IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC., and CYTYC SURGICAL PRODUCTS, LLC, Plaintiffs, vs. MINERVA SURGICAL, INC., Defendant.	**Civ. No. 15-1031-JFB** **FINAL JUDGMENT**

Pursuant to the Memorandum and Order entered on May 2, 2019 (D.I. 616) and the Jury Verdict (D.I 498),

1. Judgment is entered in favor of plaintiffs/counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc., on plaintiffs/counterclaim defendants claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $4,787,668.23; plus prejudgment interest in the amount of $270,533, plus postjudgment interest at the statutory rate of 2.44% under 35 U.S.C. § 1961(a).

2. Judgment is entered in favor of plaintiffs/counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc., on plaintiffs'/counterclaim defendants' claim for infringement of U. S. Patent No. 9,9095,348 in the amount of $1,629,304.08 in supplemental damages for Minerva's infringing sales from April 1, 2018, through August 13, 2018, plus prejudgment interest on that amount at the prime rate compounded quarterly from the date of infringement to August 13, 2018, (D.I. 520), plus post-

judgment interest thereafter at the legal rate under 28 U.S.C. § 1961 until such time as the judgment is paid.

3. Judgment is entered in favor of plaintiffs/counterclaim defendants Hologic, Inc. and CYTYC Surgical Products, LLC, and against defendant/counterclaimant Minerva, Inc. on defendant/counterclaimant Minerva's counterclaims.

4. Defendant/counterclaimant Minerva's counterclaims are hereby dismissed.

IT IS SO ORDERED.

DATED this 31st day of May 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC. and CYTYC SURGICAL PRODUCTS, LLC,	)	
Plaintiffs,	)	
v.	)	Civ. No. 15-1031-SLR
MINERVA SURGICAL, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 24th day of April, 2017, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. 6,872,183 ("the '183 patent"), 9,095,348 ("the '348 patent"), 8,998,898 ("the '898 patent"), and 9,247,989 ("the '989 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"Pressure sensor:"**[1] "A device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal." Plaintiffs had proposed "a device that senses pressure," and defendant had proposed "a device whose input detects a force per unit area and that outputs a corresponding electrical signal." (D.I. 155 at 1) At oral argument, the court articulated the above construction, and the parties agreed with the exception of the "or indirectly" component. (D.I. 225 at 37:25-38:27) Defendant argued that the pressure sensor must measure the force per unit area "directly." (D.I. 199 at 3) Plaintiffs contended that indirect forms of measuring pressure are equally valid. (D.I. 201 at 7; D.I. 202 at ¶ 19) The specification describes a "pressure sensing system" that monitors the presence of a perforation in the uterus:

> Pressure sensing system 24 monitors the pressure within the body cavity BC while fluid/gas is being (or after it has been) delivered to the body cavity, and detects whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ.

('183 patent, 2:37-43; *see also id.*, abstract; 1:53-57; 5:18-37) Nothing in the specification requires the pressure sensor to measure pressure "directly" so long as the pressure sensor can "detect whether elevated pressure can be maintained [in the uterus] . . . over a predetermined period of time."[2]

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[1] Found in '183 patent, claims 1 and 9.

[2] Defendant presented extensive extrinsic evidence to support its argument that a pressure sensor must measure pressure directly and cannot measure pressure indirectly. Dr. Robert Tucker ("Dr. Tucker") opined that a person having ordinary skill in the art "would know that pressure can be measured in millimeters of mercury ('mmHg') . . . that refers to a size of a column of elemental mercury that can be supported by the force exerted by a given amount of pressure." (D.I. 200 at ¶ 23) The data sheet for the SenSym amplified SCX series sensor (identified as an example embodiment in the '183 patent) measures pressure by its effect on "an integrated circuit sensor element." (D.I. 172, ex. P at A-3) In these examples, the measurement is based upon the effect of pressure on a physical component (e.g., a column of mercury or a semiconductor) and known physical relationships (gravity, temperature, atmospheric pressure, and so forth). Dr. Gregory T. Martin ("Dr. Martin") explained that "[i]n fact, commercially available

2. **"Monitoring:"**[3] "Monitoring."[4]

3. **"Applicator head:"**[5] "A distal end portion of an ablation device that applies energy to the uterine tissue."[6] Claim 1 of the '348 patent recites:

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

('348 patent, 19:9-21) The '348 patent describes an embodiment with reference to figures 1 and 2 in which

> an ablation device . . . is comprised generally of three major components: RF applicator head 2, main body 4, and handle 6. . . . The RF applicator

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pressure sensors almost always measure pressure by some indirect means." (D.I. 202 at ¶ 19) Based upon this record, defendant's proposed construction (limiting the term to "direct" measurement) would exclude commercially-available pressure sensors from the scope of the term "pressure sensor."

[3] Found in '183 patent, claims 1, 5-7, 9, and 11.

[4] The court adopts plaintiffs' proposal. Defendant proposed "measuring a condition in a system" but did not identify any support in the specification for such a construction. (D.I. 199 at 13-14)

[5] Found in '348 patent, claims 1, 5, 8, and 12.

[6] The court adopts plaintiffs' proposal. Defendant proposed "an applicator having a permeable or absorbent tissue contacting surface into which moisture is drawn." (D.I. 155 at 2) The specification describes the shortcomings of the prior art methods including that "water drawn from the tissue creates a path of conductivity through which current traveling through the electrodes will flow" and "the heated liquid around the electrodes causes thermal ablation to continue well beyond the desired ablation depths." ('348 patent, 2:9-19) The specification also states that "liquid build-up at the ablation site is detrimental." (*Id.* at 11:1-13) Defendant presented extensive argument for reading these limitations from the specification into the claims. (D.I. 199 at 15-24) However, "[t]he court concludes that such disclosures do not rise to the level of disclaimer, sufficient to narrow the disputed claim limitation as desired by [defendant]." (D.I. 127 at 11, n.10)

> head 2 includes an electrode carrying means 12 mounted to the distal end of the shaft 10 and an array of electrodes 14 formed on the surface of the electrode carrying means 12.

('348 patent, 4:55-61; figures 1 & 2, item 2) In another embodiment,

> applicator head 102 extends from the distal end of a length of tubing 108 which is slidably disposed within the sheath 104. Applicator head 102 includes an external electrode array 102a and an internal deflecting mechanism 102b used to expand and tension the array for positioning into contact with the tissue.

('348 patent, 12:3-8; figure 23, item 102)

4. **"An energy applicator:"**[7] "An applicator of an ablation device that delivers energy to the uterine tissue." The court adopts plaintiffs' construction for the same reasons as "an applicator head," above.

5. **"A working end:"**[8] "A distal end portion of an ablation device that applies energy to the uterine tissue." Claim 1 of the '898 patent recites an "ablation device comprising a tubular member coupled to a working end, the working end comprising a first electrode and a second electrode" ('898 patent, 19:31-33) The specification describes that "[a]n ablation device is provided which has an electrode array carried by an elongate tubular member" and "[d]uring use, the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue." ('898 patent, 2:38-44)

6. **"An indicator mechanism:"**[9] "A mechanism configured to indicate a dimension."[10] Claim 1 of the '348 patent recites "an indicator mechanism operably

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[7] Found in '989 patent, claims 1, 11, 13-15.

[8] Found in '898 patent, claims 1-5, 14, and 22.

[9] Found in '348 patent, claim 1.

[10] The court adopts plaintiffs' proposal. Defendant proposed "a measuring device used to display a value in units of measure." (D.I. 155 at 2) Nothing in the specification

coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus." ('348 patent, 19:40-42) With reference to the second embodiment of the '348 patent, the "ablation device . . . includes a measurement device for easily measuring the uterine width and for displaying the measured width on a gauge 146." ('348 patent, 14:33-36; *see also id.*, 15:55-56) Figure 32b shows that "dial face 158 includes calibration markings corresponding to an appropriate range of uterine widths." (*Id.*, 14:47-49; figure 32b, item 158)

7. **"One or more electrodes:"**[11] "One or more electrical conductors." The "applicator head" in claim 1 of the '348 patent "includ[es] one or more electrodes for ablating endometrial lining tissue of the uterus."[12,13] ('348 patent, 19:19-21) **Extrinsic evidence:** a technical dictionary definition of "electrode" is "[a]n electrical conductor through which an electric current enters or leaves a medium." (D.I. 161, ex. 21 at 3)

8. **"At least one electrode:"**[14] "One or more electrical conductors."[15]

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suggests that applicant intended to limit "an indicator mechanism" to devices that solely display uterine widths in "units of measure."

[11] Found in '348 patent, claim 1.

[12] The court adopts plaintiffs' proposal. Defendant proposed that "each electrode has a polarity and contacts the tissue surface during ablation." (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having a polarity or to contacting the tissue surface during ablation.

[13] Claim 1 of the '348 patent is a system claim. The construction proposed by defendant constrains the manner in which the claim limitation ("at least one electrode") is used (in contact with the tissue surface). Such a construction would make the claim indefinite. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (holding a claim invalid for claiming a system and a method for using that system).

