ThermaChoice® system was not able to detect perforations; instead conventional visual detection techniques were required." *See* MTA Reply 11; *see* PO Supp. Br. 4–5. Patent Owner cites to the cross-examination testimony of Dr. Mirabile to support its assertion. *Id.* (citing Ex. 2037, 39:5–9, 40:4–42:11). Patent Owner, however, mischaracterizes Dr. Mirabile's testimony. Dr. Mirabile's testimony indicates that a physician would do a visual inspection after the ThermaChoice® system detects perforation to confirm uterine perforations indicated by pressure that cannot be stabilized. *See* Ex. 2037, 39:5–9,

40:4–42:11. Dr. Mirabile's testimony does not support Patent Owner's assertion that the ThermaChoice® system cannot detect perforations using pressure. We note that claim 1 does not preclude such a visual inspection in addition to detecting unstable pressure.

Patent Owner also argues that there is no reason to add an additional step when Masterson already provides for leak detection. PO Resp. 28, 33. Patent Owner's argument is unpersuasive. As Petitioner points out, "the proposed modification . . . is not a replacement of the existing leak detection but rather a supplement that would occur at a different point in the procedure, increasing safety and efficacy." Pet. Reply 16 (citing Pet. 28–29). Dr. Mirabile testifies that "[t]he two primary concerns in a procedure such as endometrial ablation are safety and efficacy. That is, the procedure should be effective in treating the patient's medical condition and it should also be safe for the patient and not cause greater harm than the condition it is addressing." Ex. 1018 ¶ 12. We, thus, are not persuaded by Patent Owner's argument that there is no reason to modify Masterson, as proposed in the Petition.

Grounds Two and Four — Masterson, Bolduc, Isaacson/Benaron

Petitioner contends that claim 14 is unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Isaacson (Pet. 30–31) and claims 8 and 10 are unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Benaron (Pet. 34–36). Patent Owner argues that these claims are patentable for the same reasons as discussed above with respect to claims 1 and 9. PO Resp. 30, 33–36. Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's evidence and argument, we determine

that Petitioner shows by a preponderance of the evidence that claims 8, 10, and 14 are unpatentable under 35 U.S.C. § 103. *See* Pet. 30–31, 34–36 (explaining with specificity how the prior art teaches the limitations of claims 8, 10, and 14). For the reasons discussed above with respect to the patentability of claims 1 and 9, we find Patent Owner's argument unpersuasive.

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 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 (citing Ex. 1002 ¶¶ 130–132).

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows by a preponderance of the evidence that claim 5 is unpatentable under 35 U.S.C. § 103 over Masterson, Bolduc, and Himmelstein. *See* Pet. 32–33 (explaining with specificity how Masterson, Bolduc, and Himmelstein teach the limitation of claim 5). In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

Patent Owner argues that "Petitioner fails to articulate an adequate rationale for the combination" for similar reasons as discussed above with respect to claims 1 and 9. *See* PO Resp. 33–36. For the reasons discussed above with respect to the patentability of claims 1 and 9, we find Patent Owner's argument unpersuasive.

Ground Five – Isaacson and Goldrath

Petitioner contends that claims 1–4, 6, 7, 9, and 11–15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. Pet. 36–56. Petitioner cites to the Declaration of Dr. Pearce (Ex. 1002) for support. Patent Owner disputes that the claims are unpatentable over Isaacson and Goldrath. PO Resp. 36–48. Patent Owner cites to the Declaration of Dr. Martin for support (Ex. 2007) and to the Declaration of Dr. Evantash for support (Ex. 2008).

For the reasons discussed below, we determine that Petitioner shows by a preponderance of the evidence that claims 1–4, 6, 7, 9, and 11–15 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 if 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 and improve treatment safety. *Id.* at 42, 52–54 (citing Ex. 1002 ¶¶ 167–168).

Petitioner also relies upon Goldrath to teach the step of permitting ablation and preventing ablation recited in 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 (citing Ex. 1002 ¶ 169; Ex. 1007, 4:29–5:2, 22:19–26; Ex. 1013, 2:57–65, 5:44–46).

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows by a preponderance of evidence that claims 1 and 9 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. As can be seen from our summary of Isaacson and Goldrath, above, and as the Petition points out, the combination of Isaacson and Goldrath teaches each limitation of claims 1 and 9. *See* Pet. 36–47. Further, we agree with Petitioner that one of ordinary skill in the art would have been motivated to combine Isaacson and Goldrath to improve the safety of the ablation device. *See* Pet. 27–28 (citing Ex. 1007, 13:31–34, 14:25–29); Pet. Reply 23–24 (citing Ex. 1016, 83:18–23). In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

Patent Owner's rebuttal arguments pertaining to this ground mirror its arguments with respect to the combination of Masterson and Bolduc. *See, e.g.*, PO Resp. 27 ("similarly to the Masterson system"). Patent Owner argues that: 1) neither Isaacson nor Goldrath discloses monitoring for the presence of perforations in the uterus using a pressure sensor; 2), with respect to claim 9 only, neither Isaacson nor Goldrath discloses the preventing ablation step and permitting ablation; and 3) Petitioner fails to provide a sufficient rationale to combine Isaacson and Goldrath in the manner recited by the claims. PO Resp. 36–48, 51–56.

First, Patent Owner argues that neither Isaacson nor Goldrath discloses monitoring for the presence of a perforation in the uterus using a pressure sensor. *Id.* at 39–42. Patent Owner argues that "[b]ecause Isaacson's system applies a pressure source to the uterus, it behaves

similarly to the Masterson system in that pressure will remain constant even in the face of a leak, due to leaked fluid being replenished by the pressure source." *Id.* at 37. For reasons similar to those discussed above with regards to Masterson, we are not persuaded by Patent Owner that the pressure in Isaacson's system remains constant. Contrary to Patent Owner's argument, Isaacson does not disclose that pressure remains constant. Isaacson does disclose that "liquid flow and pressure is controlled" and the "[l]iquid used is controlled by positive pressure thus monitoring the amount of liquid." Ex. 1006, 19:8–12. Just like Masterson, Isaacson explicitly discloses measuring pressure with a pressure transducer. Ex. 1007, 13:31–14:2. Isaacson discloses that fluid flow rate can depend on inflow pressure and discloses calculating the pressure in the uterine cavity based on the differential between the pressure measured at an inlet port and an outlet port. *Id.* at 13:31–34. This suggests that, in Isaacson, fluid flow rate is related to uterine pressure. *See also* Ex. 1013, 2:52–55 (stating that the magnitude of a stream of fluid can be measured by flow rate or pressure). Isaacson states 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 charged to the uterus, the possibility of uterine perforation can be detected by these means." Ex. 1007, 14:25–29. Given these teachings of Isaacson, we are persuaded by Petitioner that Isaacson teaches using the pressure transducers to monitor for the presence of a perforation in the uterus. *See* Ex. 1002 ¶ 162 (testimony of Dr. Pearce). Further, Patent Owner's declarant Dr. Martin's testimony indicates that Isaacson's uterine pressure does not remain constant. *See* Ex. 1016, 81:8–10, 80:17–81:2; Ex. 2007 ¶ 79.

Patent Owner's argument implies that the monitoring must be *only* for a decrease in intrauterine pressure that is caused by a perforation. 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. As discussed above, Isaacson indicates that uterine perforation can be detected from changes in flow rate, which can be measured using pressure.

