UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

UAB RESEARCH FOUNDATION
Patent Owner

Case: IPR2015-01200

Patent 6,290,699

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,290,699

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

CODE OF FEDERAL REGULATIONS

OTHER AUTHORITIES

EXHIBIT LIST

1001	U.S. Patent No. 6,290,699 B1, "Ablation Tool For Forming Lesions In Body Tissue" to Jeffrey A. Hall and David C. McGiffin, issued Sept. 18, 2001 (the "'699 patent")
1002	*The Board Of Trustees of the University of Alabama On Behalf Of One Of Its Divisions, The University Of Alabama At Birmingham; and the UAB Research Foundation vs. Medtronic, Inc.,* Case No. 2:14-cv-01799-AKK, Complaint, Dkt. No. 1 (N.D. Ala. Sept. 22, 2014)
1003	*The Board Of Trustees of the University of Alabama On Behalf Of One Of Its Divisions, The University Of Alabama At Birmingham; and the UAB Research Foundation vs. Medtronic, Inc.,* Case No. 2:14-cv-01799-AKK, Defendant's Answer and Counterclaims, Dkt. No. 11 (N.D. Ala. Nov. 14, 2014)
1004	*The Board Of Trustees of the University of Alabama On Behalf Of One Of Its Divisions, The University Of Alabama At Birmingham; and the UAB Research Foundation vs. Medtronic, Inc.,* Case No. 2:14-cv-01799-AKK, Plaintiffs' Answer and Counterclaims, Dkt. No. 17 (N.D. Ala. Dec. 5, 2014)
1005	U.S. Patent No. 6,152,920, "Surgical Method and Apparatus For Positioning A Diagnostic Or Therapeutic Element Within The Body" to Russell B. Thompson *et al.*, issued Nov. 28, 2000 ("Thompson")
1006	U.S. Patent No. 6,096,037, "Tissue Sealing Electrosurgery Device And Methods Of Sealing Tissue" to Peter M. J. Mulier and Michael F. Hoey, issued Aug. 1, 2000 ("Mulier")
1007	PCT Application No. PCT/US97/19552, "Surgical Systems And Procedure For Treatment Of Medically Refractory Atrial Fibrillation," to James Cox, *et al.*, Publication No. WO 98/17187 issued April 30, 1998 ("Cox")
1008	Prosecution history of U.S. Patent Application No. 09/348,811, which issued as the '699 patent
1009	U.S. Patent No. 6,237,605 B1, "Methods Of Epicardial Ablation" to Matthias Vaska, *et al.*, issued May 29, 2001 ("Vaska")
1010	PCT Application No. PCT/US98/21357, "Soft Tissue Coagulation Probe," to David Swanson, *et al.,* Publication No. WO 99/18878, issued April 22, 1999
1011	Declaration of James Skarda ("Skarda Decl.")

1012	U.S. Patent No. 6,068,629, "System And Methods For Tissue Mapping And Ablation" to Michel Haissaguerre *et al.*, issued May 30, 2000 ("Haissaguerre")
1013	U.S. Patent No. 6,106,522, "Systems And Methods For Forming Elongated Lesion Patterns In Body Tissue Using Straight Or Curvilinear Electrode Elements" to Sidney D. Fleischman *et al.*, issued Aug. 22, 2000 ("Fleischman")
1014	U.S. Patent No. 6,071,281, "Surgical Method And Apparatus For Positioning A Diagnostic Or Therapeutic Element Within The Body And Remote Power Control Unit For Use With Same" to Robert Burnside *et al.*, issued June 6, 2000 ("Burnside")
1015	James L. Cox, *The Surgical Treatment of Atrial Fibrillation. IV. Surgical Technique*, 101 J. THORAC. CARDIOVASC. SURG. 584 (April 1991) ("Cox 1991")
1016	Michel Haissaguerre, *Successful Catheter Ablation of Atrial Fibrillation*, 5 J. CARDIOVASC. ELECTROPHYSIOL., 1045-1052 (Dec. 1994) ("Haissaguerre 1994")

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,290,699

On behalf of Medtronic, Inc. ("Medtronic" or "Petitioner") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, *inter partes* review ("IPR") is respectfully requested for Claims 1-10, 12-13 and 17-18 of U.S. Patent No. 6,290,699 ("the '699 patent"). Ex. 1001. As set forth below, Petitioner demonstrates there is a reasonable likelihood of prevailing in its challenge of at least one of Claims 1-10 and 12-13 and 17-18 identified in this petition as being unpatentable.

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Medtronic, Inc. is the real party-in-interest. 37 C.F.R. § 42.8(b)(1). Medtronic, Inc. is a wholly owned subsidiary of Medtronic plc, which is also a party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '699 patent is the subject of a patent infringement lawsuit brought by plaintiffs The Board of Trustees of the University of Alabama and The UAB Research Foundation against defendant Medtronic in the U.S. District Court for the Northern District of Alabama, Case No.: 14-cv-01799. The complaint was filed on September 22, 2014. Ex. 1002. Defendant Medtronic's answer and counterclaims were filed on December 5, 2014. Ex. 1003. Plaintiffs' answer to Medtronic's counterclaims was filed on December 5, 2014. Ex. 1004. Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '699 patent.

Petitioner is concurrently filing an *inter partes* review petition, IPR2015-01199, challenging Claims 1-3, 9-10, 12-13 and 17-18 of the '699 patent.

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner provides the following designation of counsel.

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is provided in the designation of lead and back-up counsel, above. Petitioner consents to service by electronic mail at the email addresses set forth above.

II. FEE PAYMENT

The required fees are submitted under 37 C.F.R. §§ 42.103(a) and 42.15(a). If any additional fees are due during this proceeding, the Office may charge such fees to

Deposit Account No. 19-4293.

III. REQUIREMENTS FOR IPR 37 C.F.R. § 42.104

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Medtronic certifies that the '699 patent is available for IPR and that Medtronic is not barred or estopped from requesting an IPR challenging the '699 patent on the grounds identified below. 37 C.F.R. § 42.104(a). Specifically, (1) Medtronic is not the owner of the '699 patent; (2) Medtronic is not barred or estopped from requesting an IPR; and (3) Medtronic files this Petition less than a year after being served with a complaint alleging infringement of the '699 patent.

B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

Petitioner requests IPR of Claims 1-10 and 12-13 and 17-18 of the '699 patent in view of the grounds set forth in the table below and requests that each of the claims be held unpatentable. A detailed explanation of the statutory grounds for the unpatentability of each claim is provided in the form of claim charts. Additional evidence supporting each ground is provided for in the Declaration of Mr. James Skarda and the appendices attached thereto.

Ground	Claims	Proposed Statutory Rejections for the '699 Patent
1	1 & 9	Claims 1 and 9 are anticipated under 35 U.S.C. § 102(e) by Thompson et al., U.S. Patent No. 6,152,920 ("Thompson") (Ex. 1005).
2	1, 4-8 & 18	Claims 1, 4-8 and 18 are anticipated under 35 U.S.C. § 102(e) by Mulier et al., U.S. Patent No. 6,096,037

Ground	Claims	Proposed Statutory Rejections for the '699 Patent
		("Mulier") (Ex. 1006).
3	2-3, 9-10, 12-13 & 18	Claims 2-3, 9-10, 12-13 & 18 are obvious under 35 U.S.C. § 103 over Mulier in view of Thompson.
4	1, 9-10 & 17-18	Claims 1, 9-10 and 17-18 are anticipated under 35 U.S.C. § 102(b) by Cox et al., PCT Publication WO 98/17187 ("Cox") (Ex. 1007).

Cox qualifies as prior art under § 102(b) because it was published on April 30, 1998, more than one year prior to the July 7, 1999 filing date of the '699 patent. Mulier qualifies as prior art under § 102(e) because it was filed on July 29, 1997 and issued on August 1, 2000.[1] Thompson qualifies as prior art under § 102(e) because it was filed on October 10, 1997 and issued on November 28, 2000.[2] None of these references were considered by the Examiner during prosecution of the '699 patent.[3]

[1] The July 29, 1997 date is the filing date of U.S. Patent Application No. 08/901,890, which is the same application that issued as Mulier and contains the same disclosure.

[2] The October 10, 1997 date is the filing date of U.S. Patent Application No. 08/949,117, which is the same application that issued as Thompson and contains the same disclosure.

[3] Although Thompson and one of the references that was considered during prosecution of the '699 patent are priority documents for the same PCT application (Ex. 1010, PCT Application No. US98/21357), the relevant disclosure cited by the

C. Claim Construction Under 37 C.F.R. § 42.104(b)(3)

A claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). Any claim term that lacks a definition in the specification is given its broadest reasonable interpretation ("BRI").[4] *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). The following discussion proposes constructions of certain terms and support therefor. Any claim terms not included in the following discussion are to be given their BRI in light of the specification as commonly understood by those of ordinary skill in the art. Should the Patent Owner, in order to avoid the prior art, contend that the claim has a construction different from its BRI, the appropriate course is for the Patent Owner to seek to amend the claim to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012).

1. Element Array

Examiner and distinguished by UAB does not appear in Thompson. *See* Ex. 1008 (Sept. 15, 2000 Office Action) at p. 2 (MDT2_1008_0069); Ex. 1008 (Dec. 4, 2000 Amendment) at pp. 12-13 (MDT2_1008_0089-90).

[4] Petitioner adopts the BRI standard as required by the governing regulations. 37 C.F.R. § 42.100(b). Petitioner reserves the right to pursue different constructions in a district court, where a different standard is applicable.

Under the BRI, the term "element array" should be construed to mean "the operative portion of the claimed device, located on the distal end of the elongate member and comprised of one or more energy emitting elements." Ex. 1001 at Abstract (disclosing that the element array "consists of one or more energy emitting (ablative) elements" and is "located at the distal end of an elongate member"); *see also id.* at 3:46-51; Ex. 1011, Skarda Decl. ¶¶ 36-37.

2. Malleable

Under the BRI, the term, "malleable" means "capable of being formed or shaped and then retaining that form or shape." *See* Ex. 1001 at 3:46-51 ("In another embodiment . . . the element array is ***malleable, having the capability of being formed or shaped***.") (emphasis added); Ex. 1011, Skarda Decl. ¶ 41.

The term "malleable" is used to refer to both the elongate members and the element arrays of the ablation devices claimed in the '699 patent. With regard to the malleability of the elongate member, the '699 patent distinguishes between one embodiment wherein the elongate member is "rigid," and other embodiments wherein the elongate member is "malleable to permit bending to a preferred configuration and yet retain enough rigidity to resist gross deformation when the element array 140 is urged against body tissue" or wherein the elongate member "is made of a malleable metal, such as nickel-titanium, which may be bent and retain its shape once bent." Ex. 1001 at 5:33-44; *see also id.* at 3:46-47; 6:60-64; Ex. 1011, Skarda Decl. ¶ 42. Similarly, the '699 patent states that the element arrays of the

claimed devices "may be rigid and formed in a predetermined shape, or may be malleable, such that they may be bent and formed as the application requires." Ex. 1001 at 6:51-56; 6:64-66; 3:48-55; Claim 1; Ex. 1011, Skarda Decl. ¶ 42; *see also id.,* ¶ 44. As discussed in more detail below, this construction is also supported by the prosecution history of the '699 patent. *See*, *e.g.*, Ex. 1008 (Dec. 4, 2000 Amendment) at MDT1_1008-0088 (distinguishing prior art reference as not disclosing a device wherein either the element array and/or elongate member was "malleable such that they can take on a desired shape ***prior to positioning in the subject*** and ***substantially retain that shape*** as said element array is positioned in the subject at the desired ablation site.") (emphasis added); *see also* Ex. 1011, Skarda Decl., ¶ 43.

3. Energy Emitting Element

Under the BRI, the term "energy emitting element" is "the portion of the element array that is used to create a lesion when it is energized (*e.g.,* by radio frequency, microwave, ultrasound, light, or cryogenic energy) and placed in contact with the tissue." Ex. 1001 at Abstract ("The present tool and associated methods provide for precisely controlled positioning of an ablative element, or an array of ablative elements, against a tissue targeted for treatment. Such treatment is in the form of a lesion, caused by energy emitted from the ablative element, selectively changing or destroying cells within the target tissue."); *see also id.* at 4:1-5; 7:47-51; Ex. 1011, Skarda Decl. ¶¶ 38-39. It should be noted that the term "energy emitting element" is used interchangeably in the '699 patent with the term "ablative element."

Ex. 1001 at 3:5-7 ("This element array consists of one or more ***energy emitting (ablative)*** elements.") (emphasis added), *see also id.* at Abstract (same); Ex. 1011, Skarda Decl. ¶ 39. The '699 patent further teaches that "[t]he energy delivered may be in the form of ***radio frequency***, microwave, ultrasound, light energy, and ***cryogenics***, among others." Ex. 1001 at 3:7-9 (emphasis added); *see also id.* at Abstract; 7:37-41; Ex. 1011, Skarda Decl. ¶ 40.

4. Nontransluminal Placement

Under the BRI, the term "nontransluminal placement" means "capable of placement or use outside of a lumen, *e.g.,* a blood vessel." Ex. 1011, Skarda Decl. ¶ 45. Nontransluminal placement includes access to the tissue to be ablated by (1) open chest procedures or (2) less invasive procedures that involve cutting the skin but do not employ a blood vessel. Ex. 1001 at 2:14-18 ("There is a need to have the ***capability*** to apply ablation therapy non-transluminally, such as during open heart surgery.") (emphasis added); Ex. 1011, Skarda Decl. ¶ 45.

As the '699 patent teaches, this "need" was due to the limitations with prior art devices that were designed for transluminal placement through a vein or artery to reach the ablation site and were not suitable for nontransluminal placement. Ex. 1001 at 1:19-24; 2:28-33 ("PTA catheters are inadequate for use in the open heart procedure, as they lack the structural support required to direct and press the electrodes against the target site. Also, due to their need to traverse narrow, tortuous vasculature, there is a definite limitation as to electrode size, shape and configuration

available from PTA catheters."); *see also* Ex. 1008 (Dec. 4, 2000 Amendment) at MDT1_1008-0086-91; Ex. 1011, Skarda Decl. ¶¶ 46-47.