[14] Found in '989 patent, claim 2.

[15] *See supra* note 12.

9. **"First and second electrodes:"**[16] "First and second electrical conductors."[17]

10. **"Sack:"**[18] "An electrode-carrying member having a bag-like shape." Claim 3 recites "[t]he method of claim 2 wherein the working end includes a sack comprised of a non-conductive material." ('898 patent, 19:47-48) With respect to the first embodiment, the specification states that "[e]lectrode carrying means 12 is preferably a sack formed of a material which is non-conductive, which is permeable to moisture and/or which has a tendency to absorb moisture, and which may be compressed to a smaller volume and subsequently released to its natural size upon elimination of compression." ('898 patent, 5:58-63) Defendant argued that the additional limitations (i.e., permeability, moisture absorption, and compression) from this embodiment should be included in the construction. (D.I. 199 at 21-22; D.I. 155 at 2) Applicant chose to explicitly limit the "sack" in claim 2 to "non-conductive material," but nothing in the intrinsic record suggests that applicant intended the term to implicitly include the limitations proposed by defendant.

11. **"Balloon:"**[19] "An inflatable member." The specification discloses an embodiment in which "a pair of inflatable balloons 52 may be arranged inside the electrode carrying means 12 as shown in figure 20." ('898 patent, 9:3-5) Defendant proposed "an inflatable member inside the energy applicator/working end and not in contact with the tissue." (D.I. 155 at 2-3) Defendant presented attorney argument that

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[16] Found in '898 patent, claims 1, 8, 14, and 22

[17] The court adopts plaintiffs' proposal. Defendant proposed that "the first and second electrodes are of opposite polarity and each contacts the tissue surface during ablation." (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having opposite polarities or to contacting the tissue surface during ablation.

[18] Found in '898 patent, claim 3.

[19] Found in '898 patent, claims 4, 5; '989 patent, claims 5, 6, 17, 18.

"[t]he 'balloon' itself does not contact the tissue. Rather, a purpose of balloon 52 is to be inflated and thereby hold the external electrodes 'in contact with the interior surface of the organ to be ablated.'" (D.I. 199 at 31 (citing '898 patent, 8:59-60)) While the disclosed embodiment includes the balloon inside the "electrode carrying means 12," which is the "energy applicator" or "working end" in the relevant patents, nothing in the specification suggests this is the only possible embodiment. Moreover, a balloon located inside the "stretchable metallized fabric mesh" of the "RF Applicator Head" of the second embodiment may contact uterine tissue. Therefore, the court adopts plaintiffs' proposal.

12. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC., AND CYTYC SURGICAL PRODUCTS, LLC,,

Plaintiffs,

v.

MINERVA SURGICAL, INC.,

Defendant.

1:15CV1031

MEMORANDUM OPINION

This matter is before the court on the following motions: defendant Minerva Surgical, Inc.'s ("Minerva") Motion to Dismiss the '183 Patent and the '989 Patent under Federal Rule of Civil Procedure 12(b)(1) or for judgment on the pleadings under Rule 12(c) (D.I. 275);[1] Minerva's motion for partial summary judgment on: invalidity; non-infringement; no willfulness; and no unfair competition (D.I. 277); and plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's (collectively "Hologic") motions for summary judgment of no invalidity (D.I. 287); infringement (D.I. 288); and assignor estoppel (D.I. 289).[2] Minerva also seeks a summary judgment that the doctrine of equivalents does not apply to Minerva's redesign, arguing prosecution history estoppel ("PHE"). (D.I. 278, Brief at 44-47).[3]

I. FACTS

[1] The '989 Patent is no longer at issue. (D.I. 367, Joint [Proposed] Pretrial Order).

[2] Also pending is Hologic's motion to strike Minerva's "Appendix A" (D.I. 278-1), "Supplemental Exhibit A" (D.I. 320-1), and "Second Supplemental Exhibit A" (D.I. 341-1) (D.I. 346). Hologic contends the exhibits should not be considered by the court in rendering its summary judgment decision because they include impermissible attorney argument and exceed the court's limits on page length. The court finds the exhibits are more in the nature of demonstrative exhibits. Whether properly the subject of a motion to strike or not, the court has not relied on the exhibits and the motion will be denied as moot. The parties also request oral argument on the pending motions (D.I. 354 and 359). The court finds oral argument is not necessary and the motion will be denied.

[3] Minerva is relying on a redesign of its handle as a noninfringing alternative for purposes of damages.

This is an action for patent infringement and related state-law claims.[4] Hologic alleges that Minerva infringes U.S. Patent No. 6,872,183 ("the '183 Patent"), titled "System and Method for Detecting Perforations in a Body Cavity," filed May 24, 2004, and issued March 29, 2005, and U.S. Patent No. 9,095,348 ("the '348 Patent"), titled "Moisture Transport System for Contact Electrocoagulation," filed August 8, 2013, and issued August 4, 2015 (collectively "the Patents-in-Suit"). The asserted patent claims that remain at issue are claims 7, 9, 11, 13, and 14 of the '183 Patent and claim 1 of the '348 Patent.[5] (D.I. 367, Joint [Proposed] Final Pretrial Order at 13; oral order dated June 15, 2018).

Additional facts are set out in the court's memorandum order on the plaintiff's motion for preliminary injunction (D.I. 127) and need not be repeated here. Briefly, the technology at issue in this litigation involves instruments and procedures for endometrial ablation, a treatment wherein the lining of the uterus is destroyed in order to treat Menorrhagia, or abnormally heavy menstrual bleeding. In the late 1990s, NovaCept Corporation ("NovaCept") under the direction of Csaba Truckai ("Truckai") and his design team developed the NovaSure system ("NovaSure") in the late-1990s. Prior to an ablation procedure, NovaSure uses computerized monitoring to detect perforations in the uterus, by applying C02 gas to the uterus and measuring any flow of gas out of the uterus. NovaSure employs an application head with a triangular shape designed to conform to the shape of the uterus, which ablates the endometrial lining throughout the cavity in two minutes or less.

[4] Hologic also alleges Minerva has engaged in (i) unfair competition in violation of under 15 U.S.C. § 1125; (ii) deceptive trade practices under 6 Del. C. § 2532; (iii) unfair competition under Delaware common law; and (iv) tortious interference with Hologic's business relationships under Delaware common law. Counterclaims against Hologic, alleging that it has engaged in (i) unfair competition under 15 U.S.C. § 1125(a) & (c); (ii) deceptive trade practices under 6 Del. C. § 2532; (iii) unfair competition under the Delaware common law; (iv) interference with contract/business advantage; (v) breach of contract; and (vi) trade libel. Hologic has moved to bifurcate the trial with respect to those issues (D.I. 374). In light of this disposition, the court finds the motion should be denied.

[5] Claim 1 of the '348 patent is a system claim.

NovaSure also provides a "moisture transport" function with a vacuum used to remove steam and moisture from the cavity during energy delivery. Minerva has developed and brought to market a new technology for the treatment of abnormal uterine bleeding, the Minerva Endometrial Ablation System ("EAS" or "accused product").

The '348 patent is directed to "an apparatus and method of ablating and/or coagulating tissue, such as that of the uterus or other organ." It uses "an electrode array," which "includes a fluid permeable elastic member preferably formed of a metallized fabric having insulating regions and conductive regions thereon." To use the apparatus, "the electrode array is positioned in contact with tissue to be ablated, ablation energy is delivered through the array to the tissue to cause the tissue to dehydrate, and moisture generated during dehydration is actively or passively drawn into the array and away from the tissue." (D.I. 281-7, Ex. 40, '348 patent, 2:34-45). The specification describes two exemplary embodiments. The first embodiment describes an ablation device comprised generally of three major components - RF applicator head, main body, and handle. (*Id.* at 4:55-58) The applicator head includes an array of electrodes formed on the surface of an electrode carrying means. (*Id.* at 4:58-61). "The second embodiment differs from the first embodiment primarily in its electrode pattern and in the mechanism used to deploy the electrode applicator head or array."(*Id.* 11:53-54). Aspects of the two "exemplary embodiments and their methods of operation may be combined without departing from the scope of the present invention." (*Id.* at 11:50-58).

Claim 1 of the '348 Patent states:

A device for treating a uterus comprising:

> an elongate member having a proximal portion and a distal portion, the elongate member comprising an outer sleeve and an inner sleeve slidably and coaxially disposed within the outer sleeve;

> an applicator head coupled to the distal portion, the applicator head defining an interior volume and having a contracted state and an expanded state, the contracted state being configured for transcervical insertion and the expanded state being configured to conform to the shape of the uterus, the applicator head including one or more electrodes for ablating endometrial lining tissue of the uterus;
>
> a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, a proximal grip and a distal grip pivotally attached to one another at a pivot point and operably coupled to the applicator head so that when the proximal grip and the distal grip are moved closer together, the applicator head transitions from the contracted state to the expanded state;
>
> a deflecting mechanism including flexures disposed within the applicator head, the flexures including first and second internal flexures and first and second external flexures, the first and second external flexures being coupled to the outer sleeve and the first and second internal flexures being coupled to the inner sleeve, wherein the deflecting mechanism is configured so that translating the inner sleeve relative to the frame causes the applicator head to transition from the contracted state to the expanded state; and
>
> an indicator mechanism operably coupled to the inner sleeve, the indicator mechanism configured to indicate a dimension of the uterus.