Second, Patent Owner argues, with respect to claim 9 only, that the combination of Isaacson and Goldrath does not disclose the monitoring step occurring before the treating step. PO Resp. 42–48. Patent Owner's argument is unpersuasive because it is not commensurate with the scope of claim 9. As discussed above, claim 9 does not require that the monitoring step be completed before the ablation begins.

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. 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 teachings 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; *see also* Pet. Reply 23–24 (reproducing Ex. 1016, 82:4–83:23). Petitioner's reasoning is supported by the testimony of Dr. Pearce. *See* Ex. 1002 ¶¶ 169, 210. We, thus, determine that Petitioner provides a sufficient rationale to combine Isaacson and Goldrath.

Patent Owner also argues that it would not have been obvious to combine Isaacson and Goldrath because neither individually teaches the claimed methods. *See e.g.,* PO Resp. 54. Patent Owner's arguments are unpersuasive. "Non-obviousness cannot be established by attacking a reference individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Dependent Claim 7

As discussed above, claim 7 depends from claim 1 and recites "preventing performance of the treating step until after the monitoring step has been carried out." Ex. 1001, 8:30–32. The parties do not dispute that claim 7 requires that ablation cannot begin until after the monitoring step has been completed.

As for claims 1 and 9, Petitioner contends that claim 7 is unpatentable over Isaacson and Goldrath. Pet. 50. Petitioner points to Isaacson's disclosure of a safety circuit and argues:

> 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. (citing Ex. 1007, 4:29–5:2, 22:19–26; Ex. 1002 ¶¶ 202–204).

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows by a preponderance of evidence that claim 7 is unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. *See* Pet. 50 (explaining with specificity how the combination of Isaacson and Goldrath teaches the limitation of claim 7). In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

Patent Owner argues that neither Isaacson nor Goldrath individually teach preventing performance of the treating step until after the monitoring step has been carried out. *See* PO Resp. 42–45, 48–49. For example, Patent Owner argues Isaacson's safety circuit would allow ablation to proceed regardless of whether the uterus is perforated. PO Resp. 43–44. Patent Owner's arguments are unpersuasive. "Non-obviousness cannot be established by attacking reference individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

As for the combination of Masterson and Bolduc, Patent Owner argues that combining Isaacson and Goldrath would not have been obvious because 1) the combination would go against conventional wisdom and 2) there is no reasons to add an additional step when Isaacson already provides for perforation detection. PO Resp. 48–49. For the reasons discussed above

with respect to the patentability of claims 1 and 9, we find Patent Owner's arguments unpersuasive.

Dependent Claims 2–4, 6, and 11–15

Petitioner contends that claims 2–4, 6, and 11–15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. Pet. 47–52. Patent Owner argues that these claims are patentable for the same reasons as discussed above with respect to claims 1 and 9. PO Resp. 51–56. Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's evidence and argument, we determine that Petitioner shows by a preponderance of the evidence that claims 2–4, 6, and 11–15 are unpatentable under 35 U.S.C. § 103 over Isaacson and Goldrath. *See* Pet. 47–52 (explaining with specificity how Isaacson and Goldrath teach the limitations of claims 2–4, 6, and 11–15). For the reasons discussed above with respect to the patentability of claims 1 and 9, we find Patent Owner's argument unpersuasive.

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.

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 (citing Ex. 1002 ¶ 231).

Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine the Petitioner shows by a preponderance of the evidence that claim 5 is unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Himmelstein. *See* Pet. 56–58 (explaining with specificity how the prior art teaches the limitation of claim 5). In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

Patent Owner argues that "Petitioner fails to articulate an adequate rationale for the combination" for similar reasons as discussed above with respect to claims 1 and 9. *See* PO Resp. 33–36. For the reasons discussed above with respect to the patentability of claims 1 and 9, we find Patent Owner's argument unpersuasive.

Patent Owner disputes that the proposed modification would have been obvious. PO Resp. 49–51. Patent Owner argues that Isaacson and Goldrath disclose an open fluid-circulation system and that leaks in an open system may result in decreased fluid volume, but not necessarily in fluid pressure. *Id.* at 49, 51. Patent Owner further argues that Petitioner has not provide a sufficient rationale to combine Isaacson, Goldrath, and

Himmelstein. *Id.* at 50. For the reasons discussed above with respect to the patentability of claims 1 and 9, we find Patent Owner's argument unpersuasive.

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. Patent Owner argues that these claims are patentable for the same reasons as discussed above with respect to claims 1 and 9. PO Resp. 51–56. Upon review of Petitioner's evidence and analysis and taking into account Patent Owner's argument, we determine the Petitioner shows by a preponderance of the evidence that claims 8 and 10 are unpatentable under 35 U.S.C. § 103 over Isaacson, Goldrath, and Benaron. Pet. 58–60 (explaining with specificity how the prior art teach the limitations of claims 8 and 10). 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.

Secondary Considerations

Patent Owner contends that commercial success demonstrates that the claims are non-obvious. PO Resp. 56–58. Patent Owner asserts that its NovaSure® system performs a Cavity Integrity Assessment procedure that practices the claimed method and that the NovaSure® system is commercially successful because of the Cavity Integrity Assessment feature. *Id.* Patent Owner relies upon the declaration of Dr. Martin (Ex. 2007 ¶ 159)

and the declaration of Dr. Evantash (Ex. 2008 ¶¶ 32–36). *Id*. Petitioner disagrees. Pet. Reply 24–26.

To be relevant, evidence of nonobviousness must be commensurate in scope with the claimed invention. *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). Thus, to be accorded substantial weight, there must be a nexus between the merits of the claimed invention and the evidence of secondary considerations. *In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). "Nexus" is a legally and factually sufficient connection between the objective evidence and the claimed invention, such that the objective evidence should be considered in determining nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). "There is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016). A patent challenger may rebut the presumption of nexus with evidence that shows the proffered objective evidence was due to extraneous factors other than the patented invention. *Id.*

In support of its argument that there is a nexus, Patent Owner relies upon the testimony of its declarant, Dr. Evantash. PO Resp. 58 (citing Ex. 2008 ¶¶ 35–36). Dr. Evantash testifies that "[p]art of the reason for the success of the NovaSure® procedure is due to its Cavity Integrity Assessment feature" and testifies that he personally uses the NovaSure® system because of its Cavity Integrity Assessment feature. Ex. 2008 ¶¶ 35–36 (citing Ex. 2032, 2; Ex. 2029, 287). As Petitioner points out (Pet. Reply 25), however, upon cross-examination, Dr. Evantash acknowledged

that other features and benefits of the NovaSure® system may contribute to NovaSure®'s alleged commercial success. *See* Ex. 1017, 30:16–31 (reduced risk of perforation), 31:3–7 (shorter treatment duration), 32:11–33:5 (use of feedback during treatment), 33:6–23 (treatment performed in doctor's office), 35:5–13 (moisture transport system), 38:9–21 (pretreatment unnecessary); *see also* Ex. 2032, 2 (describing other features of the NovaSure® system, such as "Bi-polar RF energy," that provide "proven outcomes"), Ex. 2029, 287 (describing that "Active RF coagulation . . . has superior results . . ."). In view of Petitioner's rebuttal evidence, we are not persuaded that there is a nexus between the alleged success of the NovaSure® system and its Cavity Integrity Assessment feature. Evidence before us, thus, fails to sufficiently establish the required nexus between the merits of the claimed invention and the alleged evidence of commercial success.