IV. SUMMARY OF THE '699 PATENT

A. Overview of the '699 Patent

The '699 patent relates generally to tissue ablation, a procedure wherein targeted energy is applied to body tissue to burn or scar the tissue in the treatment of certain medical conditions. *See, e.g.*, Ex. 1001, Abstract, 1:10-16; Ex. 1011, Skarda Decl., ¶ 14. Cardiac ablation was commonly used prior to the filing date of the '699 patent to treat irregularities of the heart rhythm ("arrhythmias") using cardiac ablation tools similar to those claimed in the '699 patent. Ex. 1011, Skarda Decl. ¶¶ 14-23 (citing Ex. 1001 at 1:16-18; Ex. 1005 at 1:8-18; Ex. 1009 at 1:19-51; Ex. 1006 at 1:12-21; Ex. 1007 at 2:6-14). Put simply, the '699 patent addresses known problems in the art using known solutions. Ex. 1011, Skarda Decl. ¶¶ 31-32.

With respect to the problems, the '699 patent sought to address the known problems of catheter-based or "transluminal" ablation, which is performed via catheters that are introduced through a blood vessel, typically in the leg or neck. Ex. 1011, Skarda Decl. ¶¶ 20, 32 (citing Ex. 1001 at 1:19-29; Ex. 1005 at 2:14-31; Ex. 1009 at 1:34-41). In order to travel through a blood vessel to the heart, the elongated shaft of catheter-based devices must be extremely long and flexible. Ex. 1011, Skarda Decl. ¶ 21 (citing Ex. 1001 at 1:19-29; Ex. 1005 at 2:18-33; 3:1-15; Ex. 1009 at 1:65-2:4). It was well-known prior to the filing of the '699 patent that the long and sometimes

flimsy nature of these devices made it more difficult to control the operative portion at the ablation site and ensure accurate, firm contact without overheating the tissue. Ex. 1011, Skarda Decl. ¶ 21 (citing Ex. 1001 at 2:4-7; 2:28-33; Ex. 1005 at 3:6-26; 4:38-57; Ex. 1009 at 2:4-7; 2:15-19). At the same time, because transluminal ablation is performed on a beating heart (compared with open surgery, which is often performed concomitantly with cardiac bypass, which diverts blood flow from the heart), there is also the concern of the convective cooling effects of the blood flow at the ablation site. Ex. 1011, Skarda Decl. ¶ 21 (citing Ex. 1005 at 3:27-31; Ex. 1009 at 1:47-51).

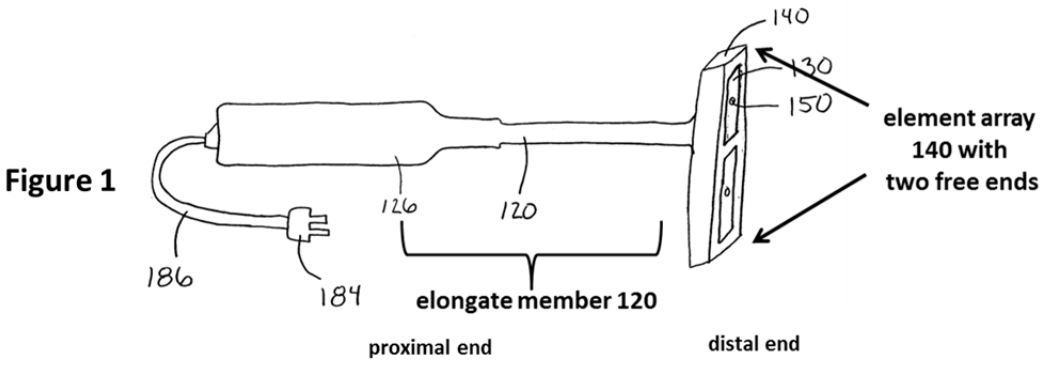
With respect to solving these well-known problems, the '699 patent provides a well-known solution: nontransluminal ablation devices which may be used during open procedures. *See, e.g.,* Ex. 1001 at 2:14-33; Ex. 1011, Skarda Decl. ¶¶ 22, 32. It was already known prior to the filing date of the '699 patent that cardiac ablation could be performed during open heart surgery using a non-transluminal ablation tool. Ex. 1011, Skarda Decl. ¶¶ 23, 32; Ex. 1005 at 4:59-62 ("Surgical devices in accordance with the present invention may also be used during procedures, such as valve replacement where the patient is on cardiopulmonary bypass, to create tissue lesions."); *see also id.* at 4:29-63; 5:58-63; Ex. 1009 at 1:36-47; 2:40-46. Indeed, as discussed in more detail in Section IV(B) below, the Examiner rejected many of the originally filed claims as anticipated and/or obvious in view of the prior art's disclosure of similar devices.

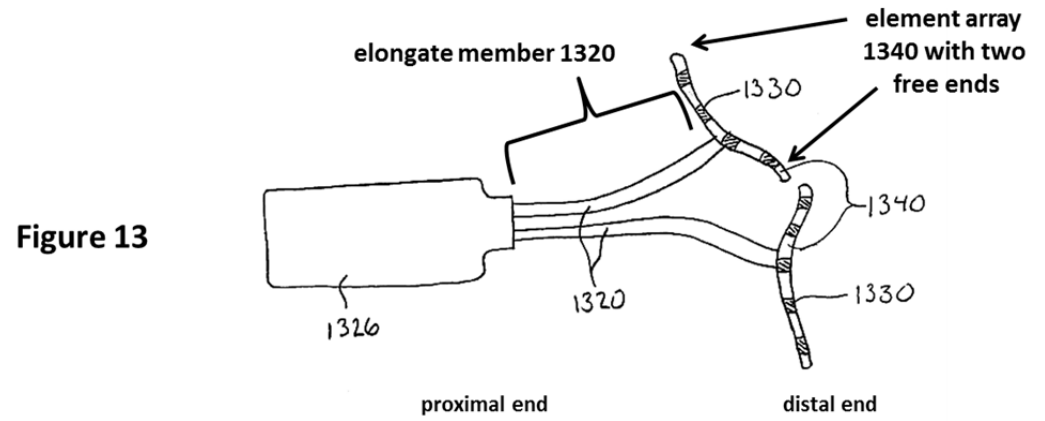
According to the inventors, the '699 patent allegedly improved on the nontransluminal ablation devices of the prior art by incorporating an element array and/or elongate shaft that are malleable such that they may be adapted to take on a desired shape prior to positioning and maintain that shape during ablation of the desired tissue. *See* Section IV(B) (citing Ex. 1008 (Dec. 4, 2000 Amendment) at MDT1_1008-0078-79, 0088-89). But malleable, nontransluminal ablation tools that allowed a physician to bend and shape the device to conform to the different shapes and sizes of tissues and organs, as well as differences among patients, was well-known in the art prior to the filing of the '699 patent. Ex. 1011, Skarda Decl. ¶¶ 22-23, 44 (citing Ex. 1005 at 5:15-40; Ex. 1006 at 2:42-45; 8:3-6; Fig. 12; Ex. 1007 at 11:29; 15:9-34).

In essence, the '699 patent adds nothing new to what was already well-known in the art prior to its filing, and is simply a return to prior art techniques for nontransluminal tissue ablation using well-known design features such as those described in the prior art. Ex. 1011, Skarda Decl. ¶ 32. Even the dependent claims of the '699 patent add design features that were also well-known in the art, including fluid delivery and temperature sensing elements. Ex. 1011, Skarda Decl. ¶ 22 (citing Ex. 1005 at 3:32-42; 12:57-67; Ex. 1006 at 5:13-24, 53-60; Ex. 1009 at 4:23-26; 7:1-4; 7:54-59; 8:25-35; 9:20-24; 10:45-64).

Annotated Figures 1 and 13 below are exemplary embodiments of the ablation tools disclosed in the '699 patent, which are comprised of an elongate member (120,

1320) with an element array (140, 1340) located at its distal end, the element array having two-free ends and a plurality of energy emitting elements (130, 1330) to accomplish the tissue ablation. Ex. 1001 at Fig. 1 & 3:5-7, 5:16-32; Fig. 13 & 5:57-64; Ex. 1011, Skarda Decl. ¶ 33.





Ex. 1001, Figs. 1 & 13 (annotated).

The specification teaches that the disclosed tool may include temperature sensing elements as part of the element array, and may include a fluid delivery system to cool the element array and/or surrounding tissue. Ex. 1001 at 3:9-4; Ex. 1011, Skarda Decl. ¶ 34. The specification also teaches that the elongate member and/or the element array may be made of malleable material that facilitates positioning of the

tool to generate the desired lesions. Ex. 1001 at 5:33-44; Ex. 1011, Skarda Decl. ¶ 34.

B. Summary of the Prosecution History of the '699 Patent

The patent application that issued as the '699 patent was filed on July 7, 1999, as U.S. Patent Application No. 09/348,811 ("the '811 application"). Claim 1, as originally filed, recited:

> An ablation tool for forming lesions in body tissue comprising: an elongate member having a distal and proximal end; an element array disposed on elongate member distal end; at least one energy emitting element disposed on the element array; and a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one energy emitting element to form a lesion in body tissue that is pressed against the at least one energy emitting element.

Ex. 1008 ('811 application) at MDT1_1008-0035.

The claims of the '811 application were rejected as anticipated by three prior art references not at issue in this Petition – Ex. 1012, U.S. Patent Nos. 6,068,629 ("Haissaguerre"); Ex. 1013, 6,106,522 ("Fleishman"); and Ex. 1014, 6,071,281 ("Burnside"). Ex. 1008 (Sept. 15, 2000 Office Action) at MDT1_1008-0069-70.

With regard to the Examiner's anticipation rejection based on Haissaguerre, UAB argued that the reference did not disclose a device wherein either the element array and/or elongate member was "malleable such that they can take on a desired shape ***prior to positioning in the subject*** and ***substantially retain that shape*** as said element array is positioned in the subject at the desired ablation site." Ex. 1008,

(Dec. 4, 2000 Amendment) at MDT1_1008-0088-89 (emphasis added); *see also id.* at MDT1-1008-0078-79 (amending Claim 1 to add "malleable" limitation). UAB argued that unlike Haissaguerre, the purported invention of Claim 1 requires the shaping of the element array and/or elongate member prior to positioning in the patient. *Id.* Of note, UAB did not distinguish the prior art Haissaguerre device on any other grounds except that it failed to meet the "malleable" limitation of amended Claim 1. *Id.* at MDT1_1008-0087-89; *see* also Ex. 1012, Figs. 13, 17 & 19.

With regard to Fleishman, UAB distinguished this reference on the grounds that Fleishman was limited to catheter-based (*i.e.,* transluminal) methods and tools for cardiac ablation, and while it disclosed the use of nontransluminal methods and tools "in other regions of the body," Fleishman taught away from the use of non-catheter based tools and techniques in cardiac tissue. Ex. 1008 (Dec. 4, 2000 Amendment) at MDT1_1008-0086-87. Thus, the "nontransluminal" limitation was added to Claim 1, and Claim 2 was limited to ablation of cardiac tissue. *Id.* at MDT1-1008-0087; *see also id.* at MDT1_1008-0078-79.

With regard to the third anticipatory reference, Burnside, UAB significantly amended its dependent claims to recite a laundry list of additional simple design modifications. *See, e.g., id.* at MDT1_1008-0090. UAB similarly argued that Burnside did not disclose, in a single embodiment, a device meeting all of the newly added limitations of Claim 1. *Id.* While acknowledging that Burnside disclosed that the disclosed devices may be used for nontransluminal placement, UAB argued that the

only examples of such devices were tools wherein the element array was a collapsible loop, and thus the reference did not disclose a nontransluminal device wherein the element array is "malleable" and has "two free ends." *Id.* at MDT1_1008-0089-90 (citing Ex. 1014 at 26:30-35). Significantly, the Examiner's rejection and UAB's response were based on this loop embodiment disclosed in Burnside.

Following these amendments and a telephonic interview, the Examiner issued a Notice of Allowance, dated April 27, 2001. Ex. 1008 (Notice of Allowance)at MDT1_1008-0102.

C. Legal Standard

1. Anticipation

Under 35 U.S.C. § 102(e), a person is not entitled to a patent if the invention was described in a U.S. patent application or patent that was filed before the date of invention by the patent applicant.

An anticipation analysis requires the presence of each and every claim limitation in a single reference either expressly or inherently. *Liebel-Flarsheim Co. v. Medrad, Inc.,* 481 F.3d 1371, 1381 (Fed. Cir. 2007). Where a prior art reference discloses multiple embodiments of the subject matter, each disclosed embodiment can be the basis for an anticipatory disclosure, as well as the combination of embodiments if such combination is supported by the specification. *CSR, PLC v. Skullcandy, Inc.,* 584 Fed. Appx., 672, 2014 WL 7101560, *7 (Fed. Cir. 2014) (holding that it was proper for PTO to combine two figures in a prior art reference to show anticipation

where the text of the specification indicated that the components shown in the figures were interchangeable, and thus could be combined); *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1268 (Fed. Cir. 2012) (holding prior art reference may be found anticipatory based on combination of different embodiments shown in figures when viewed in light of the disclosure of the reference as a whole).

2. Obviousness

The obviousness inquiry under § 103 is based on the approach set forth in *Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.

The party challenging the patent must also show that one of ordinary skill in the art would have a reason to combine the elements as recited in the claims. *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S. 398, 418-19 (2007). Prior to *KSR*, the Federal Circuit indicated that the reason to combine may be found in a relatively narrow number of sources, including the references themselves, the common knowledge of a person having ordinary skill in the art, and the nature of the problem to be solved. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009). Following *KSR*, the Supreme Court substantially expanded the possible sources for the reason to combine to include "market forces; design incentives; the interrelated teachings of multiple patents; any need or problem known in the field of endeavor at the time of invention and addressed by the patent; and the background knowledge, creativity, and common

sense of the person of ordinary skill." *Id.* (citing *KSR*, 550 U.S. at 418–21) (quotation marks omitted).