(*Id.* at 19:9-42) (emphasis added).

The ’183 patent is directed to “a system and method for detecting perforations in a body cavity.” (D.I. 281-7, Ex. 39). The system delivers a fluid (either liquid or gas) “into a body cavity to slightly pressurize the cavity. A pressure sensing system monitors the pressure within the cavity for a predetermined test period. If cavity pressure is not substantially sustained during the test period, the physician is alerted.” In the preferred form of the system, the perforation detection functionality is provided with an RF [radio frequency] ablation system. (’183 patent, 1:49-62).

What is claimed in Claim 1 of the ’183 Patent is:

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.

(*Id.* at 8:10-14). Asserted Claim 7 recites:

> The method of claim 1, further including the step of preventing performance of the treating step until after the monitoring step has been carried out.

(*Id.* at 8:30-33) Asserted Claim 9 recites:

> 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.

(*Id.* at 8:39-48). Dependent claim 11 recites:

> The method of claim 9, further including the step of:
>
> if a perforation is detected during the monitoring step, activating a notification signal alerting t e user to the presence of a perforation in the uterus.

(*Id.* at 8:54-57). Dependent claim 13 limits claim 9 reciting, "wherein the inflation medium is introduced using the ablation device." (*Id.* at 8:60-61). Claim 14 states: "The method of claim 9, wherein the ablation device is an RF ablation device." (*Id.* at 8:63-65).

The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." (*Id.* at 2:36-44) The pressure sensor "monitors pressure in the pressure signal line . . . and delivers the signal to the microprocessor." (*Id.*

at 5:23-25). The specification explains that during testing "[w]hen the pressure at gauge 84 rises and remains above 50mmHg for 4 seconds", the test is passed.

The court has construed the relevant claims of the Patents-in-Suit as follows:

Pressure sensor: [6]A device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

Applicator head: [7]A distal end portion of an ablation device that applies energy to the uterine tissue.

Indicator mechanism: [8]A mechanism configured to indicate a dimension.

One or more electrodes: [9] One or more electrical conductors.

(D.I. 227, Memorandum Order at 2-5). In addition, the term "monitoring," found in the '183 patent, claims 7, 9, and 11, requires no construction. *Id.* at 3.

The parties agree to the following additional facts. (D.I. 367-1, Joint [Proposed] Final Pretrial Order, Ex. 1, Joint Statement of Uncontested Facts). Plaintiff Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Marlborough, Massachusetts. Plaintiff Cytyc Surgical Products, LLC ("Cytyc") is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business in Marlborough, Massachusetts. Cytyc is a wholly-owned subsidiary of Hologic. Defendant Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business in Redwood City, California.

The parties agree the '183 Patent was issued by the United States Patent and Trademark Office ("USPTO") on March 29, 2005, and expires on November 10, 2020.[10]

[6] Found in '183 patent, claim 9.
[7] Found in '348 patent, claim 1.
[8] Found in '348 patent, claim 1.
[9] Found in '348 patent, claim 1.

[10] The '183 Patent claims priority to Provisional Application No. 60/164,482, filed November 10, 1999 (i.e., the '183 Priority Date). Original Utility Application No. 09/710,102, filed November 10, 2000, issued as U.S. Patent

Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller are the named inventors of the '183 Patent.

Csaba Truckai assigned his interest in the '183 Patent to NovaCept on February 9, 2001. In February 2001, Csaba Truckai assigned his interest in U.S. Application No. 09/710,102, an application to which the '183 Patent claims priority, to NovaCept. Hologic is the owner by assignment of the '183 Patent. Hologic acquired the '183 Patent from Cytyc on January 15, 2016.

The '348 Patent was issued by the USPTO on August 4, 2015 and expires on November 19, 2018.[11] Cytyc listed Csaba Truckai, Russel Mahlon Sampson, Stephanie Squarcia, Alfonso Lawrence Ramirez, and Estela Hilario as named inventors on the face of the '348 Patent.

In August 1998, Csaba Truckai assigned his interest in U.S. Application No. 09/103,072, an application to which the '348 Patent claims priority, to NovaCept. Hologic is the owner by assignment of the '348 Patent. Hologic acquired the '348 Patent from Cytyc on January 15, 2016. In May 2004, Cytyc Corporation ("Cytyc") acquired NovaCept for $325 million dollars. In 2007, Hologic acquired Cytyc Corporation.

In 1993, Csaba Truckai co-founded NovaCept, Inc. ("NovaCept") Csaba Truckai and others at NovaCept developed the NovaSure system. NovaCept received FDA premarket approval for commercial distribution of the NovaSure system on September 28, 2001.

No. 6,554,780 ("the '780 Patent"). Application No. 10/400,823, filed March 27, 2003, was a continuation of Application No. 09/710,102, and issued as U.S. Patent No. 6,743,184 ("the '184 Patent"). Application No. 10/852,684, filed May 24, 2004, was a continuation of Application No. 10/400,823, and issued as U.S. Patent No. 6,872,183 ("the '183 Patent"). The '780, '184, and '183 Patents all share a common specification. Only the claims of each are different.

[11] The '348 Patent claims priority to Provisional Application No. 60/084,791, filed May 8, 1998 (i.e., the '348 Priority Date). Original Utility Application No. 09/103,072, filed June 23, 1998, issued as U.S. Patent No. 6,813,520 ("the '520 Patent"). Application No. 10/959,771, filed October 6, 2004 was a divisional of Application No. 09/103,072, and issued as U.S. Patent No. 7,604,633 ("the '633 Patent"). Application No. 12/581,506, filed October 19, 2009, was a continuation of Application No. 10/959,771, and issued as U.S. Patent No. 8,506,563 ("the '563 Patent"). Application No. 13/962,178, filed August 8, 2013, was a continuation of Application No. 12/581,506, and issued as U.S. Patent No. 9,095,348 ("the '348 Patent"). The '520, '633, '563, and '348 Patents all share a common specification. Only the claims of each are different.

NovaCept assigned to Cytyc its patent rights including continuation applications. Hologic markets and sells the NovaSure system throughout the United States and in interstate commerce.

Csaba Truckai is a founder of Minerva. Minerva was founded in 2008. Csaba Truckai was involved in the development of the Minerva Endometrial Ablation System ("EAS"). Minerva received FDA premarket approval for commercial distribution of the Minerva EAS on July 27, 2015. Minerva began commercial distribution of the Minerva EAS in August 2015. Minerva markets and sells the Minerva EAS throughout the United States and in interstate commerce. Both the Minerva EAS and the NovaSure system are indicated for use on premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete. The Array Opening Indicator of the Minerva EAS contains a Black Indicator Line that can move relative to rows of black dots depending on the degree of expansion of the Plasma Formation Array.

Hologic alleges that Minerva infringes its patent in the use of the Minerva EAS. It alleges that use of the Minerva EAS, consistent with its instructions for use, practices each and every step of the method claims of the '183 Patent. It asserts that Minerva directly infringes these claims and induces and contributes to the infringement by its customers. It further alleges that Minerva infringes the apparatus claims of the '348 Patent by making, selling and/or offering to sell the Minerva EAS in the United States. Also, Hologic contends that Minerva's infringement of the Patents-in-Suit has been and continues to be willful.

Minerva denies that it infringes—directly or indirectly (under inducement or contributory infringement)—any of the asserted claims of the Patents-in-Suit and denies that infringement, if any, has been willful. In addition, Minerva asserts an invalidity defense to the asserted claims. With respect to the '183 patent, it argues that all the asserted claims of

the Patents-in-Suit are invalid for lack of written description and lack of enablement under 35 U.S.C. § 112.

II. Minerva's Motion to Dismiss (D.I. 275)

A. Background

A threshold issue is Minerva's motion to dismiss. Minerva seeks dismissal of Hologic's claim for infringement of the '183 Patent under Federal Rule of Civil Procedure 12(b)(1) and 12(c). Minerva asserts that the '183 Patent claims "should be dismissed as moot" because "no viable cause of action" remains. Minerva's motion is based on a final written decision of the Patent and Trial Appeals Board ("PTAB") in an *inter partes* review under 35 U.S.C. § 318(a) of the '183 patent. Minerva contends the PTAB's decision extinguishes any cause of action Hologic may have had with respect to its asserted '183 patent. Hologic has appealed the Patent Office's decision on the '183 Patent to the Federal Circuit (D.I. 344, Hologic Brief at 9).