Even if the required nexus existed, Patent Owner's evidence does not establish that the NovaSure® system is sufficiently commercially successful to overcome a determination of obviousness here. Patent Owner argues that the NovaSure® system is commercially successful because: 1) it "was sold to Patent Owner for $325 million in 2004" (citing Ex. 2034), and 2) it is "now the most popular product in the endometrial ablation market, and it has been used in 2.5 million endometrial ablation procedures worldwide" (citing Ex. 2008 ¶¶ 32, 34). First, Patent Owner's assertion that the NovaSure® system was sold for $325 million is not supported by Exhibit 2034. Exhibit 2034 states that the company Novacept, not the NovaSure® system, was sold for $325 million. Ex. 2034, 1 ("Cytyc will acquire all of the outstanding shares and options of Novacept in exchange for approximately $325 million in

cash."). Exhibit 2034 indicates that the sale price for the company reflects not just the alleged success of the NovaSure® system, but also other benefits of Cytyc acquiring Novacept. *Id.* at 1–2. For example, Exhibit 2034 states: "As a result of this acquisition . . ., our OBGYN salesforce will double to increase our competitive position for the ThinPrep(R) Pap Test and ThinPrep(R) Imaging System . . . ." *Id.* at 2.

Second, Patent Owner's assertion that the NovaSure® system is "now the most popular product in the endometrial ablation market" relies, ultimately, on documents that do not permit a determination of its popularity relative to other devices in that market. Patent Owner relies upon the testimony of Dr. Evantash (PO Resp. 57–58 (citing Ex. 2008 ¶¶ 32, 34)), which in turn, relies upon Exhibits 2032 and 2033 for support (Ex. 2008 ¶¶ 32, 34 (citing Ex. 2032, 2; Ex. 2033, 1)). Exhibits 2032 and 2033 are advertisements for the NovaSure® system that indicate that it has been used in "2.5 million" "post-market cases" (Ex. 2032, 2) and that "[a]n abundance of data has proven the NovaSure® procedure safe for over 14 years and for 2.5 million women." The fact that the NovaSure® system has been used on 2.5 million women for over 14 years, by itself, does not establish that the NovaSure® system is the most popular product in the endometrial ablation market. Neither Patent Owner nor Dr. Evantash provides any other evidence, such as the number of total endometrial ablations performed during the same time period, to establish sufficient support for their assertion of popularity.

We determine that the evidence before us does not sufficiently establish the required nexus between the merits of the claimed invention and

the alleged commercial success. In addition, Patent Owner's evidence does not sufficiently establish the commercial success of the NovaSure® system. Thus, we determine that Patent Owner's evidence of commercial success does not out-weigh Petitioner's evidence of unpatentability.

III. MOTION TO EXCLUDE

Exhibits 1002 and 1022

Patent Owner requests that Exhibits 1002 and 1022 (testimony of Dr. Pearce) be excluded under Federal Rule of Evidence (FRE) 702 because, according to Patent Owner, Dr. Pearce is not qualified. MTE 2–8; MTE Reply 1–3. Patent Owner argues that Dr. Pearce is not qualified to testify about the endometrial ablations procedures pertinent to the '183 patent because "he is not sufficiently knowledgeable about endometrial ablation procedures as of 1999." MTE, 3.

Petitioner responds that, to be qualified, an expert does not need firsthand experience using endometrial ablation devices and that Dr. Pearce's extensive experience with designing electrosurgical ablation devices is sufficient. MTE Reply 2–8.

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and

> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

We agree with Petitioner that Dr. Pearce does not need extensive firsthand experience with endometrial ablation devices to testify with regards to the design of electrosurgical ablation devices. MTE Opp. 2–8. We are not persuaded by Patent Owner that endometrial electrosurgical ablation devices are so different from other electrosurgical ablation devices, so as to render Dr. Pearce unqualified. The '183 patent, itself, belies Patent Owner's argument as its ablation device can be used in other body cavities and not just the uterus. Ex. 1001, 1:12–17, 2:13–17; *see also* Ex. 1006, 3:48–51 (disclosing an ablation device used for "hollow body organs, such as the uterus"); Ex. 2030, 47:15–48:14. Dr. Pearce has extensive knowledge related to the design of electrosurgical ablation devices and some knowledge of endometrial ablation devices. *See* Ex. 1002 ¶¶ 1–7; Ex. 2030, 24:3–25:1.

Patent Owner also argues that Dr. Pearce is unqualified because of alleged errors in Dr. Pearce's testimony. *See, e.g.*, MTE 6–7. Patent Owner's arguments go to the sufficiency of Dr. Pearce's testimony, but not its admissibility. A motion to exclude is not the proper vehicle to challenge the sufficiency of the evidence to prove a particular fact. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,767. Rather, it is within our discretion to assign the appropriate weight to be accorded to evidence. *See, e.g.*, *Yorkey v. Diab*, 601 F.3d 1279, 1284 (Fed. Cir. 2010) (holding Board has discretion to give more weight to one item of evidence over another "unless no reasonable trier of fact could have done so"); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is

entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations."); *Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) ("In giving more weight to prior publications than to subsequent conclusory statements by experts, the Board acted well within [its] discretion.")

Patent Owner's request to exclude the testimony of Dr. Pearce (Exhibits 1002 and 1022) is denied.

Exhibit 1018

As with Exhibits 1002 and 1022, Patent Owner requests that Exhibit 1018 (testimony of Dr. Mirabile) be excluded under FRE 702. MTE 8–9; MTE Reply 3–4. According to Patent Owner, Dr. Mirabile is not qualified to testify because, he never read the references (e.g., Masterson, Isaacson, etc.) asserted by Petitioner in the prior art grounds. *Id.* Petitioner disagrees. MTE Opp. 8–10.

Petitioner relies upon Dr. Mirabile's testimony to rebut certain statements of Patent Owner's declarants regarding the state of the art and the knowledge of one of ordinary skill in the art. *See, e.g.*, Pet. Reply 9–11. Dr. Mirabile's testimony is not directed to the combination of the asserted prior art references, but to the conventional wisdom with regards to endometrial ablation at the relevant time period. *See generally* Ex. 1018. Based on our review of the record, we conclude that Dr. Mirabile has sufficient knowledge, skill, experience, training, and education to testify on these topics. *See* Ex. 1018 ¶¶ 1–6; Ex. 2037, 7:20–8:1.

Patent Owner's request to exclude the testimony of Dr. Mirabile (Exhibit 1018) is denied.

Exhibit 1019

Patent Owner requests that Exhibit 1019 ("ThermaChoice® Manual") be excluded under FRE 901 as unauthenticated and under FRE 802 as hearsay. MTE 9–13; MTE Reply 4–5. First, Patent Owner argues that "Petitioner has . . . failed to establish that the [ThermaChoice® Manual] is what Petitioner says it is, and has failed to authenticate the date by which the document was allegedly publically accessible under F.R.E. 901." MTE 12. According to Patent Owner, the 1996 copyright date on the ThermaChoice® Manual is insufficient to establish that the ThermaChoice® Manual was publicly available in 1996. *Id.* at 11. Petitioner disagrees and argues that the record contains sufficient evidence to establish publication. MTE Opp. 11–13.

