

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 ~~14~~¹³ 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

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

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

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

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

¹⁶ Found in ‘898 patent, claims 1, 8, 14, and 22

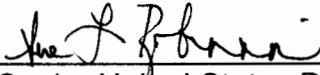
¹⁷ The court adopts plaintiffs’ proposal. Defendant proposed that “the first and second electrodes are of opposite polarity and each contacts the tissue surface during ablation.” (D.I. 155 at 2-3) Nothing in the specification suggests applicant intended to limit the claim term to having opposite polarities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