In response, Hologic asserts Minerva is estopped from contending the patent is invalid by the doctrine of assignor estoppel. It argues that Minerva profited from its assignment and subsequent sale of the intellectual property and cannot disclaim the patent's validity. Assignor estoppel is also the subject of one of Hologic's motions for summary judgment and will be discussed below.

B. Law

A party may move to dismiss for "lack of subject-matter jurisdiction" under Federal Rule of Civil Procedure 12(b)(1). The federal courts are courts of limited jurisdiction. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). The court's power to render judgment is circumscribed by the Article III requirement that a live case or controversy exist throughout all stages of litigation, including appellate review. *United States v. Huff*, 703 F.3d 609, 611 (3d Cir. 2013). This requirement is satisfied when the

parties "continue to have a 'personal stake in the outcome' of the lawsuit." *Id.* "When the parties lose their personal stake in the outcome, the case becomes moot and must be dismissed, even if it once was a live controversy at an earlier stage of the proceedings." *Id.* Courts lack subject matter jurisdiction over moot claims. *See Target Training Int'l, Ltd. v. Extended Disc N. Am., Inc.*, 645 F. App'x 1018, 1025 (Fed. Cir. 2016) ("a dismissal for mootness is a dismissal for lack of jurisdiction."). In patent cases, the existence of a case or controversy must be evaluated on a claim-by-claim basis. U.S.C.A. Const. art. III, § 2, cl. 1; *see Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1282 (Fed. Cir. 2012).

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter pleadings are closed—but early enough not to delay trial." When evaluating a motion for judgment on the pleadings, the court must consider factual allegations in a complaint in the light most favorable to the non-moving party. *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). The court may consider matters of public record as well as authentic documents upon which the complaint is based if they are attached to the complaint or as an exhibit to the motion. *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994).

"When a [patent] claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot." *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013). Under 35 U.S.C. § 141(c), "[a] party to an *inter partes* review or a post-grant review who is dissatisfied with the final written decision of the Patent Trial and Appeal Board" has a right to appeal to the Federal Circuit. *See Pers. Audio, LLC v. Elec. Frontier Found.*, 867 F.3d 1246, 1249 (Fed. Cir. 2017), *cert. denied*, No. 17-1085, 2018 WL 706268 (U.S. May 14, 2018). The Patent Office cannot cancel claims of patents until after appeal. 35 U.S.C. § 318(b) (for *inter partes* reviews, after "the time for appeal has expired or any appeal has

terminated," the Director will "issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable"). The Federal Circuit has held that "a determination of patentability . . . occur[s] only after all appeals have terminated." *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 645 (Fed. Cir. 2011) (explaining that a certificate cancelling patent claims "only happens 'when the time for appeal has expired or any appeal proceeding has terminated'").

C. Discussion

The court rejects Minerva's argument that the PTAB's final written order on *inter partes* review renders this action moot. The patent has not been cancelled. The PTAB finding is on appeal and does not have preclusive effect as to this action unless and until the appeal is resolved. Accordingly, the court finds Minerva's motion to dismiss should be denied.

In light of this disposition, the court need not address Hologic's assignor estoppel argument in connection with the motion to dismiss, but will address the doctrine in Hologic's motion for summary judgment. *See infra*.

III. The Parties' Motions to Preclude or to Strike (D.I. 290, 279 and 317)

A. Background

More preliminary issues are Hologic's motion to preclude consideration of certain evidence (D.I. 290), Minerva's motion to strike the expert testimony of Karl Leinsing and Christopher C. Barry (D.I. 279), and Minerva's motion to strike the supplemental expert report of Karl Leinsing (D.I. 317).

Hologic contends the court should exclude the lay opinion of David Clapper, Minerva's current CEO and former CEO of NovaCept, on the issue of market value for endometrial ablation devices. Further, Hologic argues the court should exclude invalidity and infringement opinions of Robert Tucker, M.D. because they are not based on the

court's claim constructions and are based on exceedingly narrow characterizations of what he understands the invention to be. It argues Dr. Tucker's reliance on an impermissible claim construction renders his opinions irrelevant and unreliable and not helpful to the finder of fact. Hologic also challenges Minerva's damages expert Blake Inglish's apportionment calculations because they are based entirely on Dr. Tucker's allegedly flawed opinions. Hologic next challenges Burt Magen's conclusion that several prototype Minerva EAS's handpieces would not infringe the claims of the '348 patent. Hologic argues that Magen's opinions are not relevant to any fact at issue since Magen's opinions relate to three proposed handpiece designs, none of which are the accused product. Hologic also argues that Magen failed to apply the court's construction of an "indicator mechanism." Last, Hologic states that the court should exclude Dr. Eugene Skalnyi from testifying regarding facts and opinions not disclosed to Hologic.

In response, Minerva contends Clapper's testimony does not relate to any scientific, technical, or other specialized knowledge that would fall under Federal Rule of Evidence 702 and is properly admissible under Rule 701. Minerva also controverts Hologic's conclusion that Dr. Tucker did not properly apply the court's claim construction. Minerva also contends the testimony of Mr. Inglish is proper and should be considered, further arguing that Mr. Magen's testimony survives Hologic's challenge.

Minerva moves to preclude Leinsing's opinions on validity and infringement. It contends Leinsing improperly relied on claim construction legal standards to render opinions on invalidity for lack of a written description under § 112. Minerva contends Hologic fails to apply the relevant authority that rejects a patentee's attempt to argue that the specification does not limit the claims (which is a claim construction argument) in the context of § 112. *See Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1322 (Fed. Cir. 2017). Hologic, on the other hand, contends that Leinsing properly considered the claims as

construed by the court and analyzed the disclosure of the Patents-in-Suit to conclude that the asserted claims of the Patents-in-Suit are described and enabled.

Next, Minerva argues Leinsing's opinions relying on unreliable and misleading documents should be excluded, arguing that unverified Internet data, with no connection to Minerva or its EAS, is not something an expert would reasonably rely upon to prove infringement. Minerva is challenging Dr. Leinsing's testimony about Bernoulli's principle, which was found on a website. In response, Hologic contends that Leinsing's opinions are valid because they rely on documents that confirm the existence of Bernoulli's principle and Minerva's own technical documents.

Last, Minerva challenges Leinsing's opinions regarding copying. Hologic argues that Leinsing never offered an opinion that Minerva's EAS copied NovaSure and that Leinsing is entitled to rebut Minerva's expert's opinions on the subject.

B. Law

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert witnesses. Rule 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. District court judges are to perform a screening function with respect to expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). *Daubert* requires courts to conduct an inquiry into the reliability and relevance of the proposed expert testimony. *Yazujian v. PetSmart*, No. 17-2512, 2018 WL 1830931, at *1–2 (3d Cir. Apr. 17, 2018). To be admissible, expert testimony must be connected to the inquiry at hand. *Id.*; *see Daubert*, 509 U.S. at 591-92.

The Court of Appeals for the Third Circuit identifies the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *Elcock v. Kmart Corp.*, 233 F.3d 734, 745-46 (3d Cir. 2000). The expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). *Daubert* applies to the other expert matters described in Rule 702, even when the proposed expert is offering non-scientific, but specialized, testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999).

"The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd,* 564 U.S. 91 (2011).

Under Rule 701, on the other hand,

> If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:
>
> (a) rationally based on the witness's perception;
>
> (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and

> (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

Fed. R. Evid. 701; *see Hirst v. Inverness Hotel Corp.*, 544 F.3d 221, 225 (3d Cir. 2008) ("The plain language of Rule 701 establishes that lay opinion testimony must satisfy the criteria set forth in subsections (a), (b), and (c) in order to be admissible.")

Some evidentiary submissions cannot be evaluated accurately or sufficiently by the trial judge in the context of a pretrial motion. *Jonasson v. Lutheran Child and Family Servs.*, 115 F.3d 436, 440 (7th Cir. 1997). A pretrial motion or motion in limine is appropriate for "evidentiary submissions that clearly ought not be presented to the jury because they clearly would be inadmissible for any purpose." *Id.* In other instances, it is necessary to defer ruling until during trial, when the trial judge can better estimate the impact of the evidence on the jury. *Id.* To the extent that a party challenges the probative value of the evidence, an attack upon the probative sufficiency of evidence relates not to admissibility but to the weight of the evidence and is a matter for the trier of fact to resolve. *United States v. Beasley*, 102 F.3d 1440, 1451 (8th Cir. 1996).

Under 35 U.S.C. § 112, "the written description inquiry looks to 'the four corners of the specification' to discern the extent to which the inventor(s) had possession of the invention as broadly claimed." *Rivera,* 857 F.3d at 1322 (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*); *see also Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) ("It is the disclosures of the applications that count."). The knowledge of ordinary artisans may be used to inform what is actually in the specification, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification. *Lockwood*, 107 F.3d at 1571-72.

C. Discussion

The court is inclined to believe that Hologic's challenges go more to the weight than admissibility of the evidence. At any rate, the court need not rule on Hologic's motion at this juncture because the challenged evidence is not particularly relevant to the motions presently under consideration by the court. The court did not rely on the testimony of any of the challenged witnesses in making its determination on the pending motions. Some of the testimony relates solely to damages and will be addressed via a proper motion at trial or in limine.