Authenticating rules are intended to ensure that documents are what they purport to be. Fed. R. Evid. 901(a). "To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is." *Id.* Examples of evidence that satisfy the authentication requirement are: "[t]he appearance, contents, substance, internal patterns, or other distinctive characteristic of the item, taken together with all the circumstances" and "[t]estimony that an item is what it is claimed to be." Fed. R. Evid. 901(b)(1), (4).

Here, Petitioner purports the ThermaChoice® Manual to be an operating manual for the Gynecare ThermaChoice® UBT system, which was in use prior to November 1999. Pet. Reply. 10–11; Ex. 1018 ¶¶ 17–18. The appearance, content, and substance of the ThermaChoice® Manual, taken

with other evidence in the record, indicates that it is what Petitioner purports it to be. The face of the ThermaChoice® Manual includes three copyright dates "©1994, 1995, 1996" and indicates that Gynecare is a division of Ethicon, Inc., a Johnson & Johnson company located in Somerville, New Jersey. Ex. 1019, Title Page. The names of Ethicon and Johnson & Johnson are shown in the familiar stylized logos of those companies. *Id.* The ThermaChoice® Manual includes diagrams of the ThermaChoice® device and explanations of the procedure for using the ThermaChoice® device. *E.g., id.* at 2, 22. For example, the explanation of the procedure discusses using pressure to indicate uterine perforations. *Id.* at 22. The copyright dates and other indicia on the title page, the diagrams, and explanations of the procedure in the ThermaChoice® Manual are consistent with other evidence of record. Patent Owner's declarant Dr. Evantash testifies that he performed hundreds of global endometrial ablation procedures beginning in approximately 1996 or 1997 and that "for the first several years, I used the Gynecare ThermaChoice® Uterine Balloon Therapy System." Ex. 2008 ¶ 8.

Petitioner also submitted a publication by Gary Lipscomb, which describes that "[t]he first global endometrial ablation system granted Food and Drug Administration (FDA) approval in the United States in December 1997 was the ThermaChoice® intrauterine hot water balloon (Gynecare, Inc, a division of Ethicon, Inc, Somerville, NJ)." Ex. 1021, 17. The Lipscomb publication also contains a description of the ThermaChoice® device and procedure that is consistent with the device and procedure described in the ThermaChoice® Manual. Ex. 1021, 7–8. For example, Lipscomb describes that the ThermaChoice® device uses pressure to indicate uterine perforations. *Id.* at 8.

Further, Dr. Mirabile's testimony corroborates that the ThermaChoice® Manual is what it is purported to be. Dr. Mirabile's testimony indicates that he bought ThermaChoice® devices for use in his practice at the time the device first came out around 1998 or 1999 and that the devices came with manuals. Ex. 2037, 37:18–38:8. Dr. Mirabile testifies that at the time he prepared his declaration (Ex. 1018), his practice no longer had the ThermaChoice® Manual because his practice no longer used the ThermaChoice® devices and that he "went online and searched for a ThermaChoice® manual." *Id.* at 38:9–39:22. Dr. Mirable's search produced the version of the ThermaChoice® Manual that was submitted as Exhibit 1019. We conclude that Dr. Mirable's testimony establishes that Exhibit 1019 is substantially equivalent to the manuals that came with his ThermaChoice® devices.

We determine that the evidence discussed above is sufficient to support a finding that the ThermaChoice® Manual is what the Petitioner purports it to be—an operating manual for the Gynecare ThermaChoice® UBT system, which was in use prior to November 1999. Patent Owner's request to exclude the ThermaChoice® Manual (Exhibit 1019) as unauthenticated is denied.

Patent Owner requests that Exhibit 1019 be excluded because the proffered evidence of the publication date is inadmissible hearsay under FRE 802. MTE 12–13. Patent Owner argues that "[t]o the extent that Petitioner is attempting to rely on the 1996 copyright date appearing in the ThermaChoice® manual to establish that it describes the state of the art in 1996: (1) the copyright date is a statement; (2) the statement was not made while testifying to the Board; and (3) Petitioner is attempting to use the

copyright statement to provide that the document was available in 1996 and pertains to technology available in 1996." *Id.* Petitioner disagrees. MTE Opp. 13–14.

Patent Owner's hearsay arguments do not support exclusion of the ThermaChoice® Manual. The only aspect of the ThermaChoice® Manual that Patent Owner identifies as improper hearsay is Petitioner's reliance on the 1996 copyright date to prove the document was available in 1996. MTE 12–13. However, as discussed above, Petitioner has presented other evidence of the ThermaChoice® Manual's public availability before November 1999. Ex. 2037, 37:18–38:8; *see also* Ex. 1018 ¶¶ 17–19; Ex. 1021, 7–8; Ex. 2008 ¶ 8. Because Petitioner relies on other evidence to show public availability within the prior art period, a determination that the 1996 copyright statement is improper hearsay for the purpose of showing publication in 1996 would not support the relief Patent Owner seeks, which is exclusion of the entire ThermaChoice® Manual.

Patent Owner's request to exclude the ThermaChoice® Manual as inadmissible hearsay is denied.

III. MOTION TO AMEND

We have concluded that claims 1–15 of the '183 patent are unpatentable. Therefore, we address Patent Owner's contingent motion to substitute claims 16–23 for claims 1–8. MTA 1.

Proposed Substitute Claims

Patent Owner proposed to substitute claims 16–23 for claims 1–8. *Id.* at 1. Patent Owner's substitute claims 16–23 represent a one-for-one

substitution for original claims 1–8 in compliance with 37 C.F.R. § 42.121(a)(3).

Proposed substitute claim 16 is reproduced below, with added text underlined and deleted text stricken through. MTA, Appendix.

> 16. A method of ablating a uterus, comprising the steps of: inserting an ablation device into ~~a~~ the uterus, the ablation device comprising an expandable applicator head; expanding the applicator head of the ablation device in the uterus; flowing an inflation medium into the uterus; monitoring for the presence of a perforation in the uterus using a pressure sensor; and after completing the monitoring step, initiating ablative treat~~ing~~ment of the interior of the uterus using the ablation device.

Proposed substitute claim 16 amends claim 1 to specify that 1) an expandable applicator head of the ablation device expands in the uterus ("the expanding step") and 2) the ablative treatment is initiated after completing the monitoring step ("the ablating after monitoring step"). MTA, 3.

Proposed substitute claim 18 is reproduced below, with added text underlined and deleted text stricken through. MTA, Appendix.

> 18. The method of claim ~~2~~17, wherein the applicator head comprises flexures that expand and tension the applicator head and wherein the electrical energy is RF energy delivered through electrodes in the applicator head.

Proposed substitute claims 17 and 19–23 depend from claim 16 and add limitations that substantively track those that are added in dependent claims 2 and 4–8, respectively, but with minor amendments to conform to the changes in claim 16 and to provide clarity. *See* MTA, 4, Appendix.

Motions to Amend in view of Aqua Products

On October 4, 2017, the Federal Circuit issued an *en banc* decision in *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017). In light of the *Aqua Products* decision, the Board will not place the burden of persuasion on a patent owner with respect to the patentability of substitute claims presented in a motion to amend. *Aqua Products*, 872 F.3d at 1327; *see also* "Guidance on Motions to Amend in view of Aqua Products" (Nov. 21, 2017) (https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf) ("Guidance"). A motion to amend still must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. *See* Guidance.