In *KSR*, the Supreme Court further noted that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR,* 550 U.S. at 421. Moreover, the obviousness analysis does not require express teachings, but may be based on the common sense, inferences, and creative steps expected of a person of ordinary skill in the art. *Id.* at 418. In sum, "a court must ask whether the improvement is more than a predictable use of prior art elements according to their established function. *Id.* at 417.

V. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1 and 9 Are Anticipated Under § 102(e) By Thompson

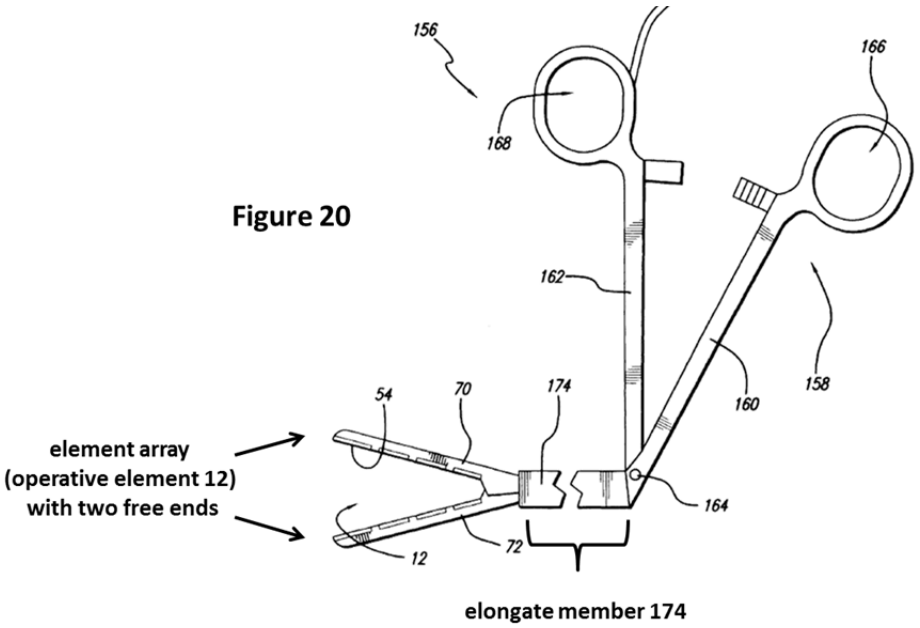
Like the '699 patent, Thompson discloses the problems associated with the prior art catheter-based methods and devices for ablating tissue, including the difficulties in controlling the long catheters at the ablation site to ensure firm, accurate contact without overheating the tissue. Ex. 1005 at 3:6-26; Ex. 1011 Skarda Decl. ¶ 50. Like the '699 patent, Thompson also describes systems and methods to address these known problems, namely tools that may be used nontransluminally to ablate

heart tissue. *See, e.g.,* Ex. 1005 at 3:54-57; 4:29-57; Ex. 1011, Skarda Decl. ¶ 50. For the reasons discussed below, Claims 1 and 9 are anticipated by Thompson.[5]

Independent Claim 1 recites "[a]n ablation tool for forming lesions in body tissue of a subject at a desired ablation site." Ex. 1001 at 7:66-67. Thompson discloses "systems and methods that simplify the creation of complex lesions [sic] patterns in soft tissue, such as myocardial tissue in the heart." Ex. 1005 at 1:8-12; Ex. 1011, Skarda Decl. ¶ 66.

Independent Claim 1 recites "an elongate member having a distal and proximal end." Ex. 1001 at 8:1. As shown in annotated Figure 20 below, Thompson discloses an ablation tool having an elongated shaft 174. Ex. 1005, Fig. 20; 22:13-22, *see also id.* at 4:5-18; Ex. 1011, Skarda Decl. ¶ 67. The break in the figure indicates to a POSITA that the shaft of 174 may be extended in length. *Id.* at ¶ 67. As may be further noted in annotated Figure 20, an elongated shaft has "a distal end and proximal end." Ex. 1005 at 2:18-26; *see also id.* at Fig. 20; Abstract; Claim 1; Ex. 1011, Skarda Decl. ¶ 68.

[5] The claim chart at the end of this Section details how each limitation recited in independent Claim 1 and dependent Claim 9 is disclosed by Thompson.



Ex. 1005, Fig. 20 (annotated).

Independent Claim 1 recites "an element array disposed on the elongate member distal end, wherein said element array has two free ends." Ex. 1001 at 8:2-3. Under the BRI, an "element array" is the operative portion of the claimed device, which is comprised of one or more energy emitting elements. Referring to annotated Figure 20 above, Thompson discloses that the ablation tool comprises an element array, identified in Thompson as operative element 12, which is secured to the distal end of the elongate member 174. Ex. 1005, Fig. 20; *see also id.* at 22:25-31; Ex. 1011, Skarda Decl. ¶ 69. The operative element 12 is comprised of two support members (depicted as 70 and 72 in Figure 20 and referred to as 170 and 172 in the specification) each having a free end. *Id.* at ¶ 69. Those support members 170 and 172 work cooperatively to form a clamp to perform the disclosed ablation. Ex. 1005 at 22:20-22 ("Actuation of the handle 158 causes the support members 170 and 172 to move relative to one another to create a clamping force."); *see also id.* at 23:28-40;

Ex. 1011, Skarda Decl. ¶ 69. These design features in Figure 20 are akin to those disclosed in the '699 patent, which teaches that the element array may be in the shape of a V or U. *See*, *e.g.*, Ex. 1001 at 3:41-45; 6:21-28; Figs. 7 & 8; *see also* Ex. 1011, Skarda Decl. ¶ 70. Thus, the element array in Figure 20 has two free ends, *i.e.,* the two furthermost points of the "V," much like the embodiment in Figures 7 & 8 of the '699 patent. *Id.* at ¶ 70.

Independent Claim 1 recites "at least one energy emitting element disposed on the element array." Ex. 1001 at 8:4-5. Under the BRI, "energy emitting element" means the portion of the element array that is used to create a lesion when it is energized (*e.g.,* by radio frequency, microwave, ultrasound, light, or cryogenic energy) and placed in contact with the tissue. As also shown in annotated Figure 20, Thompson explicitly teaches that all of the disclosed devices have an operative element 12, which in turn has a plurality of energy emitting elements in the form of electrodes 54 disposed on each support member. *See* Ex. 1005 at 15:35-45; 21:63-66; 22:25-38 & Fig. 20 (depicting element array comprising "one or more electrode elements 54 suitable for ablation"); Ex. 1011, Skarda Decl. ¶ 71.

Independent Claim 1 recites "a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one energy emitting element." Ex. 1001 at 8:6-10. Thompson discloses that wires extend through the elongate members of the disclosed devices that connect the electrodes to a control/power source by way of a connector (176). Ex. 1005, Fig. 20; 21:65-22:2;

22:25-38; Ex. 1011, Skarda Decl. ¶ 72. The connector is in turn coupled to a source of ablating energy, for example, a source which generates RF energy. *See* Ex. 1005, Fig. 28 & 24:18-25 (disclosing details of "Power Control" for the disclosed embodiments); Ex. 1011, Skarda Decl. ¶ 72.

Independent Claim 1 further recites the energization of the energy emitting element "to form a lesion in body tissue that is pressed against the at least one energy emitting element." Ex. 1001 at 8:8-10. Thompson teaches that the electrode elements ablate the body tissue after contacting the electrode elements to the tissue. *See* Ex. 1005 at 15:43-45 ("In the illustrated embodiments, the principal use of the electrode elements 54 is to transmit electrical energy and, more particularly, RF energy, to ablate heart tissue."); *see also id.* at 23:17-40; Ex. 1011, Skarda Decl. ¶ 73.

Independent Claim 1 recites "wherein the elongate member and element array are sized and configured for nontransluminal placement of the at least one energy emitting element at a target site." Ex. 1001 at 8:10-13. Under the BRI, the term "nontransluminal placement" means capable of placement or use outside of a lumen, *e.g.,* a blood vessel. Thompson specifically teaches that all of the disclosed devices are sized and configured for placement outside of a lumen or blood vessel, stating "the shaft in the present device can be relatively stiff, as compared to a catheter shaft, because the present shaft does not have to travel through the tortuous vascular path to the heart." Ex. 1005 at 4:50-53; *see also id.* at 3:1-57; 4:29-64 (distinguishing disclosed devices from transluminal, catheter-based devices); Ex. 1011, Skarda Decl.

¶ 74. Thompson further discloses that the devices can be used during open-chest surgery, *e.g.,* such as cardiopulmonary bypass or valve repair/replacement. Ex. 1005 at 4:59-5:14; Ex. 1011, Skarda Decl. ¶ 74.

Independent Claim 1 recites "at least one of the elongate member and element array are malleable such that they can take on a desired shape prior to positioning in the subject and substantially retain that shape as said element array is positioned in the subject at the desired ablation site." Ex. 1001 at 8:14-18. Dependent Claim 9 recites "the elongate member is made from a malleable material." Under the BRI, "malleable" means capable of being formed or shaped and then retaining that form or shape. Thompson teaches that both the elongate member and element array may be malleable. Ex. 1011, Skarda Decl. ¶ 75. For example, Thompson teaches that the elongate member may be comprised of a "malleable shaft," *i.e.,* "a shaft that can be readily bent by the physician to a desired shape, without springing back when released, so that it will remain in that shape during the surgical procedure." *See* Ex. 1005 at 10:54-57; Claim 1; Ex. 1011, Skarda Decl. ¶ 76. Thompson also teaches that the element array may be malleable to enable it to take the shape of the body structure to be ablated. Ex. 1005 at 5:22-26 ("Alternatively, or in addition, the distal end of the device may also be malleable, thereby allowing the physician to bend the distal end of the device into a shape corresponding to the bodily structure to be acted upon."); *see also id.* at 4:11-18; Ex. 1011, Skarda Decl. ¶ 76.

Independent Claim 1 further recites that "the desired shape [of the malleable element array and/or elongate member is] selected so as to impart a desired lesion pattern on the body tissue at the ablation site." Dependent Claim 9 recites that "the elongate member is adapted to be bent to allow easier positioning of the element array against body tissue." Ex. 1001 at 8:18-20. Both of these claims recite that the elongate member or element array are formed into a desired shape and employed to generate a lesion in the body tissue. Thompson discloses each of these concepts. Ex. 1011, Skarda Decl. ¶ 77. For example, Thompson teaches that the elongate member may be malleable such that "a physician can bend [it] into a desired configuration and remain in that configuration when released." Ex. 1005 at 5:14-22; Ex. 1011, Skarda Decl. ¶ 78. As to the element array, Thompson teaches it may be malleable so as to allow the physician to observe the shape of the atrial surface and bend the element array into the corresponding shape as needed. Ex. 1005 at 5:22-26; Ex. 1011, Skarda Decl. ¶ 78. Thompson further discloses that the use of devices having a malleable elongate member or element array configured into a particular shape enables the creation of desired lesions when the element array is pressed against the tissue. Ex. 1005 at 5:25-39; Ex. 1011, Skarda Decl. ¶ 78.

U.S. Patent No. 6,290,699	**Anticipation by Thompson**
1. An ablation tool for forming lesions in body tissue of a subject at a desired ablation site comprising:	**Thompson** discloses "systems and methods that simplify the creation of complex lesions [*sic*] patterns in soft tissue, such as myocardial tissue in the heart." Ex. 1005 at 1:8-12.
[a] an elongate member having a distal and proximal end;	**Thompson** discloses an ablation tool having an elongated shaft 174 with a distal and proximal end.

U.S. Patent No. 6,290,699	**Anticipation by Thompson**
	Ex. 1005, Fig. 20; 2:18-26; 22:13-22, *see also id.* at 4:5-18; Abstract; Claim 1.
[b] an element array disposed on the elongate member distal end, wherein said element array has two free ends;	**Thompson** discloses an element array, operative element 12, which is secured to the distal end of the elongate member 174. *Id.,* Fig. 20, *see also id.* at 22:25-31. The operative element 12 is comprised of two support members (depicted as 70 and 72 in Figure 20 and referred to as 170 and 172 in the specification) each having a free end at its distal-most point. Those support members 170 and 172 work cooperatively to form a clamp to perform the disclosed ablation. *Id.* at 22:20-22 ("Actuation of the handle 158 causes the support members 170 and 172 to move relative to one another to create a clamping force."); *see also id.* at 23:28-40.
[c] at least one energy emitting element disposed on the element array; and	**Thompson** discloses that all of the disclosed devices have an operative element 12 comprised of support members 170 and 172, which in turn have a plurality of energy emitting elements in the form of electrodes 54. *See id.* at 15:35-45; 21:63-66; 22:25-38 & Fig. 20 (depicting element array comprising "one or more electrode elements 54 suitable for ablation").
[d] a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one energy emitting element to form a lesion in body tissue that is pressed against the at least one energy emitting element,	**Thompson** discloses that wires extend through the elongate members of the disclosed devices that connect the electrodes to a control/power source by way of a connector (176). *Id.*, Fig. 20; 21:65-22:2; 22:25-38. **Thompson** discloses that the connector is in turn coupled to a source of ablating energy, for example, a source which generates RF energy. *See id.,* Fig. 28 & 24:18-25. **Thompson** discloses that the electrode elements ablate the body tissue to form a lesion after contacting the electrode elements to the tissue. *See id.* at 15:43-45; 23:17-40.
[e] wherein the elongate member and element array are sized and configured for nontransluminal placement of the at least one energy emitting element at a target site, and	**Thompson** discloses that "the shaft in the present device can be relatively stiff, as compared to a catheter shaft, because the present shaft does not have to travel through the tortuous vascular path to the heart." *Id.* at 4:50-53; 3:1-57; 4:29-64 (distinguishing disclosed devices from transluminal, catheter-based devices). **Thompson** also discloses that the devices can be used