For the most part, the court finds Minerva's challenges are similarly in the nature of objections or are the proper subjects of motions in limine. Minerva's arguments go more to the weight than to admissibility of the challenged evidence. The court disagrees with Minerva's characterization of Leinsing's testimony with respect to 35 U.S.C. § 112 issues. Leinsing's testimony merely relates to the content of the specifications, not to teaching limitations that are not in the specifications. Similarly, Minerva's challenge to testimony on the Bernoulli principle is similarly unavailing. There is no serious dispute that the principle is a widely accepted principle of physics and fluid dynamics that is verified in other testimony and exhibits. The motions to preclude will be denied at this time without prejudice to reassertion.

With respect to Minerva's motion to preclude opinions on copying and independent development, the court finds Minerva's position is misplaced. Minerva concedes that Leinsing never states that the Minerva EAS is a copy of the NovaSure system and Minerva's own technical expert expressed an opinion similar to that of Leinsing. (D.I. 292-2, Hologic Ex. 30, Rebuttal Declaration of Robert Tucker, M.D., ¶ 54.) ("Minerva's EAS is not identical to, substantially similar to, or a copy of the NovaSure, and in fact incorporates Minerva's own patentably-distinct technology.")

Again, the issue is moot for purposes of the present motion because the court did not consider the challenged information in connection with its determination. Accordingly, Minerva's motion will be denied, without prejudice to reassertion at trial to the extent that Leinsing's testimony remains relevant to issues in the trial.

Minerva also challenges Hologic's expert Christopher C. Barry's damages testimony. It contends he failed to apply the correct lost profits standards or the correct reasonable royalty standards.

The court is unable to evaluate the relevance of the challenged evidence in the context of a pretrial motion. Minerva's concerns may warrant a cautionary or limiting instruction, but the court cannot determine the ambit of such an instruction at this time. The court will admit the evidence at issue only on a showing that it is relevant to the issues in the case, is proper under the law, and only to the extent that the relevance of the evidence outweighs its potential to cause prejudice or confusion under Fed. R. Evid. 403. The court finds the motion can be adequately resolved at trial, either in a hearing immediately prior to commencement of the trial, as an objection with a sidebar, or with a review of the evidence outside the presence of the jury. Accordingly, the court finds that Minerva's motion to preclude expert opinions should be overruled at this time, without prejudice to its reassertion via timely objection to the admissibility of such evidence at trial.

Minerva's also moves to strike the supplemental expert declaration of Karl Leinsing. (D.I. 317.) Minerva contends the report is untimely and argues it has been prejudiced by having prepared and submitted its opening summary judgment and *Daubert* briefing in reliance on the timely Leinsing reports and deposition, only to be blindsided by new opinions based on new evidence raised for the first time in the Supplemental Leinsing Declaration. The court again finds the evidence is not particularly relevant and notes that Minerva had an opportunity to respond to any new information in its reply briefing. Further,

the court notes that Minerva could have moved to reopen discovery in order to re-depose Leinsing, if necessary. The court is inclined to agree with Hologic that the allegedly new information merely elaborates on Leinsing's ultimate opinions. The court did not rely on the new information and finds the motion should be denied as moot without prejudice to reassertion to the extent the opinions remain relevant to issues in the trial.

IV. Motions for Summary Judgment

A. Hologic's Motion for Summary Judgment on Assignor Estoppel (D.I. 289).

1. Background

In response to Minerva's motion to dismiss, and in support of its motion for summary judgment, Hologic argues that the court should find as a matter of law that Minerva's invalidity defenses and counterclaims are barred by assignor estoppel.

Undisputed evidence shows that Truckai founded Minerva. He used his expertise to research, develop, test, manufacture, and obtain regulatory approval for the Minerva EAS. It is undisputed that Truckai's job responsibilities as Minerva's President and CEO included bringing the accused product to market to directly compete with Hologic. Hologic contends the accused product incorporates the same patented technology that Truckai's company sold to Hologic. It is undisputed that Truckai, an inventor on each of the Patents-in-Suit, executed broad assignments of his inventions to NovaCept, which was then sold to Hologic's predecessor for $325 million dollars.

Hologic contends that the balance of equities strongly favor a finding of privity and the application of assignor estoppel in light of Truckai's role as Minerva's founder, his efforts to invent, develop, test, and manufacture the accused device, and his broad executive leadership of Minerva. In essence, it argues that—more than 19 years after Mr. Truckai executed his initial patent assignment—Minerva and Truckai attempt to destroy the value of

what Truckai sold to Hologic so that Minerva can directly compete with Hologic using the patented technology he already sold to Hologic.

2. Law

Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity. *Diamond Sci. Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224 (Fed. Cir. 1988) (recognizing "the implicit representation by the assignor that the patent rights that he is assigning (presumably for value) are not worthless . . . . To allow the assignor to make that representation at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee.") The doctrine of assignor estoppel is applied "to prevent unfairness and injustice." *Id.* "[A]n assignor should not be permitted to sell something and later assert that what was sold is worthless, all to the detriment of the assignee." *Diamond*, 848 F.2d at 1224. "[A]ssignor estoppel prevents an assignor from asserting that its own patent, for which it may have received value upon assignment, is invalid and worthless." *Pandrol USA, LP v. Airboss Ry. Prod., Inc.*, 424 F.3d 1161, 1167 (Fed. Cir. 2005). The Federal Circuit recently reaffirmed the "continued vitality of the doctrine of assignor estoppel." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1283 (Fed. Cir. 2017) (citations omitted).

Assignor estoppel also operates to bar other parties in privity with the assignor, such as a corporation founded by the assignor. *Diamond*, 848 F.2d at 1224. "Privity, like the doctrine of assignor estoppel itself, is determined upon a balance of equities." *Shamrock Techs. Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990). "In other words, '[i]f an inventor assigns his invention to his employer company A and leaves to join company B, whether company B is in privity and thus bound by the doctrine will depend on the equities dictated by the relationship between the inventor and company B in light of the

act of infringement.'" *Juniper Networks, Inc. v. Palo Alto Networks, Inc.*, 15 F. Supp. 3d 499, 509 (D. Del. 2014) (quoting *Shamrock Techs.*, 903 F.3d at 793). "The closer that relationship, the more the equities will favor applying the doctrine to company B." *Id.*

Status as the founder of a company is generally "dispositive of the issue of privity." *Juniper Networks*, 15 F. Supp. 3d at 508; *see also Diamond*, 848 F.2d at 1224; *Synopsis, Inc. v. Magma Design Automation, Inc.*, C-04-3923 MMC, 2005 WL 1562779, at *4-5 (N.D. Cal. July 1, 2005); *Vitronics Corp. v. Conceptronic, Inc.*, No. C-91-696-L, 1992 WL 515321, at *4-5 (D.N.H. July 20, 1992) ("no question that privity is established" for founder and executive officer); *Nortel Networks Inc. v. Foundry Networks, Inc.*, No. 01-CV-10442-DPW, 2003 WL 26476584, at 8-9 (D. Mass. March 24, 2003). Assignor estoppel was not designed to prevent companies from competing for talented employees; rather, it was intended to prevent the assignor (whether acting individually or through another entity) from "making [a] representation [of the patent's validity] at the time of assignment (to his advantage) and later . . . repudiat[ing] it (again to his advantage)." *Acushnet Co. v. Dunlop Maxfli Sports Corp.*, No. CIV. A. 98-717-SLR, 2000 WL 987979, at *3 (D. Del. June 29, 2000) (quoting *Diamond*, 848 F.2d at 1224).

Assignor estoppel generally arises in the context of an anticipation or obviousness defense. *Diamond,* 848 F.2d at 1224; *see also Babcock v. Clarkson*, 63 F. 607, 609 (1st Cir.1894) (stating "[T]he estoppel historically has applied to invalidity challenges based on 'novelty, utility, patentable invention, anticipatory matter, and the state of the art.'") However, the doctrine has also been applied with reference to a § 112 defense. *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, No. 99-0182-CV-W-SOW, 2003 WL 24272366, at *1 (W.D. Mo. Oct. 15, 2003), *aff'd*, 424 F.3d 1161 (Fed. Cir. 2005). Assignor estoppel does not limit an assignor's ability to defend a subsequent patent suit in ways other than challenging validity. *Mentor Graphics Corp. v. Quickturn Design Sys., Inc.*, 150 F.3d 1374,

1379 (Fed. Cir. 1998). The assignor is permitted to introduce evidence of prior art to narrow the scope of the assigned patent's claims in an effort to show that the accused device falls outside the scope of the assigned patent, and assignor estoppel does not preclude the estopped party from arguing that the patentee is itself collaterally estopped from asserting a patent found invalid in a prior proceeding. *Id.* at 1380. An estopped party may also argue for a narrow claim construction, or that the accused devices are within the prior art and therefore cannot infringe. *Id.* at 1379–80.