Requirements of 35 U.S.C. 316(d) and 37 C.F.R. § 42.121

Pursuant to 35 U.S.C. § 316(d)(3), "[a]n amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter." Similarly, 37 C.F.R. § 42.121(a)(2)(ii) provides that a motion to amend may be denied where the amendment seeks to enlarge the scope of the claims of the patent or introduces new subject matter.

We determine that Patent Owner's Motion to Amend meets the requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. For example, the substitute claims comply with the requirements of 35 U.S.C. § 316(d)(3) and 37 C.F.R. § 42.121(2)(ii), discussed above. *See generally* MTA 3–9; MTA Reply 1–3. Petitioner disagrees. MTA Opp. 1–7; Pet. Supp. Br. 2–3.

First, Petitioner argues that substitute claim 16 and substitute claim 23 impermissibly enlarge the scope of claim 1 and claim 8, respectively. MTA Opp. 3–7; Pet. Supp. Br. 2–3. Claim 1 recites "*treating* the interior of the

uterus using the ablation device." Substitute claim 16 replaces that limitation with "*initiating* ablative treatment of the interior of the uterus using the ablation device." MTA, Appendix. According to Petitioner, the Specification of the '183 defines ablative treatment or treating "by its effect on the body; destroying the cells of the organ lining or coagulating tissue proteins." MTA Opp. 4 (citing Ex. 1001, 1:22–28, 3:7). Petitioner argues that the amendment removes the "treating" requirement from the claim 16, because "the amended claim only requires that the device operation be 'initiated'—actual delivery of the therapeutic effect or treatment may or may not occur." MTA Opp. 3–5. Petitioner likewise argues that substitute claim 23 impermissibly enlarges the scope of claim 8 because substitute claim 23 recites "preventing performance" and claim 8 recites "suspending performance." MTA Opp. 3, 6.

Patent Owner responds that the amendment to claim 16 does not enlarge the scope of claim 1. MTA Reply 1–2. Patent Owner argues that

> Petitioner assumes that the term 'treating' in the original claims requires completion of treatment or some other duration of treatment. ([MTA Opp.] at 5.) Nothing in the specification mandates such a construction of the term 'treating' and it is not the broadest reasonable interpretation.

Id. Patent Owner argues that "initiating ablative treatment" is narrower than "treating." *Id.*

We agree with Patent Owner that substitute claims 16 and 23 do not enlarge the scope of claims 1 and 8, respectively, and that the term "treating" in the original claims does not require completion of treatment or that it produces some effect on the body, such as destroying the cells of the organ

lining or coagulating tissue proteins. *See* MTA Reply 1–2. Petitioner cites to the following passage of the '183 patent as defining the term "treating":

> Ablation of the interior lining of a body organ is a procedure which involves heating the organ lining to temperatures which destroy the cells of the lining or coagulate tissue proteins. Such a procedure may be performed as a treatment to one of many conditions, such as chronic bleeding of the endometrial layer of the uterus or abnormalities of the mucosal layer of the gallbladder.

MTA Opp. 4 (reproducing Ex. 1001, 1:22–28). Contrary to Petitioner's argument and as can be seen from the above, the passage does not define the term 'treating' by its effect on the body, such as destroying the cells of the organ lining or coagulating tissue proteins.

Also contrary to Petitioner's argument, claim 8 indicates that the treating step of claim 1 does require treating to continue until some effect on the body, such as destroying the cells of the organ lining or coagulating tissue proteins, is achieved. Claim 8 depends from claim 1 and recites "suspending performance of the treating step if a perforation is detected in the monitoring step." Ex. 1001, 8:34–35. Claim 1 recites "treating the interior of the uterus using the ablation device." Claim 8 indicates that the treating step of claim 1 does require completion of treatment, otherwise, the "treating" could not be suspended.

We, thus, determine that substitute claim 16 and substitute claim 23 do not enlarge the scope of claim 1 and claim 8, respectively.

Second, Petitioner argues that substitute claim 18 impermissibly introduces new matter. MTA Opp. 7; Pet. Supp. Br. 3. Substitute claim 18 recites "wherein the electrical energy is RF energy delivered through electrodes *in* the applicator head." MTA, Appendix (emphasis added).

Petitioner argues that the '183 patent "refers to *external* electrodes *on* an application head, and do not support the recited electrodes *in* an applicator head." MTA Opp. 7.

Patent Owner responds that "the '183 disclosure plainly contemplates that the electrodes are integral with the applicator head and that portions are interior to it." MTA Reply. 3. Patent Owner points to column 2, lines 21–25, column 3, lines 30–35, column 4, lines 4–12, column 5, lines 5–12, and Figs. 2B and 4 of the '183 patent as supporting this limitation. *See* MTA 7; MTA Reply 3. Additionally, Patent Owner also points out that Petitioner's declarant Dr. Pearce cites to similar language in Truckai as disclosing the limitation. MTA Reply 2–3. For example, Dr. Pearce testifies:

> Truckai '880 discloses that RF energy is "delivered through electrodes in the applicator head" as also required by claim 18. Specifically, Truckai '880 discloses that the "RF applicator head includes . . . an array of electrodes 14 formed on the surface of the electrode carrying means 12." [Ex. 1023] at 3:59-62; Fig. 2.

Ex. 1022 ¶ 15.

Amended claims which introduce elements or limitations which are not supported by the original disclosure of the patent and fail to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, improperly introduce new matter. Section 112, first paragraph, requires that the "specification shall contain a written description of the invention . . . ." To satisfy the written description requirement, the disclosure must reasonably convey to skilled artisans that the patentee possessed the claimed invention as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The requirement under § 112

does not demand that the specification recite the claimed invention verbatim. *Id*. at 1352 (citations omitted).

The ’183 patent discloses an embodiment in which electrode array 44 is formed of “a stretchable metallized fabric mesh . . . plated with gold or other conductive material.” Ex. 1001, 3:29–57; *see also id*. at Fig. 2B (depicting mesh electrode array 44). We agree with Patent Owner that this disclosure sufficiently discloses electrodes that are integral with and partly interior to an applicator head and provides sufficient written description support for the limitation of substitute claim 16.

Further, as Petitioner points out (MTA Opp. 11–12), the ’183 patent states “[a]blation devices of this type are shown and described in U.S. Patent No. 5,769,880 . . . , which [is] incorporated herein by reference.” Ex. 1001, 2:60–64. U.S. Patent No. 5,769,880 is Truckai[8]. Ex. 1023. With respect to the patentability of claim 18, Dr. Pearce testifies that Truckai meets this limitation because it discloses that the “RF applicator head includes . . . an array of electrodes 14 formed *on* the surface of the electrode carrying means 12.” Ex. 1022 ¶ 15 (quoting Ex. 1023, 3:59–62, citing *id.* at Fig. 2) (emphasis added). Truckai discloses numerous means of attaching the electrodes to the electrode carrying means, including, for example, the electrode array being formed of a metallized fabric. *Id.* at 4:59–5:19. Dr. Pearce’s testimony, thus, indicates that the ’183 patent’s disclosure of an array of electrodes 44 formed *on* the surface of the electrode carrying means provides sufficient support for the limitation.

[8] U.S. Patent No. 5,769,880 (issued June 23, 1998) (Ex. 1023).