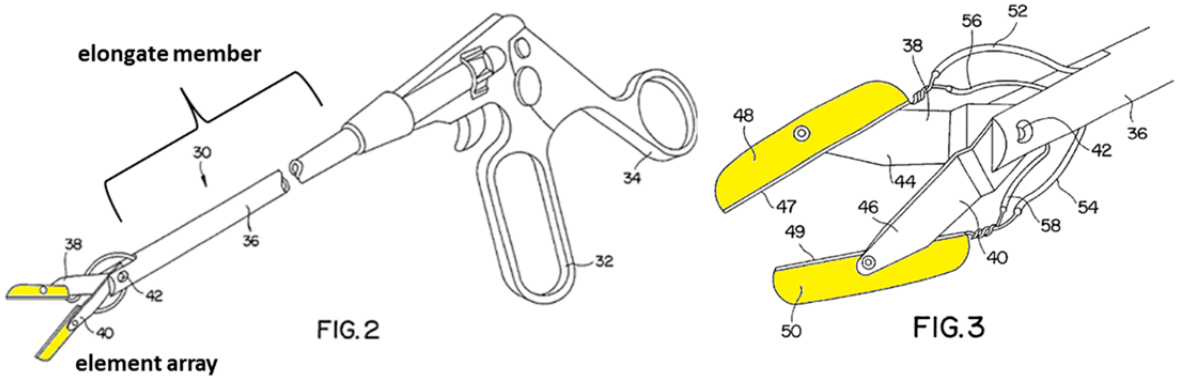
U.S. Patent No. 6,290,699	**Anticipation by Thompson**
	for open surgery, *e.g.,* during cardiopulmonary bypass. *Id.* at 4:59-5:14.
[f] wherein at least one of the elongate member and element array are malleable such that they can take on a desired shape prior to positioning in the subject and substantially retain that shape as said element array is positioned in the subject at the desired ablation site, the desired shape selected so as to impart a desired lesion pattern on the body tissue at the ablation site.	**Thompson** discloses that the elongate member may be comprised of a "malleable shaft," *i.e.,* "a shaft that can be readily bent by the physician to a desired shape, without springing back when released, so that it will remain in that shape during the surgical procedure." *Id.* at 10:54-57, Claim 1. **Thompson** also teaches that the element array may be malleable. *Id.* at 5:22-26, 4:11-18. **Thompson** discloses that the elongate member may be malleable such that "a physician can bend [it] into a desired configuration and remain in that configuration when released." *Id.* at 5:14-22. **Thompson** teaches that the element array may be malleable so as to allow the physician to observe the shape of the atrial surface and bend the element array into the corresponding shape as needed to impart the desired lesion. *Id.* at 5:22-26. **Thompson** discloses that the use of devices having a malleable elongate member or element array configured into a particular shape enables the creation of desired lesions when the element array is pressed against the tissue. *Id.* at 5:25-39.
9. The tool according to claim 1 wherein the elongate member is made from a malleable material, and wherein the elongate member is adapted to be bent to allow easier positioning of the element array against body tissue.	**Thompson** discloses that the elongate member of the ablation probe may be malleable to allow it to be bent and thereby positioned against body tissue. *See id.* at 10:54-57 ("A malleable shaft is a shaft that can be readily bent by the physician to a desired shape, without springing back when released, so that it will remain in that shape during the surgical procedure."); *see also id.* at 5:15-22; 5:25-39; Claim 1.

B. Ground 2: Claims 1, 4-8 and 18 Are Anticipated Under § 102(e) by Mulier

For the reasons below, Claims 1, 4-8 and 18 are anticipated by Mulier.[6]

Independent Claim 1 recites "[a]n ablation tool for forming lesions in body tissue of a subject at a desired ablation site." Ex. 1001 at 7:66-67. Mulier discloses an electrosurgery medical device for ablating tissue. *See* Ex. 1006, Abstract; 8:47-52; Ex. 1011, Skarda Decl. ¶ 80.

Independent Claim 1 recites "an elongate member having a distal and proximal end." Ex. 1001 at 8:1. As shown in annotated Figure 2 below, Mulier discloses an electrosurgery medical device comprising an "elongated shaft 36." Ex. 1006 at 4:34-35; Ex. 1011, Skarda Decl. ¶ 81. As shown in annotated Figure 2, this shaft has a distal and proximal end. *Id.*, ¶ 82.



Ex. 1006, Figs. 2 & 3 (annotated).

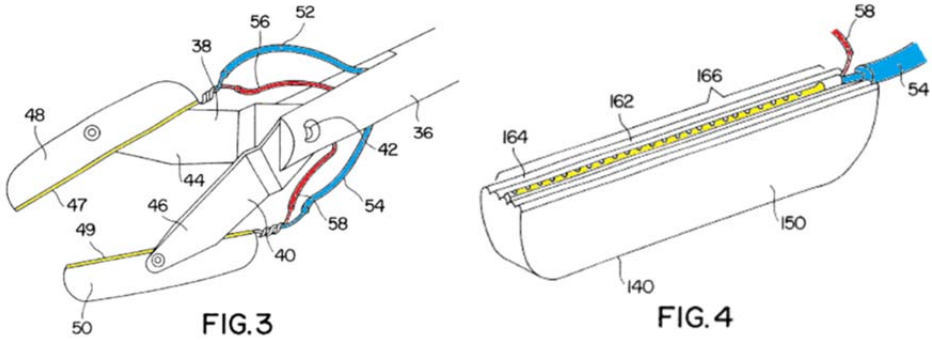
[6] The claim chart at the end of this Section details how each limitation recited in independent Claim 1 and dependent Claims 4-8 and 18 is disclosed by Mulier.

Independent Claim 1 recites "an element array disposed on the elongate member distal end, wherein said element array has two free ends." Ex. 1001 at 8:2-3. Under the BRI, an "element array" is the operative portion of the claimed device, which is comprised of one or more energy emitting elements. As highlighted in yellow in Figures 2 and 3 above,[7] Mulier discloses an element array comprised of jaw portions (48 and 50). These jaw portions are cooperatively joined by link portions (44 and 46) at pivot connection (42) and disposed on the distal end of the elongate member (36). Ex. 1006 at 4:33-46; Claim 7; Ex. 1011, Skarda Decl. ¶ 83. These elements work "in combination, [as] co-operating device jaws" to ablate tissue, and thus form the element array, which has two free ends, *i.e.,* the two distal points of the jaws of the element array. Ex. 1006 at 2:8-14, Fig. 2 (38 and 40) and Fig. 3 (48 and 50); Ex. 1011, Skarda Decl. ¶ 83.

Independent Claim 1 recites "at least one energy emitting element disposed on the element array." Ex. 1001 at 8:4-5. Under the BRI, "energy emitting element" is the portion of the element array that is used to create a lesion when it is energized (*e.g.,* by radio frequency, microwave, ultrasound, light, or cryogenic energy) and placed in contact with the tissue. As shown in annotated Figures 3 and 4 below, Mulier discloses energy emitting elements in the form of electrode strips (47 and 49) and

[7] Mulier discloses that "FIG. 3 is a detail view of the forceps of FIG. 2." Ex. 1006 at 2:62-63; Ex. 1011, Skarda Decl. ¶ 83.

"solution infusion openings (166)" disposed on jaw portions (48 and 50). Ex. 1006, Fig. 3; 4:55-61; Ex. 1011, Skarda Decl. ¶ 84. Mulier teaches that these electrode strips may be "uniquely formed of a material such as hollow stainless steel needle tubing" with multiple "solution infusion openings (166)" that allow electrolytic solution to pass through. Ex. 1006 at 5:25-40; 4:54-63; 7:13-41; Ex. 1011, Skarda Decl. ¶ 84. The solution passes through the solution infusion openings and the compression of tissue against the electrode strips and energized solution results in the formation of lesions in the desired tissue. *Id.* at 1:37-52; 1:64-2:7; 4:54-63; 5:25-67; 7:13-41; Ex. 1011, ¶¶ 84-85. "The purpose of the openings 166 is to infuse solution onto and/or into the tissue adjacent to and otherwise in contact with the forceps jaw portions inner surfaces." Ex. 1006 at 5:38-40; 1:37-47; Ex. 1011, Skarda Decl. ¶ 85.



Ex. 1006, Figs. 3 & 4 (annotated).

Independent Claim 1 recites "a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one

energy emitting element." Ex. 1001 at 8:6-8. In Figures 3 and 4 above,[8] Mulier discloses wires (56 and 58, shown in red) which are electrically connected to solution supply tubes (52 and 54, shown in blue) which supply electrolytic solution to the energy emitting elements (electrode strips 47 and 49, shown in yellow) via openings (166) on the jaw portions (48 and 50). Ex. 1006 at 4:54-63; 5:25-37; Figs. 3-5; Ex. 1011, Skarda Decl. ¶ 86. Mulier further discloses that "[a] wide variety of the currently installed electrosurgical generators could and will provide proper waveforms and power levels for driving the described forceps," for example, waveforms of a frequency of 500kHz and a power of 30 watts. Ex. 1006 at 6:54-60; Ex. 1011, Skarda Decl. ¶ 86.

Independent Claim 1 further recites the energization of the energy emitting element "to form a lesion in body tissue that is pressed against the at least one energy emitting element." Ex. 1001 at 8:9-10. Mulier discloses that "[c]ompression of tissue followed by application of solution and energy is understood to permanently maintain compressed deformation of tissue, when present, and to shrink tissue and cause proteins to fix in place." Ex. 1006 at 6:11-14; 1:37-52; 1:64-2:7; Ex. 1011, Skarda Decl. ¶ 87. Such compression against the energy emitting elements (*i.e.,* the electrode strips and fluid-dispensing openings) results in formation of a lesion on the ablated

[8] Mulier teaches that both jaw portions in Figure 4 "could be placed in substitution for jaw portions 48, 50 in FIG. 3." Ex. 1006 at 5:5-7; Ex. 1011, Skarda Decl. ¶ 86.

tissue. *See, e.g.,* Ex. 1006 at 3:16-4:22; 8:47-53; Ex. 1011, Skarda Decl. ¶ 87. Mulier also discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." Ex. 1006 at 1:49-52; 6:4-9; Ex. 1011, Skarda Decl. ¶ 87.

Independent Claim 1 recites "wherein the elongate member and element array are sized and configured for nontransluminal placement of the at least one energy emitting element at a target site." Ex. 1001 at 8:10-13. Under the BRI, the term "nontransluminal placement" means capable of placement or use outside of a lumen, *e.g.,* a blood vessel. Mulier describes, *inter alia,* open surgical devices, which are forceps used during open-chest (and thus, nontransluminal) procedures such as cardiopulmonary bypass. *See*, *e.g.*, Ex. 1006 at 1:60-63; Ex. 1011, Skarda Decl. ¶ 88.

Independent Claim 1 recites "wherein at least one of the elongate member and element array are malleable such that they can take on a desired shape prior to positioning in the subject and substantially retain that shape as said element array is positioned in the subject at the desired ablation site, the desired shape selected so as to impart a desired lesion pattern on the body tissue at the ablation site." Ex. 1001 at 8:14-20. Under the BRI, "malleable" means capable of being formed or shaped and then retaining that form or shape. Mulier discloses that "[f]or adaption to unique tissue geometries, the operative portions of the device may be malleable, to be manipulated to substantially any needed contour." Ex. 1006 at 2:42-45; Ex. 1011,

Skarda Decl. ¶89. Mulier further discloses that the "operative portion" of the device, *i.e.,* the element array, is comprised of "malleable tubing," which Mulier teaches "may be employed, to permit the surgeon to shape the operative portions of the invented devices to specific physiological situations." Ex. 1006*,* Fig. 12; 8:3-6; Ex. 1011, Skarda Decl. ¶ 89.

Dependent Claims 4, 7 and 8 recite an element array having a specific shape, "wherein at least one energy emitting element is disposed on the element array." Ex. 8:34-35, 8:45-49, 8:50-54. Claim 4 recites an element array comprising a "planar surface." *Id.* at 8:36. In Figures 9 and 10, Mulier discloses an element array wherein the jaw portions are planar and have at least one energy emitting element disposed on that planar surface. *See* Ex. 1006*,* Fig. 9 (depicting jaw portions 440 and 458), Fig. 10 (depicting jaw portions 538 and 540), & Fig. 11 (depicting cross-section of Figs. 9 and 10, along with energy-emitting element 466); *see also id.* at 7:55-63; Ex. 1011, Skarda Decl. ¶ 90. Dependent Claim 7 recites a tool where the element array is "elongated." Mulier discloses an electrosurgery device wherein the element array is elongated. *See*, *e.g.*, Ex. 1006, Figs. 9-11; 7:57-61; Ex. 1011, Skarda Decl. ¶ 91. Dependent Claim 8 recites the tool of Claim 7 "wherein the element array is curved." Ex. 1001 at 8:50-51. In Figures 9 and 10, Mulier discloses an electrosurgery device wherein "[t]he jaw portions of these devices are curved." Ex. 1006 at 7:43-49, 2:33-40; Ex. 1011, Skarda Decl. ¶ 92.

Mulier further teaches that the element array in Figure 2 may be replaced by the element arrays disclosed in Figures 9-12:

> Those skilled in the art will recognize that the preferred embodiments may be altered and modified without departing from the true spirit and scope of the invention as defined in the appended claims. For example, if the invented device is incorporated in forceps [e.g., Figs. 6-12], the forceps may be varied in a range from excision and cutting biopsy forceps, to endoscopic forceps, dissecting forceps, and traumatic, atraumatic and flexible endoscopic grasping forceps.

Ex. 1006 at 8:20-28 (emphasis added); Ex. 1011, Skarda Decl. ¶ 93. Indeed, Mulier teaches that with regard to Figure 10 specifically, the jaws of that embodiment may be used in either endoscopic devices or open surgical devices. Ex. 1006 at 7:50-53 (referring to Fig. 10 and stating, "In endoscopic or open surgery, such lesions or tumors may be encircled and/or isolated, surrounding tissue sealed, and the lesions or tumors thereafter resected."); Ex. 1011, Skarda Decl. ¶ 93.