3. Discussion

Considering the balance of equities and the relationship of Truckai to Minerva, the court first finds privity between Truckai and Minerva. It is clear that Truckai executed a broad assignment of his patent rights to NovaCept and later sold NovaCept to Hologic's predecessor for $325 million dollars. Minerva does not seriously dispute those facts. It argues instead that the doctrine is not applicable to bar a § 112 defense. It relies on a balance-of-equities argument, contending Hologic attempts to assert overly broad claims and therefore keep Minerva's competing product out of the market.

The court finds Minerva's overly broad claims argument is effectively foreclosed by the court's adoption of Hologic's claim construction. Considering the balance of equities and the relationship of Minerva and Truckai, the evidence demonstrates that Truckai is in privity with Minerva, therefore, assignor estoppel applies to Minerva's defenses to Hologic's patent infringement claims.

B. Cross-motions for Summary Judgment on the Issue of Validity (D.I. 277 and 287)

1. Background

Minerva contends that all the asserted claims are invalid for failure to meet the written description and enablement requirements of 35 U.S.C. § 112. It raises the same or

similar arguments that it raised in connection with claim construction, again arguing the distinction between a flow sensor and a pressure sensor and comparing the Patents-in-Suit to its own patents for the accused EAS and, in particular, to its Uterine Integrity Test (UIT). Hologic contends it is entitled to a summary judgment of "no invalidity," arguing that Minerva is not applying the court's claim construction in its analysis.

2. Law

The burden is on the party challenging the validity of a patent to show invalidity by clear and convincing evidence. *Impax Labs., Inc. v. Aventis Pharma., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008). A patent specification must contain an adequate written description. 35 U.S.C. § 112, ¶ 1. Under 35 U.S.C. § 112, the specification is required to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112.

The written description "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation and quotations omitted); *see Streck,* 665 F.3d at 1285. The test is whether the disclosure "conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "This test requires an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" *Id.* (quoting *Ariad*, 598 F.3d at 1351. "Given this perspective, in some instances, a patentee can rely on information that is 'well-known in the art' to satisfy written description." *Id.*; *see Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011).

"It is well-established that the 'hallmark of written description is disclosure.'" *Streck*, 665 F.3d at 1285 (quoting *Ariad*, 598 F.3d at 1351). "The level of detail required to satisfy

the written description requirement depends, in large part, on the nature of the claims and the complexity of the technology." *Id.* "'Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party.'" *Id.* (quoting *PowerOasis, Inc. v. T–Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

The claims as filed are part of the specification, and may provide or contribute to compliance with § 112. *Id.* Minutiae of descriptions or procedures perfectly obvious to one of ordinary skill in the art, yet unfamiliar to laymen, need not be set forth. *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998). Missing subject matter in a description can be shown to be part of the prior art that would be understood as part of the description of the subject matter of the count. *Id.*

There is no requirement that a patent describe the unclaimed features of the infringing product. *See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1333 (Fed. Cir. 2003). "[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). "Not every claim must contain every limitation or achieve every disclosed purpose." *ScriptPro LLC v. Innovation Assocs., Inc.*, 833 F.3d 1336, 1342 (Fed. Cir. 2016).

"Enablement 'is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention.'" *Streck*, 665 F.3d at 1288 (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (citation omitted)). "To be enabling, a patent's specification must 'teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Id.* (quoting *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citations

omitted)). It is well-established, however, that a specification need not disclose what is well-known in the art. *Id.*; *see Hybritech*, 802 F.2d at 1384 ("[A] patent need not teach, and preferably omits, what is well known in the art.").

The asserted claims rather than the accused device must be "enabled" by the patent-in-suit. *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A. No. 08-91-GMS, 2011 WL 446203, at *6 (D. Del. Feb. 7, 2011); *see Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001)). The enablement requirement is met if any mode of making and using the invention is disclosed. *See Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070-71 (Fed. Cir. 2005).

"The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Streck*, 665 F.3d at 1288 (quoting *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) (setting forth the following factors to consider when determining whether a disclosure requires undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims). "'[I]t is not necessary that a court review all the Wands factors to find a disclosure enabling. They are illustrative, not mandatory.'" *Id.* (quoting *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)).

3. Discussion

The court finds Minerva's invalidity defenses are barred by assignor estoppel. However, even if Minerva were not estopped from raising the defense, the court would find Minerva's motion for a summary judgment of invalidity lacks merit.

Minerva's argument that the Patents-in-Suit had to provide written description and enablement of the accused devices plasma formation feature is unavailing. The claims at issue herein do not recite a plasma formation feature. Minerva's emphasis on the accused device and its plasma formation feature reflects its misguided notion that the improvements over the claimed material (the plasma formation feature) would have to have been disclosed. That an accused product might include other, un-claimed features does not mean the accused product avoids infringement.

Similarly, the court rejects Minerva's argument that undue experimentation would be required to practice the invention. Minerva failed to produce evidence that the experimentation required to create surgical instruments and methods for use in endometrial ablation such as those described in the claims of the Patents-in-Suit would be unduly laborious for one of ordinary skill in the art. The evidence shows that any such experimentation would involve repetition of commonly known or used techniques and application of techniques well known in the art. Minerva's expert's testimony on the subject does not controvert Hologic's testimony that a person of ordinary skill in the art would have known that a flow sensor could be used as a pressure sensor. Conclusory expert assertions do not give rise to a genuine issue of material fact.

The court already rejected Minerva's argument that exemplary embodiments define "the invention" and require a "moisture transport system" with a "permeable external array" during the claim construction phase. Minerva's other criticisms for the descriptions are also directed at exemplary embodiments and raise previously rejected arguments that would serve to improperly limit that claims.

The court finds Minerva's Section 112 arguments rest on a flawed definition of the claims that ignores the court's claim constructions. Minerva has not satisfied its burden of showing invalidity by clear and convincing evidence. No reasonable jury could find that

Minerva has met its burden of proving by clear and convincing evidence that the claimed "applicator head," "indicator mechanism" and "one or more electrodes" are not properly described or enabled in the asserted claims of the Patents-in-Suit. Minerva's arguments with respect to undue experimentation focus on the amount of experimentation necessary to make Minerva's EAS, which is not the relevant enablement analysis.

Hologic, on the other hand has shown that the '183 and '348 Patent disclosures adequately describe the claims as construed by the court. The relevant enablement analysis is whether the specification teaches how to make and use a system that performs the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal. The patent disclosure reasonably conveys to a person of ordinary skill in the art that the inventors had possession of "[a] distal end portion of an ablation device that applies energy to the uterine tissue" including "[o]ne or more electrical conductors" and "[a]n applicator of an ablation device that delivers energy to the uterine tissue."

The court finds no reasonable jury could find that Minerva can meet its clear and convincing evidence burden of showing that the claims of the Patents-in-Suit do not describe monitoring for the presence of a perforation in the uterus using a pressure sensor. Accordingly, the court finds Hologic's motion for a summary judgment of no invalidity should be granted and Minerva's corresponding motion should be denied.

C. Minerva's Motion for Summary Judgment on the Doctrine of Equivalents and Prosecution History Estoppel. (D.I. 278, Brief at 44-47)

1. Background

Minerva argues that prosecution history shows that the Patent Examiner rejected Hologic's pending claims as obvious under 35 U.S.C. § 103, and therefore invalid over prior art in August 2015. In response to the rejection Hologic, among other things, struck "a

handle coupled to the proximal portion" from pending claim 19 (later issued as Claim of the '348 patent), and replaced it with more detail about the handle including: "wherein the handle comprises a proximal grip and a distal grip pivotally attached to one another at a pivot point."[12] D.I. 278 at 45. Minerva contends that Hologic elected to narrow the scope of what issued as independent claim 1 of the '348 Patent by adding the "pivot point" limitation in order to overcome the prior art rejection and secure the patent, and accordingly, prosecution history estoppel operates to foreclose Hologic from relying on the doctrine of equivalents to allege infringement.

Hologic contends that Minerva seeks an improper advisory opinion in connection with this argument. It argues that the device with Minerva's new pivot handle is not an accused product because it has not been commercialized.

2. Law

The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. *Id.* at 733. "Estoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'" *Id.* (quoting *Schriber–Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220–221 (1940)). The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes. *Id.* "When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed

[12] Minerva raises a similar argument with respect to the '989 Patent, but that Patent is no longer at issue.

equivalent to the literal claims of the issued patent." *Id.* "On the contrary, "[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,] . . . and [t]he difference which [the patentee] thus disclaimed must be regarded as material.'" *Id.* (quoting *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136–137 (1942)). The Supreme Court has "'consistently applied prosecution history estoppel only where claims have been amended for a limited set of reasons,' such as 'to avoid the prior art, or otherwise to address a specific concern—such as obviousness—that arguably would have rendered the claimed subject matter unpatentable.'" *Id.* (quoting *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30–32 (1997).

Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope. *Festo Corp.,* 535 U.S. at 736. If a § 112 amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. *Id.* at 736-37. On the other hand, if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply. *Id.* A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112. *Id.* at 737. The patentee is regarded as "having conceded an inability to claim the broader subject matter or at least as having abandoned his right to appeal a rejection." *Id.*; *see O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1366 (Fed. Cir. 2008) (finding that the "district court erred in allowing the jury to find infringement under the doctrine of equivalents" because PHE applied). "Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter." *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008).

3. Discussion

Minerva's motion is directed at the pivot-point limitation of the '348 Patent. It argues that "[b]ecause Hologic elected to narrow the scope of what issued as independent claim 1 of each of the '348 and '989 by adding the 'pivot point' limitation in order to overcome the prior art rejection and secure the patent, PHE forecloses Hologic from now relying on the DOE in litigation to allege infringement." The court finds no clear and unmistakable surrender of all equivalents to the pivot point limitation. Further, the court is not convinced that the added detail is more than tangential to patentability. Notably, the limitation relates more to the '989 Patent, which is no longer at issued, than to the '348 Patent. Moreover, the court agrees with Hologic's position that a ruling on the purported handle redesign would be an improper advisory opinion since the product is not being marketed and is not alleged to be infringing Hologic's patent. The court need not address whether Minerva's "new" handle design would infringe Hologic's '348 Patent because that design is not at issue. Minerva has not shown it is entitled to summary judgment on the issue.

D. Cross-Motions for Summary Judgment on the Issue of Infringement (D.I. 277 and 288)

1. Background

Hologic moves for summary judgment in the issue of infringement, contending that Minerva has failed to raise a genuine issue of fact to counter the court's finding that evidence submitted in preliminary injunction proceedings supports a prima facie showing of infringement. It argues that there is no genuine dispute that the Minerva EAS embodies apparatus claim 1 of the '348 Patent. Claim 1 comprises a preamble and five limitations. Hologic argues that only the fifth limitation, "an indicator mechanism configured to indicate a dimension of the uterus" is at issue and contends that the Minerva "PFA Width Indicator" is such an indicator mechanism that measures a dimension of the uterus. Further, it argues

that it is undisputed that Minerva's EAS infringes the asserted claims of the '183 Patent in that it detects perforations using a pressure sensor.

Minerva contends that a summary judgment of no infringement is warranted because Hologic cannot show that Minerva's UIT meets the court's construction of "pressure sensor" for at least two reasons: (1) the flow sensor's "input" does not "detect[], directly or indirectly, a force per unit area"; and (2) its "output" is not "a corresponding electrical signal," as the court's construction requires. It also contends the UIT does not perform the monitoring step using a pressure sensor as the claim requires. Minerva's arguments are premised on its contention that Minerva's flow sensor detects a flow rate—not a pressure at its input.

In its earlier order, the court stated:

> "Pressure sensor." The specification explains that "a pressure sensing system" is "fluidly coupled to the medical device via [a] pressure detection/signal line" and used to monitor the pressure within the body cavity. Fluid or gas is delivered to the body cavity and the pressure sensing system detects "whether elevated pressure can be maintained above a predetermined threshold level over a predetermined period of time. If it cannot, the user is alerted that there may be a perforation in the organ." ('183 patent, 2:36-44) The pressure sensor "monitors pressure in the pressure signal line ... and delivers the signal to the microprocessor." (*Id.* at 5:23-25) The specification explains that during testing "[w]hen the pressure at gauge 84 rises and remains above 50 mmHg for 4 seconds, the test has passed." *(Id.* at 6:44-46)

(D.I. 127, Memorandum Order at 13-14. The court went on to find:

> Hologic has identified Minerva EAS' flow meter as meeting the "pressure sensor" limitation. Minerva argues that the flow meter does not measure pressure (differential or otherwise) to operate and its output is not a pressure measurement. (D.I. 86 at 8-11) Minerva EAS' operator manual describes a "uterine integrity test" aimed at detecting perforations. (D.I. 12, ex. 11 at 9, 33) Minerva's expert, Dr. Tucker, testified, "[a]s the pressure goes down, the flow rate goes up. As the pressure goes up, the flow rate goes down." (D.I. 115, ex. 2 at 64:17-20) The design documents for Minerva EAS state that "if the uterine cavity and the system is perforation free, gas used to insufflate the uterine cavity will stop flowing once the gas pressure in the uterine cavity matches the supply pressure." (D.I. 87, ex. 82 at 2337) The court concludes that the evidence supports a prima facia showing of infringement.

(*Id.* at 14) (footnotes omitted).

2. Law

The patentee has the burden of proving infringement by a preponderance of the evidence. *Centricut, LLC v. Esab Group, Inc*., 390 F.3d 1361, 1367 (Fed. Cir. 2004). Patent infringement and invalidity are two separate issues. *See Medtronic, Inc. v. Cardiac Pacemakers, Inc*., 721 F.2d 1563, 1583 (Fed. Cir. 1983) (stating that "[t]hough an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity.").

The determination of infringement is a two-step process: first, the court construes the asserted claims as a matter of law to determine their meaning, and second, the trier of fact compares the properly construed claims to the accused product to determine whether it contains each limitation of the claims, either literally or under the doctrine of equivalents. *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). Application of the claim to the accused device is a question of fact. *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1345 (Fed. Cir. 2001). The infringement inquiry remains focused at all times on the claim language, as illuminated by the written description and the prosecution history. *Id.* at 1345–46. "[I]t is elementary patent law that a patent may issue on an improvement which infringes another's patent." *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 669 (Fed. Cir. 1988).

Although it has not stated a *per se* rule, the Federal Circuit has noted that "relevant expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential" to the infringement inquiry. *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1369–70 (Fed. Cir. 2004) (holding that a patentee could not withstand summary judgment on the issue of literal infringement in a case involving complex technology in the absence of

expert testimony). "'[T]ypically expert testimony will be necessary in cases involving complex technology.'" *Id.* at 1370.

3. Discussion

The court finds that Minerva's non-infringement arguments were essentially mooted when the court rejected Minerva's erroneous claim constructions. Minerva's arguments for non-infringement all depend on claim construction that is contrary to the court's construction. Applying the court's construction, Hologic has shown that Minerva's accused product infringes the asserted claims of the patents. Minerva's non-infringement arguments go to differences in or additions to its device that are not claimed in the patents, but are improvements.

The court's construction of the term "pressure sensor" in claim 9 of the '183 Patent as "[a] device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal" is determinative. Minerva contends the claim requires directly detecting a force per unit area. Nothing in the specification requires the pressure sensor to measure pressure directly or to convert to a unit of measure. The undisputed facts show that use of the Minerva EAS practices the step of monitoring for the presence of a perforation in the uterus using a device whose input detects, directly or indirectly, a force per unit area and outputs a corresponding electrical signal.

Bernoulli's equation is a well-known principle of fluid dynamics that would have been known to persons of ordinary skill in the art at the time of the invention. Minerva's expert conceded that a person of ordinary skill in the art in 1998 would have known that it was "just a fundamental law of fluid dynamics" that there would have to be a pressure differential to generate flow. The equation describes the physical relationship between pressure and flow rate and, therefore, it shows that Minerva's use of a flow meter involves "indirectly"

detecting pressure. Minerva's flow sensor, in conjunction with the orifice, is a pressure sensor because it indirectly detects pressure via flow rate.

Minerva does not dispute that use of the Minerva EAS practices all of the remaining limitations of the asserted claims. No reasonable jury could find that the remaining steps in the method for ablating a uterus claimed in the patent—inserting an ablation device, flowing an inflation medium, and treating the disorder—are not performed when using the Minerva EAS. Also, Minerva does not dispute that use of the Minerva EAS prevents performance of the treating step until after the monitoring step has been carried out, as claimed in Claim 7 of the '183 Patent.

Claim 9 of the '183 Patent comprises a preamble and four limitations, only one of which is in serious dispute—"monitors for the presence of a perforation in the uterus using a pressure sensor." Minerva does not dispute that use of the Minerva EAS practices a method of detecting a perforation in a uterus or that use of the Minerva EAS practices the step of "passing an inflation medium into the uterus" or the steps of then permitting or preventing the ablation, depending on detection of a perforation. Minerva's argument with respect to monitoring with a pressure sensor is again precluded by the court's claim construction. Further, Minerva does not dispute that practicing the Minerva EAS includes activating a notification signal alerting the user to the presence of a perforation in the uterus included in claim 11 or introducing the inflation medium using the ablation device as recited in Claim 13 or using an RF ablation device as recited in Claim 14 of the '183 Patent.

Minerva's reliance on elements of its device—i.e., use of argon gas and plasma energy—to differentiate its device is unavailing. Those elements are not claimed by Hologic. Minerva's argument that Minerva EAS embodies Minerva's patent (U.S. Patent No. 8,343,078) is relevant but is not dispositive of the issue of infringement. *National Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1192 (Fed. Cir. 1996) (stating "[t]he grant of a

separate patent on the accused device does not automatically avoid infringement, either literal or by equivalency. Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may or may not avoid infringement of the prior patent."). That an infringer may patent improvements to an invention does not negate the fact of infringement.