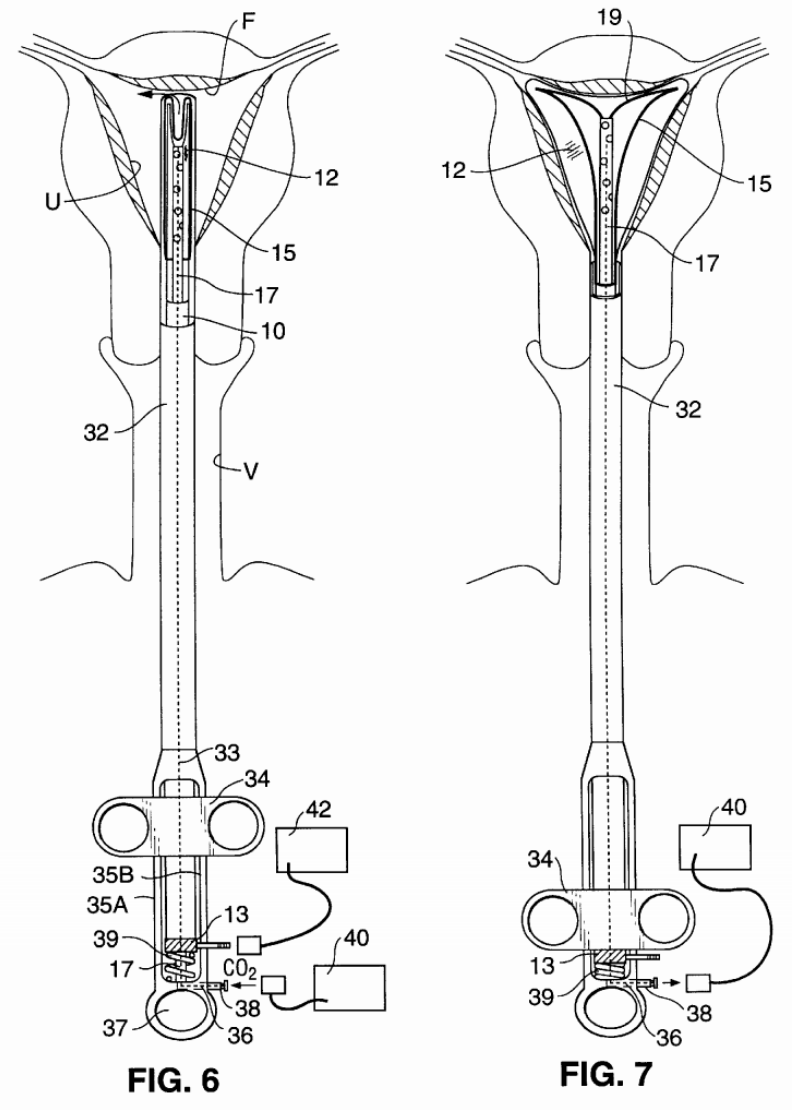
We, thus, determine that substitute claim 18 does not impermissibly introduce new matter.

Patentability

As discussed above, Patent Owner does not have the burden of persuasion with respect to the patentability of substitute claims presented in its Motion to Amend. *See Aqua Products*, 872 F.3d at 1327; *see also* Guidance. We determine whether the substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by the petitioner. *See Aqua Products*, 872 F.3d at 1325–26; *see also* Guidance. For the reasons explained below, considering the entirety of the record before us, we determine that the preponderance of the evidence shows that the proposed substitute claims are not patentable over the prior art of record.

Overview of Truckai

Truckai is titled "Moisture Transport System for Contract Electrocoagulation" and issued on June 23, 1998. Ex. 1023, (45), (54). Truckai discloses an apparatus for performing ablation of organs, such as the uterus. *Id.* at Abstract, 1:5–9. Truckai's apparatus includes an RF applicator head 2, main body 4, and handle 6. *Id.* at 3:57–59. RF applicator head 2 includes an electrode carry means 12 having an array of electrodes 14. *Id.* at 3:59–62. Electrode carry means 12 is formed of a sack of material, such as metallized fabric. *See id.* at 4:59–5:19. RF applicator head 2 is compressed prior to and expanded after being inserted in the uterus. *See id.* at 8:49–9:5. Figures 6 and 7 of Truckai are reproduced below side-by-side.



Figures 6 and 7 depict Truckai's ablation device having RF applicator head 2 in an unexpanded and expanded state, respectively. *Id.* at 2:66–3:7. Carbon dioxide gas fills the RF applicator head through tube 17 to also expand the uterine cavity. *Id.* at 8:52–55, 9:26. During treatment, RF energy is applied to the electrodes. *Id.* at 9:47–51.

Combination of Truckai, Masterson, and Bolduc

Substitute Claim 16

Petitioner contends that substitute claim 16 is unpatentable over Truckai, Masterson, and Bolduc. MTA Opp. 8–17. Substitute claim 16 corresponds to claim 1. Petitioner points to its arguments made with respect to the unpatentability of claim 1 and claim 7[9] over Masterson and Bolduc for support. *See e.g., id.* at 8, 15. Petitioner additionally proffers a second declaration of Dr. Pearce for support. Ex. 1022. Petitioner argues that the addition of the expanding step and the ablating after monitoring step to the limitations of claim 1 do not make substitute claim 16 patentable. MTA Opp. 8–18.

Petitioner contends that Truckai discloses a method of ablating a uterus using an ablation device having an expandable applicator head. MTA Opp. 11–14. Petitioner argues that the combination of Masterson and Bolduc teaches "the concept of using a pressure sensor to monitor for the presence of a perforation in the uterus" and "preventing initiation of treatment of the uterus until after the monitoring step is performed" *Id.* at 15 (citing Pet. 26–29; Ex. 1002 ¶¶ 54–60; Ex. 1022 ¶¶ 33–37). According to Petitioner, it would have been obvious to a person of ordinary skill in the art "to apply [the] combined teachings of Masterson and Bolduc to an ablation device utilizing the structural aspects described in Truckai '880, such as an expandable applicator head containing flexures and electrodes" in order to

[9] Claim 7 depends from claim 1 and, like claim 16, adds a limitation that requires the monitoring step to be completed before ablation begins. Ex. 1001, 8:30–32 ("including the step of preventing performance of the treating step until after the monitoring step has been carried out").

decrease risk associated with applying pressurized fluid to a cavity, such as the possibility of fluid escaping through a perforation. MTA Opp. 15–17 (citing Ex. 1022 ¶¶ 39–42). Petitioner also notes that the '183 patent discloses that Truckai's ablation device is an example of an RF ablation device that may be used with the system disclosed in the '183 patent. MTA Opp. 11–12 (citing Ex. 1001, 2:60–64).

Upon review of the entire record before us, including Petitioner's evidence and analysis and taking into account Patent Owner's arguments, discussed below, we determine that a preponderance of the evidence establishes that substitute claim 16 is unpatentable under 35 U.S.C. § 103 over Truckai, Masterson, and Bolduc. In reaching our determination, we considered Patent Owner's arguments and evidence of secondary considerations, also discussed below.

Patent Owner argues that none of Truckai, Masterson, and Bolduc discloses the ablating after monitoring step. *See, e.g.*, MTA 12–14, 18–19; MTA Reply 4–6, 9–12. Patent Owner further argues that "Petitioner has failed to show any reliable rationale for combining the references, including newly advanced [Truckai]" and in particular, that "a person of ordinary skill in the art would not have extended the procedure times of Masterson and Isaacson . . . to monitor for perforations before commencing ablation." MTA Reply 9; Pet. Supp. Br. 2–4. Patent Owner's arguments are substantially the same as its arguments regarding the combination of Masterson and Bolduc with respect to claims 1, 7, and 9 in the Patent Owner's Response. *Compare* MTA Reply 9–12 *to* PO Resp. 23–30, 32–33.

Patent Owner's arguments are unpersuasive. For the same reasons as discussed above with respect to the unpatentability of claims 1, 7, and 9 over

Masterson and Bolduc, we determine that one of ordinary skill in the art would have added a pressure sensor to monitor for uterine perforations prior to ablating the uterus, as taught by the combination of Masterson and Bolduc, to Truckai's ablation device in order to increase safety. *See* MTA Opp. 15–17 (citing Ex. 1022 ¶¶ 39–42).

Patent Owner also argues that neither Masterson nor Bolduc teaches the expanding step of substitute claim 16. *See generally* MTA 18–19. Petitioner relies upon Truckai to teach the expanding step, however, and Patent Owner does not dispute that Truckai teaches the expanding step. *See generally* MTA 18–19; MTA Reply. We agree that Truckai provides that teaching and that one of skill in the art would have had reason to combine the teachings in Masterson, Bolduc, and Truckai as discussed above. Thus, after considering the entirety of the record before us, we determine that the preponderance of the evidence establishes that substitute claim 16 is unpatentable over the prior art of record.

Substitute Claim 17

Petitioner contends that substitute claim 17 is unpatentable over Truckai, Masterson, and Bolduc. MTA Opp. 14–18 (citing Ex. 1022 ¶ 26). Substitute claim 17 depends from substitute claim 16 and additionally recites "wherein the treatment step includes delivering electrical energy to the tissue." MTA, Appendix. As Dr. Pearce points out (Ex. 1022 ¶ 26), Truckai meets this limitation because Truckai discloses using an RF applicator head having an electrode array to direct the flow of current through the tissue to form a region of ablation. Ex. 1023, 9:47–51.

Patent Owner makes no arguments directed to the additional limitation of substitute claim 17. *See generally* MTA, MTA Reply.

After considering the entirety of the record before us, including Petitioner's evidence and analysis, we determine that the preponderance of the evidence establishes that substitute claim 17 is unpatentable under 35 U.S.C. § 103 over Truckai, Masterson, and Bolduc. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, discussed below.

Substitute Claim 18

Substitute claim 18 depends from claim 16 and additionally recites "wherein the applicator head comprises flexures that expand and tension the applicator head and wherein the electrical energy in RF energy delivered through electrodes in the applicator head." MTA, Appendix. Petitioner contends that Truckai discloses the additional limitation of claim 18. MTA Opp. 13 (citing Ex. 1023, 7:6–21, 7:59–62, Fig. 6, Fig. 7; Ex. 1022 ¶ 14; Ex. 1023 ¶ 15); Ex. 1022 ¶¶ 27–29. As Dr. Pearce points out (Ex. 1022 ¶¶ 14–15, 27–29), Truckai's RF applicator head has spring members that expand and tension the RF applicator head (Ex. 1023, 7:6–21, 7:59–62, Fig. 6, Fig. 7) and has "an array of electrodes 14 formed on the surface of the electrode carrying means 12" to direct the flow of current through the tissue to form a region of ablation (Ex. 1023, 3:59–62, 9:47–51, Fig. 2).

Patent Owner does not dispute that Truckai discloses the limitations recited by claim 18. *See generally* MTA, MTA Reply.

After considering the entirety of the record before us, including Petitioner's evidence and analysis, we determine that the preponderance of

the evidence establishes that substitute claim 18 is unpatentable under 35 U.S.C. § 103 over Truckai, Masterson, and Bolduc. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, discussed below.

Substitute Claims 19–23

Substitute claims 19, 21, and 22 correspond to claims 4, 6, and 7. Petitioner contends that substitute claims 19, 21, and 22 are unpatentable over Truckai, Masterson, and Bolduc for the same reasons claims 4, 6, and 7 are unpatentable over Masterson and Bolduc. MTA Opp. 14–28 (citing Ex. 1022 ¶¶ 30–32).

Substitute claim 20 corresponds to claim 5. Petitioner contends that substitute claim 20 is unpatenable over Truckai, Masterson, Bolduc, and Himmelstein for the same reasons claim 5 is unpatentable over Masterson, Bolduc, and Himmelstein. MTA Opp. 18 (citing Pet. 32–33; Ex. 1002 ¶¶ 128–141; Ex. 1022 ¶¶ 42–46).

Substitute claim 23 corresponds to claim 8. Petitioner contends that substitute claim 23 is unpatenable over Truckai, Masterson, Bolduc, and Benaron for the same reasons claim 8 is unpatentable over Masterson, Bolduc, and Benaron. MTA Opp. 18 (citing Pet. 34–36; Ex. 1002 ¶¶ 142–157; Ex. 1022 ¶¶ 47–52).

Patent Owner makes no arguments directed to the additional limitations of substitute claims 19–23. *See generally* MTA, MTA Reply.

After considering the entirety of the record before us, including Petitioner's evidence and analysis, we determine that the preponderance of the evidence establishes that substitute claims 19–23 are unpatentable under

35 U.S.C. § 103. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, discussed below.

Truckai, Isaacson, and Goldrath

Substitute Claim 16

Petitioner contends that substitute claim 16 is unpatentable over Truckai, Isaacson, and Goldrath. MTA Opp. 8–14, 18–21. Petitioner points to its arguments made with respect to the unpatentability of claim 1 and claim 7 over Isaacson and Goldrath for support. *See e.g.*, *id.* at 18–19. Petitioner additionally proffers a second declaration of Dr. Pearce for support. Ex. 1022. Petitioner argues that the addition of the expanding step and the ablating after monitoring step to the limitations of claim 1 do not make substitute claim 16 patentable. MTA Opp. 8–14, 18–21.

Petitioner contends that Truckai discloses a method of ablating a uterus using an ablation device having an expandable applicator head. MTA Opp. 11–14. Petitioner argues that the combination of Isaacson and Goldrath teaches "the concept of using a pressure sensor to monitor for the presence of a perforation in the uterus" and "preventing initiation of treatment of the utuerus until after the monitoring step is performed" *Id.* at 19 (citing Pet. 52–55; Ex. 1002 ¶¶ 162–169; Ex. 1022 ¶¶ 62–66). According to Petitioner, it would have been obvious to a person of ordinary skill in the art "to apply [the] combined teachings of Isaacson and Goldrath to an ablation device utilizing the structural aspects described in Truckai '880, such as an expandable applicator head containing flexures and electrodes" in order to decrease risk associated with applying pressurized

fluid to a cavity, such as the possibility of fluid escaping through a perforation. MTA Opp. 19–20 (citing Ex. 1022 ¶¶ 67–69). Petitioner notes that the '183 patent discloses that Truckai's ablation device is an example of an RF ablation device that may be used with the system disclosed in the '183 patent. MTA Opp. 11–12 (citing Ex. 1001, 2:60–64).

After considering the entirety of the record before us, including Petitioner's evidence and analysis, discussed above, and taking into account Patent Owner's arguments, discussed below, we determine that a preponderance of the evidence establishes that substitute claim 16 is unpatentable under 35 U.S.C. § 103 over Truckai, Isaacson, and Goldrath. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, also discussed below.

Patent Owner argues that none of Truckai, Isaacson, and Goldrath discloses the ablating after monitoring step. *See e.g.*, MTA 12, 14–16; MTA Reply 6–9. Patent Owner further argues that "Petitioner has failed to show any reliable rationale for combining the references, including newly advanced [Truckai]" and in particular, that "a person of ordinary skill in the art would not have extended the procedure times of Masterson and Isaacson . . . to monitor for perforations before commencing ablation." MTA Reply 9; PO Supp. Br. 3–4. Patent Owner's arguments are substantially the same as its arguments regarding the combination of Isaacson and Goldrath with respect to claims 1, 7, and 9 in the Patent Owner's Response. *Compare* MTA Reply 9–12 *to* PO Resp. 36–49.

Patent Owner's arguments are unpersuasive. For the same reasons as discussed above with respect to the unpatentability of claims 1, 7, and 9 over Isaacson and Goldrath, we determine that one of ordinary skill in the art

would have added a pressure sensor to monitor for uterine perforations prior to ablating the uterus, as taught by the combination of Isaacson and Goldrath, to Truckai's ablation device in order to increase safety. *See* MTA Opp. 19–20 (citing Ex. 1022 ¶¶ 67–69).

Patent Owner also argues that neither Isaacson nor Goldrath teaches the expanding step of substitute claim 16. *See generally* MTA 18–19. Petitioner, however, relies upon Truckai to teach the expanding step. Patent Owner does not dispute this. *See generally* MTA 18–19; MTA Reply. We are persuaded that Truckai teaches this limitation and that one of skill in the art would have had reason to combine the teachings in Isaacson, Goldrath, and Truckai for the reasons discussed above.

Substitute Claim 17

Petitioner contends that substitute claim 17 is unpatentable over Truckai, Isaacson and Goldrath. MTA Opp. 14–18 (citing Ex. 1022 ¶ 54). Substitute claim 17 depends from substitute claim 16 and additionally recites "wherein the treatment step includes delivering electrical energy to the tissue." MTA, Appendix. As Dr. Pearce points out (Ex. 1022 ¶ 54), Truckai meets this limitation because Truckai discloses using an RF applicator head having an electrode array to direct the flow of current through the tissue to form a region of ablation. Ex. 1023, 9:47–51.

Patent Owner makes no arguments directed to the additional limitation of substitute claim 17. *See generally* MTA, MTA Reply.

After considering the entirety of the record before us, including Petitioner's evidence and analysis, we determine that the preponderance of the evidence establishes that substitute claim 17 is unpatentable under 35

U.S.C. § 103 over Truckai, Isaacson, and Goldrath. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, discussed below.

Substitute Claim 18

Petitioner contends that Truckai discloses the additional limitation of claim 18. MTA Opp. 13 (citing Ex. 1023, 7:6–21, 7:59–62, Fig. 6, Fig. 7; Ex. 1022 ¶ 14; Ex. 1023 ¶ 15); *see also* Ex. 1022 ¶¶ 55–57. As Dr. Pearce points out (Ex. 1022 ¶¶ 14–15, 55–57), Truckai's RF applicator head has spring members that expand and tension the RF applicator head (Ex. 1023, 7:6–21, 7:59–62, Fig. 6, Fig. 7) and has "an array of electrode 14 formed on the surface of the electrode carrying means 12" to direct the flow of current through the tissue to form a region of ablation (Ex. 1023, 3:59–62, 9:47–51, Fig. 2).

Patent Owner does not dispute that Truckai discloses the limitations recited by claim 18. *See generally* MTA, MTA Reply.

After considering the entirety of the record before us, including Petitioner's evidence and analysis, we determine that the preponderance of the evidence establishes that substitute claim 18 is unpatentable under 35 U.S.C. § 103 over Truckai, Isaacson, and Goldrath. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, discussed below.

Substitute Claims 19–23

Substitute claims 19, 21, and 22 correspond to claims 4, 6, and 7. Petitioner contends that substitute claims 19, 21, and 22 are unpatenable

over Truckai, Isaacson, and Goldrath for the same reasons claims 4, 6, and 7 are unpatentable over Isaacson and Goldrath. *See* MTA Opp. 18–21 (citing Ex. 1022 ¶¶ 58–61).

Substitute claim 20 corresponds to claim 5. Petitioner contends that substitute claim 20 is unpatenable over Truckai, Isaacson, Goldrath, and Himmelstein for the same reasons claim 5 is unpatentable over Isaacson, Goldrath, and Himmelstein. MTA Opp. 22 (citing. Pet. 56–58; Ex. 1002 ¶¶ 227–242; Ex. 1022 ¶¶ 71–75).

Substitute claim 23 corresponds to claim 8. Petitioner contends that substitute claim 23 is unpatenable over Truckai, Isaacson, Goldrath, and Benaron for the same reasons claim 8 is unpatentable over Isaacson, Goldrath, and Benaron. MTA Opp. 22 (citing. Pet. 58–60; Ex. 1002 ¶¶ 243–259; Ex. 1022 ¶¶ 76–81).

Patent Owner makes no arguments directed to the additional limitations of substitute claims 19–23. *See generally* MTA, MTA Reply.

Upon review of Petitioner's evidence and analysis, we determine that substitute claims 19–23 are unpatentable under 35 U.S.C. § 103. In reaching our determination, we considered Patent Owner's argument and evidence of secondary considerations, discussed below.

Secondary Considerations

Patent Owner contends that secondary considerations confirm the nonobviousness of the proposed substitute claims. MTA 24–25. Patent Owner makes substantially the same arguments and relies upon substantially the same evidence as it did in the Patent Owner's Response. *Compare* MTA 24–25 *to* PO Resp. 56–58. Petitioner disagrees for the same reasons set

forth in the Petitioner's Reply. *Compare* MTA Opp. 22–25 *to* Pet. Reply 24–26. For the same reasons as discussed above with respect to the unpatentability of claims 1–8, we determine Patent Owner's evidence of commercial success does not outweigh Petitioner's evidence of unpatentability of substitute claims 16–23.

IV. CONCLUSION

For the reasons set forth above, we conclude that claims 1–15 are unpatentable, Patent Owner's Motion to Exclude Evidence is denied, and Patent Owner's Motion to Amend is denied.

This is a final written decision of the Board under 35 U.S.C. § 318(a).

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–15 of U.S. Patent No. 6,872,183 B2 are *unpatentable*;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is *denied*;

FURTHER ORDERED that Patent Owner's Motion to Amend is *denied*; and

FURTHER ORDERED that parties to the proceeding seeking judicial review of this decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Michael Rosato
Matthew Argenti
Steven Parmelee
Neil Desai
WILSON SONSINI GOODRICH & ROSATI
mrosato@wsgr.com
margenti@wsgr.com
sparmelee@wsgr.com
ndesai@wsgr.com

PATENT OWNER:

Jennifer A. Sklenar
Alissa H. Faris
ARNOLD & PORTER LLP
Jennifer.Sklenar@aporter.com
Alissa.Faris@aporter.com