Dependent Claim 4 further recites "whereby the pressing of said planar surface against body tissue also presses at least one energy emitting element against body tissue." Ex. 1001 at 8:36-38. Similarly, dependent Claims 7 and 8 recite lesions formed by "the pressing of said element array against body tissue." *Id.* at 8:48-49, 8:53-54. Mulier discloses that "[t]he tissue sealing itself is understood to occur by flow of electrolytic solution to the manipulating portion [jaws] of the forceps in combination with energization of the solution with electrical energy, and when

included, in combination with pressure on, or compression of[,] the tissue." Ex. 1006 at 6:4-9; 1:49-52; Ex. 1011, Skarda Decl. ¶ 94.

Dependent Claims 5, 6, 7 and 8 recite element arrays and/or energy emitting elements which produce lesions of a specific shape. Dependent Claim 5 recites "the at least one energy emitting element has a shape which produces circular lesions." Ex. 1001 at 8:39-41. Similarly, dependent Claim 8 recites formation of a "curved lesion." *Id.* at 8:53-54. Mulier discloses an electrosurgery device (430) wherein the element array and corresponding energy emitting elements are shaped to produce circular and curved lesions. *See* Ex. 1006, Figs. 9 & 10; *see also id.* at 2:33-40 ("Also as preferred, the operative portions of the device may take the form of a circular, semicircular or other regular and irregular geometric shape, to contain and/or isolate tissue to be affected and perhaps resected."); 7:43-49 ("The jaw portions of these devices [in Figs. 9 and 10] are curved . . . ."); Ex. 1011, Skarda Decl. ¶ 95. Dependent Claim 6 recites "the at least one energy emitting element has a shape which produces a plurality of elongated lesions." Ex. 1001 at 8:42-44. Similarly, dependent Claim 7 recites forming "an elongated lesion." *Id.* at 8:48-49. Mulier discloses an electrosurgery device wherein the element array and corresponding energy emitting elements are shaped to produce elongated lesions. *See*, *e.g.*, Ex. 1006, Figs. 9-11; 7:57-61 ("As most preferred, the tubing incorporates a central, depressed, cross-sectionally rectangular, and elongated groove 462 and equilaterally spaced, cross-sectionally triangular, parallel, and elongated outer grooves 464, 465. Laser drilled openings 466, similar to openings

166 described above, are located in and spaced along the central groove 462."); Ex. 1011, Skarda Decl. ¶ 96.

Dependent Claim 18 recites the tool of Claim 1 "further comprising a plurality of orifices located adjacent active elements on the element array adapted for dispensing fluid therefrom." Ex. 1001 at 9:25-27. As explained above in Claim 1, Mulier teaches that the element array is comprised of energy emitting elements, *i.e.,* electrode strips (47 and 49) and corresponding "solution infusion openings (166)" through which electrolytic solution passes. Ex. 1006 at 4:54-63; 5:25-37; 7:13-28; Ex. 1011, Skarda Decl. ¶ 97. As also discussed above, the compression of tissue against the electrode strips and energized solution results in the formation of lesions in the desired tissue. *Id.* at 1:37-52; 1:64-2:7; 4:54-63; 5:25-67; 7:13-41; Ex. 1011, Skarda Decl. ¶ 97. Thus, a person of ordinary skill in the art would understand that the electrode strips and solution infusion openings are both "active elements." *Id.*

As shown in annotated Figure 4 below, Mulier teaches that the solution infusion openings 166, which serve as both fluid dispensing orifices and active elements, are adjacent to one another on the element array. Ex. 1011, Skarda Decl. ¶ 98. As further shown in annotated Figure 4 below, Mulier discloses that the solution infusion openings are also adjacent to the electrode strip, which is an active element. *Id.* For either of these reasons, a person of ordinary skill in the art would understand that Mulier discloses an ablation tool comprising a plurality of fluid dispensing orifices located adjacent to active elements on the element array. *Id.*

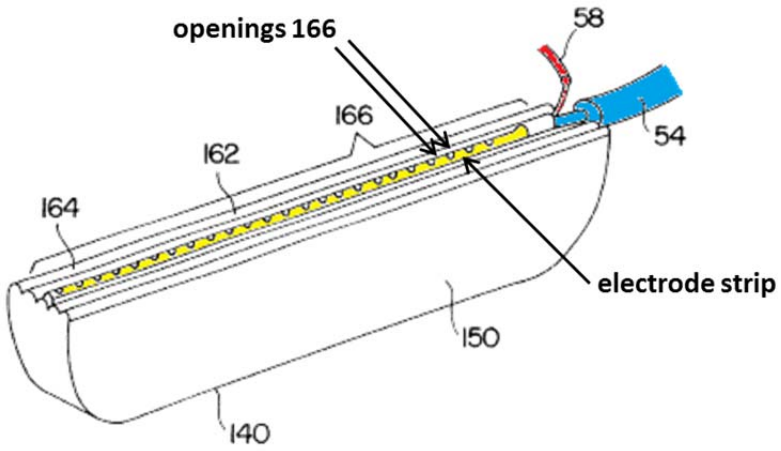


FIG. 4

Ex. 1006, Figs. 3 & 4 (annotated).

U.S. Patent No. 6,290,699	Anticipation by Mulier
1. An ablation tool for forming lesions in body tissue of a subject at a desired ablation site comprising:	**Mulier** discloses an electrosurgery medical device for ablating tissue. *See* Ex. 1006, Abstract, 8:47-52.
[a] an elongate member having a distal and proximal end;	**Mulier** discloses an electrosurgery medical device comprising an "elongated shaft" (36) with a distal and proximal end. *See id.* at 4:34-35.
[b] an element array disposed on the elongate member distal end, wherein said element array has two free ends;	In **Mulier**, jaw portions (48 and 50), which are cooperatively joined by link portions (44 and 46) at pivot connection (42), together comprise an element array. *See id.*, Figs. 2 & 3. The jaw portions (48 and 50) are disposed on the distal end of the elongate member (36). *See id.*, Figs. 2 & 3, 4:33-46. The jaws work in combination to ablate tissue as one element array. *Id.* at 2:8-14. Each jaw portion of the element array has a free end at its distal-most point. *See id.*, Fig. 2 (38 and 40) and Fig. 3 (48 and 50).
[c] at least one energy emitting element disposed on the element array; and	**Mulier** discloses an energy emitting elements, *i.e.,* electrode strips (47 and 49) and corresponding "solution infusion openings (166)" disposed on jaw portions (48 and 50). *Id.*, Fig. 3, 4:55-61, Fig. 4. **Mulier** teaches that these electrode strips may be "uniquely formed of a material such as hollow stainless steel needle tubing" with multiple solution infusion openings (166) that allow electrolytic solution to pass through. *Id.* at 5:25-40; *see also id.* at 1:37-47; 4:54-63;

U.S. Patent No. 6,290,699	Anticipation by Mulier
	7:13-41. **Mulier** teaches that the compression of tissue against the electrode strips and energized solution results in the formation of lesions in the desired tissue. *Id.* at 1:37-52; 1:64-2:7; 4:54-63; 5:25-67; 7:13-41.
[d] a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one energy emitting element to form a lesion in body tissue that is pressed against the at least one energy emitting element,	**Mulier** discloses a source of energy coupled to the at least one energy emitting element. *See Mulier*, Figs. 3-5 & 4:55-61, 5:25-37. **Mulier** further discloses that "[a] wide variety of the currently installed electrosurgical generators could and will provide proper waveforms and power levels for driving the described forceps," for example, waveforms of a frequency of 500kHz and a power of 30 watts. *Id.* at 6:54-60. Further, **Mulier** discloses that "[c]ompression of tissue followed by application of solution and energy is understood to permanently maintain compressed deformation of tissue, when present, and to shrink tissue and cause proteins to fix in place." *Id.* at 6:11-14; *see also id.* at 1:37-52; 1:64-2:7. **Mulier** also discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." *Id.* at 1:49-52; 6:4-9.
[e] wherein the elongate member and element array are sized and configured for nontransluminal placement of the at least one energy emitting element at a target site, and	**Mulier** describes open surgical devices that are deployed by non-transluminal placement. *See*, *e.g.*, *id.* at 1:60-63.
[f] wherein at least one of the elongate member and element array are malleable such that they can take on a desired shape prior to positioning in the subject and substantially retain that shape as said element array is positioned in the subject at the desired ablation site, the desired shape selected so as to impart a desired lesion pattern on the body tissue at the ablation site.	**Mulier** discloses that "[f]or adaption to unique tissue geometries, the operative portions of the device may be malleable, to be manipulated to substantially any needed contour." *Id.* at 2:42-45. Mulier further discloses that the operative portion of the device, *i.e.,* the element array, is comprised of "malleable tubing," which Mulier teaches "may be employed, to permit the surgeon to shape the operative portions of the invented devices to specific physiological situations." *Id.,* Fig. 12, 8:3-6.
4. The tool according to claim	In Figs. 9 and 10, **Mulier** discloses an element array

U.S. Patent No. 6,290,699	Anticipation by Mulier
1, wherein the element array further comprises a planar surface, said at least one energy emitting element disposed on said planar surface,	wherein the jaw portions are planar and have at least one energy emitting element disposed on that planar surface. *Id.*, Figs. 9-11, 7:55-63. **Mulier** further teaches that the element array in Fig. 2 may be replaced by the element arrays disclosed in Figs. 9-12. *Id.* at 8:20-28. Mulier specifically discloses that the jaws of Fig. 10 may be used in either endoscopic devices or open surgical devices. *Id.* at 7:50-53.
whereby the pressing of said planar surface against body tissue also presses at least one energy emitting element against body tissue.	**Mulier** further discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." *Id.* at 1:49-52. **Mulier** additionally discloses that "[t]he tissue sealing itself is understood to occur by flow of electrolytic solution to the manipulating portion [jaws] of the forceps in combination with energization of the solution with electrical energy, and when included, in combination with pressure on, or compression of[,] the tissue." *Id.* at 6:4-9.
5. The tool according to claim 4 wherein the at least one energy emitting element has a shape which produces circular lesions.	**Mulier** discloses an electrosurgery device wherein the element array and corresponding energy emitting elements are shaped to produce circular lesions. *Id.*, Fig. 9, 2:33-40 ("Also as preferred, the operative portions of the device may take the form of a circular, semicircular or other regular and irregular geometric shape, to contain and/or isolate tissue to be affected and perhaps resected."); *id.* at 7:43-49.
6. The tool according to claim 4 wherein the at least one energy emitting element has a shape which produces a plurality of elongated lesions.	**Mulier** discloses an electrosurgery device wherein the element array and corresponding energy emitting elements are shaped to produce a plurality of elongated lesions. *Id.*, Figs. 9-11, 7:57-61 ("As most preferred, the tubing incorporates a central, depressed, cross-sectionally rectangular, and elongated groove 462 and equilaterally spaced, cross-sectionally triangular, parallel, and elongated outer grooves 464, 465. Laser drilled openings 466, similar to openings 166 described above, are located in and spaced along the central groove 462.").
7. The tool according to claim 4 wherein the element array is elongated, and the at least one	**Mulier** discloses an electrosurgery device wherein the element array and corresponding energy emitting elements are shaped to produce elongated lesions. *Id.*,

U.S. Patent No. 6,290,699	Anticipation by Mulier
energy emitting element is disposed on the element array whereby an elongated lesion is formed by the pressing of said element array against body tissue.	Figs. 9-11, 7:57-61. **Mulier** further discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." *Id.* at 1:49-52, 6:4-9.
8. The tool according to claim 7 wherein the element array is curved, and the at least one energy emitting element is disposed on the element array whereby a curved lesion is formed by the pressing of said element array against body tissue.	**Mulier** discloses an electrosurgery device wherein the element array and corresponding energy emitting elements are shaped to produce curved lesions. *Id.*, Figs. 9 and 10, 7:43-49 ("The jaw portions of these devices [in Figs. 9 and 10] are curved …."); 2:33-40. **Mulier** further discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." *Id.* at 1:49-52, 6:4-9.
18. A tool according to claim 1, further comprising a plurality of orifices located adjacent active elements on the element array adapted for dispensing fluid therefrom.	**Mulier** teaches that the element array is comprised of active elements in the form of energy emitting elements, *i.e.,* electrode strips (47 and 49) and corresponding "solution infusion openings (166)" through which electrolytic solution passes. *Id.* at 4:54-63; 5:25-37; 7:13-28. **Mulier** teaches that the compression of tissue against the electrode strips and energized solution results in the formation of lesions in the desired tissue. *Id.* at 1:37-52; 1:64-2:7; 4:54-63; 5:25-67; 7:13-41; Fig. 4. **Mulier** teaches that the solution infusion openings 166 serve as both fluid dispensing orifices and active elements and are adjacent to one another on the element array. *Id.* at Fig. 4. **Mulier** discloses that the solution infusion openings are also adjacent to the electrode strip. *Id.*

C. Ground 3: Claims 2-3, 9-10, 12-13 and 18 are Obvious Under § 103(a) Over Mulier in view of Thompson

The discussion regarding anticipation by Mulier is incorporated into this Ground. As discussed above, Mulier discloses each and every limitation in independent Claim 1. *See supra* at Section V(B). The combination of Mulier in view of Thompson renders Claims 2, 3, 9-10, 12-13 and 18 obvious.

As an initial matter, Mulier discloses all of the limitations of Claims 2 and 3 except a temperature sensing element, while Thompson discloses the temperature sensing element limitation.

Dependent Claim 2 recites the tool of Claim 1 "adapted to treat cardiac tissue." Ex. 1001 at 8:21-22. Mulier discloses an electrosurgery device that may be used for cardiac tissue ablation. *See* Ex. 1006 at 8:47-53 (teaching that the disclosed devices may be used in body tissues and organs, *e.g.*, the heart); 1:19-21 (describing RF ablation of heart tissue as being well known in the art); Ex. 1011, Skarda Decl. ¶ 101.

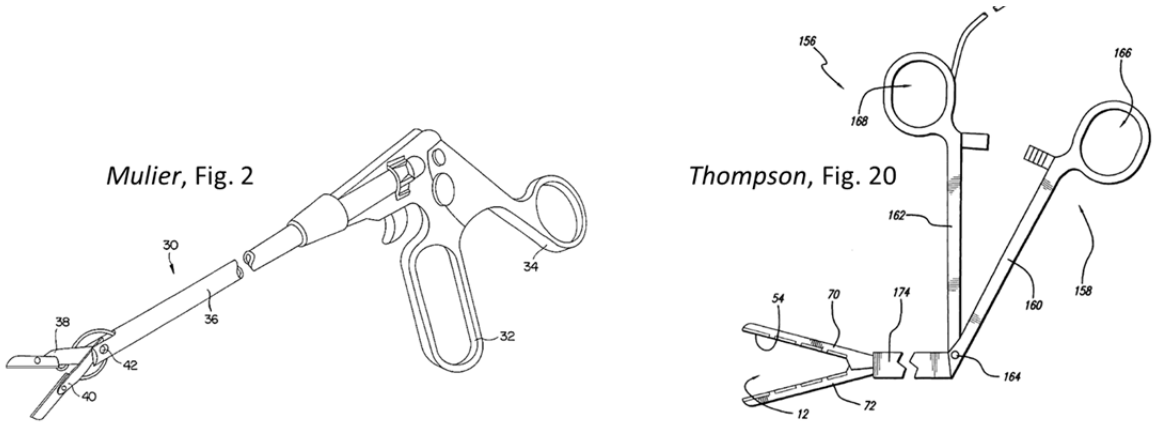
Dependent Claim 2 further recites "wherein the element array further comprises at least one temperature sensing element." Ex. 1001 at 8:22-24. Thompson teaches the importance of temperature control at the ablation site, and employs temperature sensors to help achieve it. Ex. 1005 at 3:16-22; 32-35; 12:57-62; 18:35-52; Ex. 1011, Skarda Decl. ¶ 102. It would have been an obvious design choice to add the temperature sensors disclosed in Thompson to the ablation devices disclosed in Mulier in order to better control temperature at the ablation site. *Id.* at ¶ 102. Mulier itself teaches that when temperature is not controlled, desiccation and charring of the tissue may occur above a certain temperature, Ex. 1006 at 3:35-4:4; 4:12-16; 5:13-24, and temperature sensors at the ablation site provide a potential solution to such problems. *See also* Ex. 1011, Skarda Decl. ¶ 102.

Dependent Claim 2 additionally recites "wherein the ablation tool further comprises a fluid delivery path extending through the elongate member and the

element array so as to be able to direct fluid from the ablation tool to the ablation site during operation." Ex. 1001 at 8:24-27. Mulier discloses a fluid delivery path extending though the elongate member and element array to deliver fluid to the ablation site during ablation. *See* Ex. 1006, Abstract; 5:38-49 ("Infusion of fluid through the jaws is to be maintained in a continuous flow during and throughout the application of RF energy …."); *see also id.* at 2:8-14; 5:38-49; Ex. 1011, Skarda Decl. ¶ 103. Mulier teaches the importance of this solution in ensuring even tissue contact while avoiding overheating. Ex. 1006 at 5:13-24 (teaching that the use of solution during ablation "minimize[es] unwanted arcing, charring and smoke"); 5:38-67 (disclosing the advantages of infusing the ablation site with solution); Ex. 1011, Skarda Decl. ¶ 103.

In view of the fact that both references recognized the same temperature-related problems associated with ablating tissue, one would have been motivated to solve those problems by adding the temperature sensing elements disclosed in Thompson to the ablation device disclosed in Mulier. *See KSR,* 550 U.S. 398 at 421 ("[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed."); *Perfect Web*, 587 F.3d 1329 (noting that the motivation to combine may be found in the references themselves); Ex. 1011, Skarda Decl. ¶ 104. A POSITA would further had a reason to combine Mulier and Thompson given that both references disclose systems and methods for using RF energy to create complex

lesions in tissue such as the heart and are in the same field of art, cardiac ablation. *Id.* Moreover, as may be observed in the figures below, both Mulier and Thompson also teach the use of ablation tools having a highly similar design to accomplish nontransluminal cardiac ablation. *Compare* Ex. 1006, Fig. 2 *with* Ex. 1005, Fig. 20; Ex. 1011, Skarda Decl. ¶ 104.



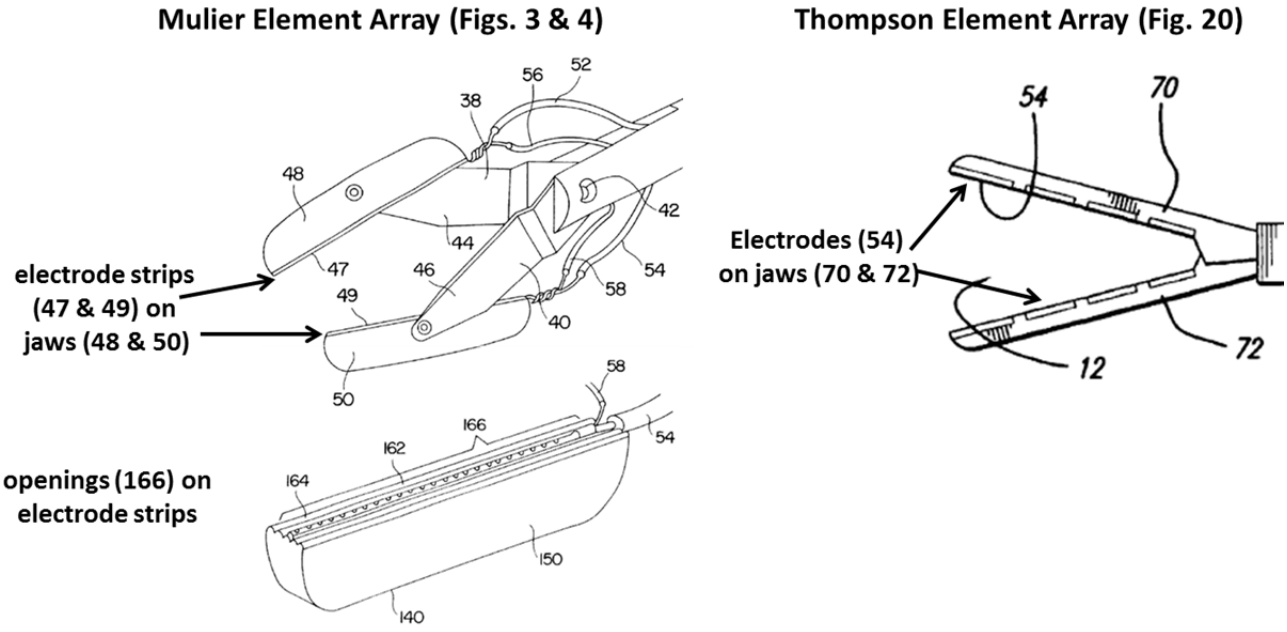
Ex. 1006, Fig. 2; Ex. 1005, Fig. 20.

Dependent Claim 3 recites that "the at least one energy emitting element further comprises an electrically conductive material capable of emitting radio frequency energy, and said source of energy is capable of producing radio frequency energy." Ex. 1001 at 8:28-32. Mulier discloses that at least one of the energy emitting elements, *i.e.*, electrode strips (47 and 49), is made of stainless steel. Ex. 1006 at 5:25-31; Ex. 1011, Skarda Decl. ¶ 105. Stainless steel is an electrically conductive material capable of emitting RF energy. *Id.* at ¶ 105. Mulier further discloses that "[a] wide variety of the currently installed electrosurgical generators could and will provide proper waveforms and power levels for driving the described forceps," for example,

waveforms of a frequency of 500kHz and a power of 30 watts. Ex. 1006 at 6:54-60; Ex. 1011, Skarda Decl. ¶ 105. Further, "[i]nfusion of fluid through the jaws is to be maintained in a continuous flow during and throughout the application of RF energy…." Ex. 1006 at 5:46-49; Ex. 1011, Skarda Decl. ¶ 105.

As noted above in Section V(B), Mulier discloses all of the limitations of Claim 18. The combination of Mulier in view of Thompson additionally renders Claim 18 obvious. Dependent Claim 18 recites the tool of Claim 1 "further comprising a plurality of orifices located adjacent active elements on the element array adapted for dispensing fluid therefrom." Ex. 1001 at 9:25-27. As discussed above and depicted in annotated Figure 3 below, Mulier discloses an element array (jaws 48 and 50) comprised of energy emitting elements, *i.e.,* electrode strips (47 and 49) and corresponding "solution infusion openings 166." Ex. 1006 at 4:54-63; 5:25-37; 7:13-28; Ex. 1011, Skarda Decl., ¶ 107. As also discussed above, the openings are fluid dispensing orifices that deliver fluid to the ablation site to both lubricate and cool the tissue as well as assist with the ablation. *See* Ex. 1006 at 1:37-52; 1:64-2:14; 4:54-63; 5:25-67; 7:13-41; Ex. 1011, Skarda Decl., ¶ 107. As shown in annotated Figure 20 below, Thompson teaches the use of electrodes comprised of a conductive material to transmit RF energy to the ablation site. *See* Ex. 1005 at 15:35-45; 21:63-66; 22:25-38 & Fig. 20; Ex. 1011, Skarda Decl., ¶ 107. It would have been an obvious design choice to a person of ordinary skill in the art to modify the element array of Mulier (jaws 48 and 50) to additionally include the active elements disclosed in Thompson

(electrodes 54), adjacent to the fluid-dispensing orifices (openings 166) in order to provide supplemental ablation. Ex. 1011, Skarda Decl. ¶ 107; *KSR,* 550 U.S. at 421.



Ex. 1006, Figs. 3 & 4 (annotated); Ex. 1005, Fig. 20 (annotated).

A POSITA would have been motivated to combine these references for the reasons set forth above for Claim 2, including the similar design and purpose of the devices disclosed in each. Ex. 1011, Skarda Decl., ¶ 108. Thus, a POSITA would have been motivated to adapt the jaws of Mulier to include additional active elements, such as the electrodes disclosed in Thompson, adjacent to the fluid dispensing orifices. *Id.*

Claim 2. The tool according to claim 1, wherein the ablation tool is adapted to treat cardiac tissue,	**Mulier** discloses an electrosurgery device that could be used to ablate the tissue of an organ, *e.g.,* the heart. *See* Ex. 1006 at 8:47-53; 1:19-21.
wherein the element array further comprises at least one	**Mulier** teaches that when temperature is not controlled, desiccation and charring of the tissue

temperature sensing element, and	may occur above a certain temperature. Ex. 1006 at 3:35-4:4; 4:12-16; 5:13-24. **Thompson** teaches the importance of temperature control at the ablation site, and employs temperature sensors to help achieve it. Ex. 1005 at 3:16-22; 3:32-35; 12:57-62; 18:35-52.
wherein the ablation tool further comprises a fluid delivery path extending through the elongate member and the element array so as to be able to direct fluid from the ablation tool to the ablation site during operation.	**Mulier** discloses a fluid delivery path extending though the elongate member and element array. *See* Ex. 1006, Abstract; 5:46-49 ("Infusion of fluid through the jaws is to be maintained in a continuous flow during and throughout the application of RF energy …."); 2:8-14; 5:38-49. **Mulier** teaches the importance of this solution in ensuring even tissue contact while avoiding overheating. *Id.* at 5:13-24; 5:38-67.
3. The tool according to claim 2, wherein the at least one energy emitting element further comprises an electrically conductive material capable of emitting radio frequency energy, and said source of energy is capable of producing radio frequency energy.	**Mulier** discloses that at least one of the energy emitting elements (*i.e.*, electrode strips (47 and 49)) is made of stainless steel, which is an electrically conductive material capable of emitting RF energy. *Id.* at 5:25-31. **Mulier** further discloses that "[a] wide variety of the currently installed electrosurgical generators could and will provide proper waveforms and power levels for driving the described forceps," for example, waveforms of a frequency of 500kHz and a power of 30 watts. *Id.* at 6:54-60, *see also id.* at 5:46-49.
18. A tool according to claim 1, further comprising a plurality of orifices located adjacent active elements on the element array adapted for dispensing fluid therefrom.	**Mulier** discloses an element array (jaws 48 and 50) comprised of energy emitting elements, *i.e.,* electrode strips (47 and 49) and corresponding "solution infusion openings 166." Ex. 1006 at 4:54-63; 5:25-37; 7:13-28. **Mulier** discloses that the openings are fluid dispensing orifices that deliver fluid to the ablation site to both lubricate and cool the tissue as well as assist with the ablation. *See id.* at 1:37-52; 1:64-2:14; 4:54-63; 5:25-67; 7:13-41. **Thompson** teaches the use of electrodes comprised of a conductive material to transmit RF energy to the ablation site. *See* Ex. 1005 at 15:35-45; 21:63-66; 22:25-38 & Fig. 20.

The combination of Mulier in view of Thompson also renders dependent Claim 10, and Claim 12 which depends from Claim 10, obvious. Mulier discloses all of the limitations of Claims 10 and 12 except an element array that is perpendicular to the elongate member, which is disclosed in Thompson.

Claim 10 recites the tool of Claim 1, and additionally recites an ablation device wherein the element array is an "elongated cylindrical rod which is attached to the elongate member distal end so that it extends in a substantially perpendicular direction relative to the elongate member and having [*sic*] a diameter defining a surface." Ex. 1001 at 8:59-63. Mulier discloses an element array comprised of malleable, elongated tubing, which has a diameter defining a surface. *See* Ex. 1006*,* Fig. 12; 7:64-8:8 ("Alternate cross-sectional shapes of tubing may be employed, as exemplified in FIG. 12."); Ex. 1011, Skarda Decl. ¶ 110. Although Mulier does not disclose that the element array is perpendicular to the elongate member, it would have been an obvious design modification given the benefits taught by Thompson of an ablation device wherein the element array resembles a cylindrical rod and is perpendicular to the elongate member. *Id.*; *PerfectWeb*, 587 F.3d at 1329 (noting that the motivation to combine may be found in the references themselves); *see also KSR,* 550 U.S. at 421. Specifically, Thompson discloses an embodiment wherein the element array resembles a cylindrical rod that has a diameter defining a surface and is perpendicular to the elongate member, which is useful to "hold the bodily structure such that it is parallel to the surgical device." Ex. 1005 at 22:61-65 & Fig. 24; *cf.,* 22:45-51 & Figs. 20, 21

(disclosing advantages of device in which the element array extends parallel to the elongate member, *e.g.,* the devices disclosed in Mulier); Ex. 1011, Skarda Decl. ¶ 111. A POSITA would have also been motivated to combine Mulier and Thompson for the reasons set forth above for Claim 2. *Id.*

Claim 10 also recites "at least one energy emitting element disposed on the element array," and that "pressing the element array against body tissue also presses the at least one energy emitting element against body tissue." Ex. 1001 at 8:64-67. Under the BRI, "energy emitting element" means the portion of the element array that is used to create a lesion when it is energized (*e.g.,* by radio frequency, microwave, ultrasound, light, or cryogenic energy) and placed in contact with the tissue. As discussed for Claim 1 in Section V(B) above, Mulier discloses energy emitting elements in the form of electrode strips (47 and 49) and openings (166). Ex. 1006, Fig. 3; 4:55-61; 5:25-37; 4:54-63; 7:13-28; Ex. 1011, Skarda Decl. ¶ 112. Mulier further discloses that the purpose of openings 166 is to infuse solution onto the desired tissue, which results in formation of a lesion. Ex. 1006 at 5:38-40; 6:11-14; 1:37-52; Ex. 1011, Skarda Decl. ¶ 112. Mulier also discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." Ex. 1006 at 1:49-52; 6:4-9; Ex. 1011, Skarda Decl. ¶ 112.

Dependent Claim 12 further recites the tool of Claim 10 "wherein the element array is malleable, whereby the element array is adapted to be bent into a complex

shape to allow for producing lesions of complex shape when the element array is pressed against body tissue." Ex. 1001 at 9:9-12. As discussed in Section V(B) above, Mulier discloses an ablation tool wherein the element array is malleable, which enables "adaption to unique tissue geometries" such that that element array may "be manipulated to substantially any needed contour." *See* Ex. 1006 at 2:42-45; Fig. 12 & 8:3-6; 7:45-49; Ex. 1011, Skarda Decl. ¶ 113. Mulier also teaches that the compression of the tool against body tissue results in the formation of a lesion on the ablated tissue. Ex. 1006 at 6:11-14; 1:37-52; Ex. 1011, Skarda Decl. ¶ 113. Mulier also discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." Ex. 1006 at 1:49-52; 6:4-9; Ex. 1011, Skarda Decl. ¶ 113.

10. The tool according to claim 1 wherein the element array has the shape of an elongated cylindrical rod which is attached to the elongate member distal end so that it extends in a substantially perpendicular direction relative to the elongate member and having a diameter defining a surface, and	**Mulier** discloses an element array comprised of malleable, elongated tubing, which has a diameter defining a surface. *See* Ex. 1006*,* Fig. 12, 7:64-8:8. **Thompson** discloses an element array, 192', resembling an elongated cylindrical rod having a diameter defining a surface and wherein the element array is perpendicular to the elongate member. Ex. 1005 at 22:61-65 & Fig. 24; *cf.,* 22:45-51 & Figs. 20, 21.
the at least one energy emitting element disposed on the element array, thereby pressing the element array against body tissue also presses the at least one energy emitting element against body tissue.	**Mulier** discloses an element array comprised of at least one energy emitting element, *i.e.,* electrode strips (47 and 49) and corresponding "solution infusion openings (166)" through which electrolytic solution passes. *Id.* at 4:54-63; 5:25-37; 7:13-28. As also discussed above, the compression of tissue against the electrode strips and energized solution results in the

	formation of lesions in the desired tissue. *Id.* at 1:37-52; 1:64-2:7; 4:54-63; 5:25-67; 7:13-41. **Mulier** discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." *Id.* at 1:49-52; 6:4-9.
12. The tool according to claim 10 wherein the element array is malleable, whereby the element array is adapted to be bent into a complex shape to allow for producing lesions of complex shape when the element array is pressed against body tissue.	**Mulier** discloses that "[f]or adaption to unique tissue geometries, the operative portions of the device may be malleable, to be manipulated to substantially any needed contour." *Id.* at 2:42-45, Fig. 12 & 8:3-6; 7:45-49. **Mulier** also teaches that the compression of the tool against body tissue results in the formation of a lesion on the ablated tissue. *Id.* at 6:11-14; 1:37-52. **Mulier** further discloses that "pressure [of the instrument] on the tissue is applied, and most preferably the effect of pressure is optimized, as by applying pressure across the tissue to be effected that is substantially uniform." *Id.* at 1:49-52; 6:4-9.

The combination of Mulier in view of Thompson further renders Claims 9 and 13 obvious. Mulier discloses all of the limitations of Claims 9 and 13 except a malleable elongate member, while Thompson discloses the malleable elongate member.

Claim 9 recites the tool of Claim 1 wherein the elongate member is malleable, and Claim 13 recites the tool of Claim 12 (discussed above), and further requires that both the element array and elongate member be malleable. Claims 9 and 13 also both require that the malleable elongate member "is adapted to be bent to allow easier positioning of the element array against body tissue." Ex. 1001 at 8:56-58, 9:9-12. As discussed above, Mulier and Thompson both disclose ablation tools of a similar

design for cardiac ablation, including tools having a malleable element array to achieve lesions of a desired shape and size. *See* Ex. 1006 at 2:42-45; Fig. 12 & 8:3-6; 7:45-49; Ex. 1005 at 4:11-18; 5:22-39; 10:19-21; Ex. 1011, Skarda Decl. ¶ 115. Thompson further discloses a nontransluminal ablation tool in which the elongate member is also malleable. Ex. 1005 at 10:54-57; 10:19-21; Claim 1; *see also supra* Section V(A) (discussing anticipation of Claim 1 of the '699 patent by Thompson); Ex. 1011, Skarda Decl. ¶ 115. Thompson also discloses that the malleable elongate member provides a tool that "a physician can bend into a desired configuration and remain in that configuration when released." *See* Ex. 1005 at 5:14-22; 10:19-21; Claim 1; Ex. 1011, Skarda Decl. ¶ 115.

It would have been an obvious design modification to make the elongate member disclosed in Mulier malleable as disclosed in Thompson, particularly given Mulier's express teachings that the disclosed devices (1) should be malleable "for adaptation to unique tissue geometries" and "to be manipulated to substantially any needed contour," Ex. 1006 at 2:41-44; 8:17-24, (2) need to be able to "adapt the invention to specialized surgical situations of tissue manipulation," *id.* at 7:45-49, and (3) may be adapted to include "additional structures and features," *id.* at 2:44-46; *see also id.* at 8:17-24; Ex. 1011, Skarda Decl. ¶ 116. *PerfectWeb*, 587 F.3d at 1329; *see also KSR,* 550 U.S. 398 at 420-21. A POSITA would have also been motivated to combine Mulier and Thompson for the non-temperature-related reasons set forth above for Claim 2. Ex. 1011, Skarda Decl. ¶ 116.

9. The tool according to claim 1 wherein the elongate member is made from a malleable material, and wherein the elongate member is adapted to be bent to allow easier positioning of the element array against body tissue.	**Mulier** teaches that the disclosed devices should be malleable "for adaptation to unique tissue geometries" and "to be manipulated to substantially any needed contour." Ex. 1006, 2:41-44; *see also id.* at 8:17-24. **Mulier** also teaches the need to "adapt the invention to specialized surgical situations of tissue manipulation," *id.* at 7:45-49, and may be adapted to include "additional structures and features," *id.* at 2:44-46; 8:17-24. **Thompson** discloses that the elongate member may be comprised of a "malleable shaft," *i.e.,* "a shaft that can be readily bent by the physician to a desired shape, without springing back when released, so that it will remain in that shape during the surgical procedure" and such that "a physician can bend into a desired configuration and remain in that configuration when released." *See* Ex. 1005 at 10:54-57; 5:14-22, Claim 1.
13. The tool according to claim 12 wherein the elongate member is malleable, whereby the elongate member is adapted to be bent to allow easier positioning of the element array against body tissue.	*See* Claim 9 above.

D. Ground 4: Claims 1, 9-10 and 17-18 Are Anticipated Under 35 U.S.C. § 102(b) by Cox

Like the '699 patent, Cox discusses some of the limitations known in the art associated with prior art methods of treating atrial fibrillation. Ex. 1007, 3:16 to 4:7; Ex. 1011, Skarda Decl. ¶61. To address these known problems, Cox discloses the same solution provided in the '699 patent, namely surgical devices and methods for strategically ablating tissue, including heart tissue, using "an ablating probe having an elongated shaft positionable through the chest wall." Ex. 1007, Title; Abstract; *see also*

id., at 5:3-7; Ex. 1011, Skarda Decl. ¶ 61. For the reasons discussed below, Claims 1, 9-10 and 17-18 are anticipated by Cox.[9]

Independent Claim 1 recites "[a]n ablation tool for forming lesions in body tissue of a subject at a desired ablation site." Ex. 1001 at 7:66-67. Cox discloses, "The invention provides surgical systems and methods for ablating heart tissue within the interior and/or exterior of the heart." Ex. 1007, Title; Abstract; *see also id.* at 5:3-7; Ex. 1011, Skarda Decl. ¶ 118.

Independent Claim 1 recites "an elongate member having a distal and proximal end." Ex. 1001 at 8:1. Referring to annotated Figure 28 below, Cox discloses an ablation device having an "elongate member" formed by the coupling of elongated shafts 66 and 206 via one or more coupling devices 208. *See* Ex. 1007, Abstract; 13:2-5; 41:5-10; 41:31-42:12; Ex. 1011, Skarda Decl. ¶ 119. As shown in annotated Figure 28 below, this shaft has a distal and proximal end. *Id.* at ¶ 120.

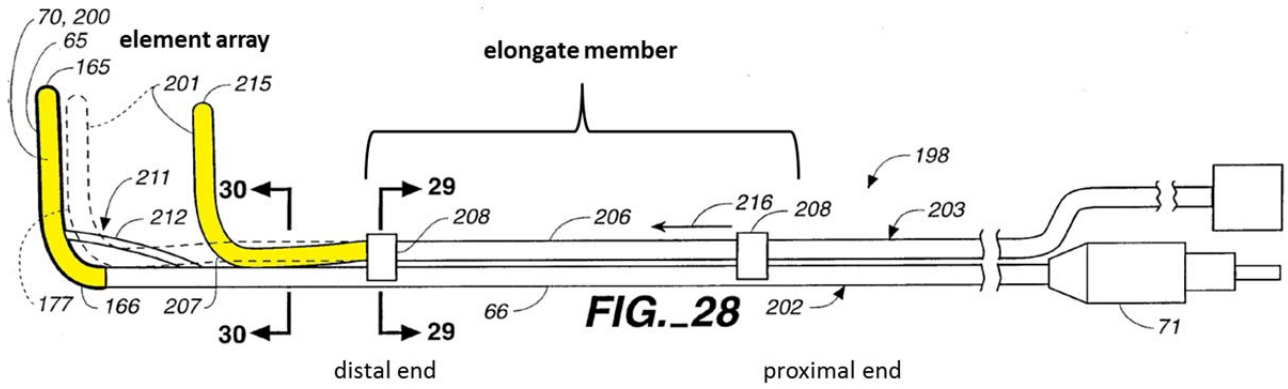


FIG._28

[9] The claim chart at the end of this Section details how each limitation recited in independent Claim 1 and dependent Claims 9-10, and 17-18 is disclosed by Cox.

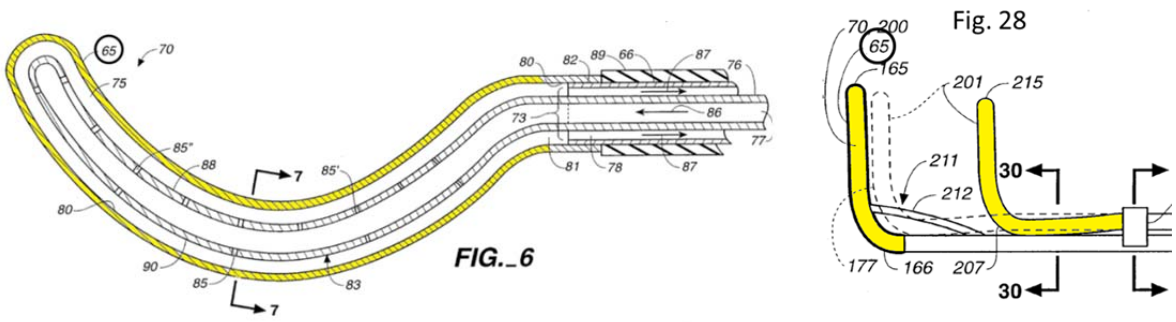
Ex. 1007, Fig. 28 (annotated).

Independent Claim 1 recites "an element array disposed on the elongate member distal end, wherein said element array has two free ends." Ex. 1001 at 8:2-3. Under the BRI, an "element array" is the operative portion of the claimed device, which is comprised of one or more energy emitting elements. Cox discloses an element array located at the distal end of the elongate member, comprised of an outer and inner jaw, 200 and 201, depicted in yellow highlighting in annotated Figure 28 above. Ex. 1007, Fig. 28; Ex. 1011, Skarda Decl. ¶ 121. More specifically, Cox teaches that the "inner jaw portion 201 formed and dimensioned to cooperate with the outer jaw portion 200" and that the jaws work together for "cooperative clamping" of the targeted tissue. Ex. 1007 at 41:15-30; 42:27-30; *see also id.* at 45:17-21; Figs. 17 & 28; Ex. 1011, Skarda Decl. ¶ 121. Referring again to annotated Figure 28, Cox teaches that the jaws of the element array have an ablative surface 65, *i.e.,* an energy emitting element (discussed in the next paragraph) and two free ends, 165 and 215. Ex. 1007, at 13:18-20 ("Proximate [to] the distal end of each probe is an elongated ablating end 70 [of 200] having an ablating surface 65 formed to transmurally ablate heart tissue."); *see also id.* at 45:8-27 (disclosing embodiment of Figure 28 wherein both the inner and outer jaw of the ablation tool in Figure 28 have an ablating surface 65 for ablation of both sides of the clamped tissue); 43:14-18 (describing Figure 28 with element array having two free "jaw portion distal ends 165, 215"); Ex. 1011, Skarda Decl. ¶¶ 122-123. The inner and outer jaws function as a

clamp, working together to perform the disclosed cardiac ablation methods and thereby forming the element array. *Id.* at ¶ 121. Thus, the element array in Figure 28 has two free ends, *i.e.,* the two distal points of the jaws, 165 and 215. *Id.* at ¶ 123.

Independent Claim 1 and dependent Claim 10 recite "at least one energy emitting element disposed on the element array." Ex. 1001 at 8:4-5. Under the BRI, "energy emitting element" means the portion of the element array that is used to create a lesion when it is energized (*e.g.,* by radio frequency, microwave, ultrasound, light, or cryogenic energy) and placed in contact with the tissue. As noted above, the element array in Cox is a clamp comprised of jaws 200 and 201. As further shown in annotated Figures 6 and 28 below,[10] the jaws of the element array have an ablating surface 65, which is "formed to contact the heart tissue for localized, transmural ablation." Ex. 1007 at 16:25-29; *see also id.*, at 13:18-20; 16:19-25; Ex. 1011, Skarda Decl. ¶ 124. Cox further discloses that when the device is a cryosurgical probe, the ablating surface, 65 (highlighted in yellow in annotated Figure 6 below), is energized by pressurized cryogen. Ex. 1007 at 6:6-15; *see also id.* at 17:16-21; Ex. 1011, Skarda Decl. ¶ 124.

[10] Figure 6 provides a typical, cross-sectional view of the jaws of the element array in the disclosed devices, including the device in Figure 28. Ex. 1007 at 16: 25-29.



Ex. 1007, Figs. 6 & 28 (annotated).

Independent Claim 1 recites "a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one energy emitting element." Ex. 1001 at 8:6-8. Like the '699 patent, Cox teaches the use of different types of energy to ablate tissue, including, but not limited to cryogenic freezing and Radio Frequency (RF) ablation. Ex. 1007 at 5:13-20; 13:31-37; Ex. 1011, Skarda Decl. ¶ 125. In the representative cryogenic ablation device disclosed in Figure 6, Cox discloses that a source of energy is coupled to the energy emitting element, ablating surface 65, using a delivery hose. Ex. 1007, at 14:6-21; 14:29-15:4; 20:38-21:10; 32:8-13 & 26-34; Ex. 1011, Skarda Decl. ¶ 125.

Independent Claim 1 further recites the energization of the energy emitting element "to form a lesion in body tissue that is pressed against the at least one energy emitting element." Ex. 1001 at 8:9-10. Dependent Claim 10 similarly recites "pressing the element array against body tissue also presses the at least one energy emitting element against body tissue." *Id.* at 8:65-67. As noted above, Cox teaches that "[d]irect conductive contact of the cooled, elongated ablating surface 65 with the

selected heart tissue causes cryogenic ablation thereof." Ex. 1007 at 21:8-13; Ex. 1011, Skarda Decl. ¶ 126. As a consequence of this conductive contact, Cox teaches that a lesion is formed. Ex. 1007*; see also id.* at 5:33-38; 16:25-29; 44:26-45:3; Ex. 1011, Skarda Decl. ¶ 126.

Independent Claim 1 further recites "wherein the elongate member and element array are sized and configured for nontransluminal placement of the at least one energy emitting element at a target site." Ex. 1001 at 8:10-13. Under the BRI, the term "nontransluminal placement" means capable of placement or use outside of a lumen, *e.g.,* a blood vessel. Cox discloses that the surgical system employing the ablation probe is preferably performed through closed-chest surgery, but may also be performed though open-chest surgery, and is therefore sized and configured for nontransluminal placement. *See* Ex. 1007 at 21:26-29; Ex. 1011, Skarda Decl. ¶ 127.

Independent Claim 1 recites "wherein at least one of the elongate member and element array are malleable such that they can take on a desired shape prior to positioning in the subject and substantially retain that shape as said element array is positioned in the subject at the desired ablation site, the desired shape selected so as to impart a desired lesion pattern on the body tissue at the ablation site." Ex. 1001 at 8:14-20. Dependent Claim 9 similarly recites the tool of Claim 1 "wherein the elongate member is made from a malleable material" and is "adapted to be bent to allow easier positioning of the element array against the body tissue." *Id.* at 8:55-57. Under the BRI, "malleable" means capable of being formed or shaped and then

retaining that form or shape. Cox discloses that in order to accommodate differences between patients, it is "highly advantageous and desirable" that the exhaust shaft (*i.e.,* elongate member) is "malleable," which "permits reshaping and bending of the [exhaust shaft] to reposition the ablating surface for greater ablation precision." Ex. 1007 at 15:9-34; *see also id.* at 11:29; Ex. 1011, Skarda Decl. ¶ 128.

Dependent Claim 10 recites "[t]he tool according to claim 1 wherein the element array has the shape of an elongated cylindrical rod which is attached to the elongate member distal end so that it extends in a substantially perpendicular direction relative to the elongate member and having a diameter [*sic*] defining a surface." Ex. 1001 at 8:59-63. As shown in Figure 28, Cox discloses an element array having the shape of two elongated cylindrical rods, both of which have a diameter defining a surface. Ex. 1007 at 16:34-35 ("The ablating end 70 is preferably provided by a closed-end, elongated tube."); *see also id.,* at 19: 28-30, Figs. 6 & 7;[11] Ex. 1011, Skarda Decl. ¶ 129. As further demonstrated in Figure 28, the jaws of the clamp that form the element array are attached to the elongate member distal end and are substantially perpendicular relative to the elongate member. *Id.*

[11] As discussed above, Figure 6 provides "a typical, cross-sectional view of an ablating end 70 of one of the probe devices of the present invention," *i.e.*, one of the jaws of the element array in Fig. 28. Ex. 1007 at 16:25-29. Figure 7, in turn, is the transverse cross-sectional view of Figure 6. Ex. 1011, Skarda Decl. ¶ 129.

Dependent Claim 17 recites the tool of Claim 1 "wherein the element array transversely extends off a distal end portion of the elongate member." Ex. 1001 at 9:22-24. Cox discloses a tool wherein the element array is comprised of two elongated cylindrical rods, each of which is L-shaped or perpendicular to the elongate member such that it transversely extends off a distal portion of the elongate member. *See* Ex. 1007*,* Fig. 28; Ex. 1011, Skarda Decl. ¶ 130.

Dependent Claim 18 recites the tool of Claim 1 "further comprising a plurality of orifices located adjacent active elements on the element array adapted for dispensing fluid therefrom." Ex. 1001 at 9:25-27. Ex. 1001 at 9:25-27. In Figure 6, Cox discloses that the active element of the element array, *i.e.,* ablative surface 65, is adjacent to "a plurality of relatively small diameter apertures 85 which extend through the delivery portion 83 into the delivery passageway 77 to communicate the pressurized cryogen between the delivery passageway and the boiler chamber 75." Ex. 1007, at 17:16-21; Ex. 1011, Skarda Decl. ¶ 131.

U.S. Patent No. 6,290,699	Anticipation by Cox
1. An ablation tool for forming lesions in body tissue of a subject at a desired ablation site comprising:	**Cox** discloses "surgical systems and methods for ablating heart tissue within the interior and/or exterior of the heart." *See* Ex. 1007, Title; Abstract; *see also id.* at 5:3-7.
[a] an elongate member having a distal and proximal end;	**Cox** discloses an ablation device having an elongated shaft with a distal and proximal end. *See*, *e.g.*, *id.*, Abstract; *see also id.*, Fig. 28 (depicting elongate member, which is formed by the coupling of elongated shafts 66 and 206 via coupling device 208); 13:2-5; 41:5-10; 41:31-42:12.
[b] an element array disposed on the elongate member distal end, wherein said element	**Cox** discloses an element array located at the distal end of the elongated shaft, comprised of an outer and inner jaw (200 and 201, respectively). *Id.*, Fig. 28. **Cox**

U.S. Patent No. 6,290,699	Anticipation by Cox
array has two free ends;	discloses that "inner jaw portion 201 formed and dimensioned to cooperate with the outer jaw portion 200" and that the jaws work together for "cooperative clamping" of the targeted tissue. *Id.* at 41:15-30; 42:27-30; *see also id.* at 45:17-21; Figs. 17 & 28. **Cox** discloses that the jaws have an ablating surface (65). *Id.* at 13:18-20; 45:8-27. **Cox** discloses that the element array has two free ends. *See*, *e.g.*, *id.*, Fig. 28 & 43:14-18 (depicting a clamping probe with element array having two free "jaw portion distal ends 165, 215").
[c] at least one energy emitting element disposed on the element array; and	**Cox** discloses jaws 200 and 201 have an ablating surface 65, which is "formed to contact the heart tissue for localized, transmural ablation." *See*, *e.g.*, *id.*, Fig. 28; 16:25-29; *see also id.* at 13:18-20; 16:19-25. **Cox** discloses a cryogenic ablation device wherein the ablating surface, 65, is energized by pressurized cryogen. *Id.* at 6:6-15; 17:16-21; *see also id.,* Fig. 6; 6:25-29.
[d] a source of energy coupled to the at least one energy emitting element, said source of energy capable of energizing the at least one energy emitting element to form a lesion in body tissue that is pressed against the at least one energy emitting element,	**Cox** teaches the use of different types of energy to ablate tissue, including cryogenic freezing and RF ablation. *Id.* at 5:13-20; 13:31-37. **Cox** discloses that a source of energy is coupled to the ablating surface of the probe using a delivery hose. *See id.* at 14:6-21; 14:29-15:4; 20:38-21:10; 32:8-13 & 26-34. **Cox** teaches that "such contact with the ablating surface for a sufficient period of time causes transmural ablation of the [heart] wall." *See id.* at 5:33-35; *see also id.* at 21:8-10 ("Direct conductive contact of the cooled, elongated ablating surface 65 with the selected heart tissue causes cryogenic ablation thereof."); 44:26-45:3.
[e] wherein the elongate member and element array are sized and configured for nontransluminal placement of the at least one energy emitting element at a target site, and	**Cox** discloses that the surgical system employing the ablation probe is preferably performed through closed-chest surgery, but may also be performed though open-chest surgery. *See id.* at 21:26-29.
[f] wherein at least one of the elongate member and element array are malleable such that they can take on a desired shape prior to positioning in the subject and substantially	**Cox** discloses that the elongate member is malleable: "Accordingly, it is highly advantageous and desirable to provide an exhaust shaft 66 and delivery tube 76 combination which is malleable. This material property permits reshaping and bending of the exhaust shaft and delivery tube as a unit to reposition the ablating

U.S. Patent No. 6,290,699	Anticipation by Cox
retain that shape as said element array is positioned in the subject at the desired ablation site, the desired shape selected so as to impart a desired lesion pattern on the body tissue at the ablation site.	surface for greater ablation precision." *Id.* at 15:9-34; *see also id.* at 11:29.
9. The tool according to claim 1 wherein the elongate member is made from a malleable material, and wherein the elongate member is adapted to be bent to allow easier positioning of the element array against body tissue.	As noted above with respect to Claim 1[f], **Cox** discloses a malleable elongate member, which "permits reshaping and bending of the exhaust shaft and delivery tube as a unit to reposition the ablating surface for greater ablation precision." *Id.* at 15:9-34; *see also id.* at 11:29.
10. The tool according to claim 1 wherein the element array has the shape of an elongated cylindrical rod which is attached to the elongate member distal end so that it extends in a substantially perpendicular direction relative to the elongate member and having a diameter defining a surface, and	**Cox** discloses an element array having the shape of two elongated cylindrical rods that are attached to the elongate member distal end. *See*, *e.g.*, *id.*, Fig. 28; 16:34-35. The outer and inner jaws (200 and 201) attached to the elongate member distal end in Fig. 28 are cylindrical rods and have a diameter defining a surface. *Id.*, Figs. 6 & 7; *see also id.* at 19:28-30 ("In the preferred form, as shown in FIGURE 7, the transverse, cross-sectional dimension of the ablating end 70 is circular shaped having a substantially uniform thickness."); 16:34-35. The outer and inner jaws (200 and 201) are substantially perpendicular relative to the elongate member. *Id.*, Fig. 28.
the at least one energy emitting element disposed on the element array, thereby pressing the element array against body tissue also presses the at least one energy emitting element against body tissue.	**Cox** teaches that "such contact with the ablating surface for a sufficient period of time causes transmural ablation of the [heart] wall." *See id.* at 5:33-35; *see also id.* at 21:8-10 ("Direct conductive contact of the cooled, elongated ablating surface 65 with the selected heart tissue causes cryogenic ablation thereof."); 44:26-45:3.
17. A tool according to claim 1, wherein the element array transversely extends off a distal end portion of the elongate member.	**Cox** discloses a tool wherein the element array is comprised of two elongated cylindrical rods, each of which is L-shaped or perpendicular to the elongate member such that it transversely extends off a distal portion of the elongate member. *See id.,* Fig. 28.
18. A tool according to claim	**Cox** discloses that the ablative surface 65 of the

U.S. Patent No. 6,290,699	Anticipation by Cox
1, further comprising a plurality of orifices located adjacent active elements on the element array adapted for dispensing fluid therefrom.	element array is adjacent to "a plurality of relatively small diameter apertures 85 which extend through the delivery portion 83 into the delivery passageway 77 to communicate the pressurized cryogen between the delivery passageway and the boiler chamber 75." *Id.*, Fig. 6 & 17:16-21.

VI. CONCLUSION

Accordingly, Petitioners respectfully requests that the PTAB grant this petition for institution of an *inter partes* review and the cancellation of Claims 1-10 and 12-13 and 17-18 of the '699 patent for each grounds presented herein.

Dated: May 19, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document(s)

1. PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,290,699, including all Exhibits, attachments, and supporting documentation, and

2. Power of Attorney,

were served on May 19, 2015 via USPS Express Mail Service delivery directed to UAB Research Foundation's counsel of record at the following address:

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