The evidence shows that Minerva has directly infringed the asserted claims of the '183 and '348 Patents by having its paid consultants perform infringing endometrial ablations in its promotional videos. Further, it produces operating manuals, instructions for use, instructional videos, training materials, and on-site training on how to use the Minerva EAS that infringes the Patents. Also, Minerva clearly induces and contributes to infringement by its customers. Minerva's customers infringe by using Minerva's included components for their intended purpose consistent with Minerva's instructions.

Consistent with the court's claim construction, the court finds that undisputed evidence in the record establishes that Minerva has infringed the asserted claims of Hologic's patents. Accordingly, the court finds that Hologic's motion for summary judgment on the issue of infringement should be granted and Minerva's corresponding motion should be denied.

E. Minerva's Motion for Summary Judgment on Unfair Competition (D.I. 277)

1. Background

Minerva moves for summary judgment on Hologic's unfair competition claims. Minerva states that all four of Hologic's unfair competition claims hinge on the same theory—i.e., that Minerva's sales staff deceptively described Minerva's EAS as the "new NovaSure," "NovaSure 2.0" and/or is from "the makers of NovaSure."[13] It asserts that

[13] In its amended complaint, in addition to its Lanham Act claim, Hologic asserted claims for deceptive trade practice under Delaware statutory and common law alleging Minerva "has engaged in and continues to engage

Hologic's claims fail as a matter of law because Hologic has failed to produce or elicit any evidence supporting its allegations of deceptive statements, and cannot establish causation or harm. Minerva also argues that any allegedly disparaging comments were mere puffery.

Hologic contends the motion should be denied because Minerva has not addressed its claim relating to disparagement. It further argues that it has shown a likelihood of confusion as a result of Minerva's alleged conduct. It argues, at the least, a jury should resolve the issue of whether there is a likelihood of confusion.

Hologic has presented evidence that Minerva's employees obtained Hologic's confidential and proprietary data and information and circulated it to the sales team. There is also evidence that Minerva employees made allegedly disparaging remarks about Hologic to potential customers, hired former NovaSure sales representatives, used misleading sales tactics and allegedly advised customers to break Hologic contracts.

2. Law

Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), prohibits false designations of origin, false descriptions, and dilution. The Act creates "two distinct bases of liability: false association . . . and false advertising." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1384 (2014). Subsection (a)(1)(B) forbids "commercial advertising or promotion" that "misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities[.]" 15 U.S.C. § 1125(a)(1)(B). To prove a violation under the statute, a plaintiff must prove that it has a valid, protectable trademark; owns rights to the mark; the defendant used the mark in interstate commerce; without the consent of the defendant in a manner

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in conduct that disparages the prior NovaSure systems" and was likely to cause confusion; unfair competition under Delaware common law, alleging the defendant wrongfully interfered with business relationships by targeting Plaintiffs' existing customers and disparaging the prior NovaSure systems and tortious interference with a business relationship under Delaware common law.

that is likely to cause confusion among ordinary purchasers as to the source of the product and the defendant's use of the mark caused an injury to the plaintiff's commercial interest in sales or business reputation. 15 U.S.C. § 1125(a)(1)(A); *see Lexmark Int'l, Inc.* 134 S. Ct. at 1384; *Parks LLC v. Tyson Foods, Inc.*, 863 F.3d 220, 230 (3d Cir. 2017). The Lanham Act's "likelihood of confusion" standard is predominantly factual in nature, making summary judgment inappropriate when a jury could reasonable conclude that there is a likelihood of confusion. *NTP Marble, Inc. v. AAA Hellenic Marble, Inc.*, No. 09-CV-05783, 2012 WL 607975, at *7 (E.D. Pa. Feb. 27, 2012) (same).

The Delaware Deceptive Trade Practices Act ("DTPA") prohibits "disparage[ment] of the goods, services or business of another by false or misleading representations of fact," committed "in the course of a business, vocation, or occupation or that generally "creates a likelihood of confusion or of misunderstanding." 6 Del. C. §§ 2532(a)(8) & (a)(12). "The DTPA has a lower burden of proof than the Lanham Act since 'a complainant need not prove competition between the parties or actual confusion or misunderstanding' to prevail in an action under the DTPA, 6 Del. C. § 2532(b)." *Keurig, Inc. v. Strum Foods*, Inc., 769 F. Supp. 2d 699, 712 (D. Del. 2011). The Act is intended to address unfair or deceptive trade practices that interfere with the promotion and conduct of another's business. *Wright v. Portfolio Recovery Affiliates*, No. CIV.A. 09-612-GMS, 2011 WL 1226115, at *5 (D. Del. Mar. 30, 2011).

3. Discussion

The court's review of the materials submitted in support of and against Minerva's motion show that there are genuine issues of material fact on several issues essential to resolution of the deceptive trade practices claims and counterclaims. There are issues of fact on the nature and extent of alleged misrepresentations and/or disparagement, deception, and the likelihood of confusion. Resolution of those issues requires

assessments of credibility. Accordingly, Minerva has not shown it is entitled to summary judgment on Hologic's deceptive trade practices claims. The court finds the motion should be denied.

F. Minerva's Motion for Summary Judgment on Willfulness (D.I. 277)

1. Background

Minerva contends there are no genuine issues of material fact on the issue of willful infringement. It contends the patents did not issue until after Minerva had developed the accused product and Hologic has not produced evidence of deliberate copying.

Hologic argues that it does not seek pre-issuance damages, but is relying on Minerva's pre-issuance conduct to support its showing of willful infringement. It also argues that there are genuine issues of fact on issues of copying, knowledge, investigation, and good faith.

2. Law

Enhanced damages under 35 U.S.C. § 284 "are not to be meted out in a typical infringement case, but are instead designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1932 (2016). The award of enhanced damages is limited to egregious cases of misconduct beyond typical infringement. *Id.* at 1935. "As with any exercise of discretion, courts should continue to take into account the particular circumstances of each case in deciding whether to award damages, and in what amount." *Id.* at 1933.

The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless. *Id.* at 1933; *see WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1362 (Fed. Cir. 2016) (stating "*Halo* emphasized that subjective willfulness alone—i.e., proof that the defendant acted despite a risk of infringement that was 'either known or so obvious that it

should have been known to the accused infringer,'—can support an award of enhanced damages" (quoting *Halo*, 136 S. Ct. at 1930)(internal citations omitted)).

"'[W]hether an act is 'willful' is by definition a question of the actor's intent, the answer to which must be inferred from all the circumstances." *WCM Indus., Inc. v. IPS Corp.*, 721 F. App'x 959, 970 (Fed. Cir. 2018) (quoting *Gustafson, Inc. v. Intersystems Indus. Products, Inc.*, 897 F.2d 508 (Fed. Cir. 1990)). There is no *per se* rule that a finding of willful infringement cannot stand whenever manufacture of an accused device begins prior to the issuance of a patent, instead courts must look to the totality of the circumstances presented in the case. *Id.*; *see also ACCO Brands, Inc. v. ABA Locks Mfrs.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007) (noting that the willfulness inquiry is one of fact and "is determined from the totality of the circumstances.").

3. Discussion

The court finds there are genuine issues of fact with respect to willfulness. There is evidence from which a jury could find Minerva acted despite a risk of infringement that was either actually known or was so obvious that it should have been known to Minerva. Resolution of the issue involves a determination of intent and credibility. These are issues for the fact-finder. Accordingly, the court finds Minerva's motion for summary judgment should be denied.

An appropriate order will issue this date.

DATED this 28th day of June, 2018.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC., AND CYTYC SURGICAL PRODUCTS, LLC,

Plaintiffs,

v.

MINERVA SURGICAL, INC.,

Defendant.

1:15CV1031

ORDER

In conformity with the Memorandum Opinion issued this date,

IT IS ORDERED:

1. The parties' motions for oral argument (D.I. 354 and D.I. 359) are denied.

2. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion to strike argumentative exhibits (D.I. 346) is denied.

3. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion to bifurcate (D.I. 374) is denied.

4. The parties' motions to preclude or strike expert testimony (D.I. 279, 290, and 317) are denied.

5. Defendant Minerva Surgical, Inc.'s motion to dismiss (D.I. 275) is denied.

6. Defendant Minerva Surgical Inc.'s motion for partial summary judgment (D.I. 277) is denied.

7. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for a summary judgment of no invalidity (D.I. 287) is granted.

8. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for a summary judgment of infringement (D.I. 288) is granted.

9. Plaintiffs Hologic, Inc.'s and Cytyc Surgical Products, LLC's motion for summary judgment with respect to assignor estoppel (D.I. 289) is granted.

10. The action will proceed to trial for a determination of damages and willfulness in connection with the patent claim and for a determination of the parties' state-law claims and counterclaims.

DATED this 28th day of June, 2018.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge