Appendix A-5
Invalidity of U.S. 9,125,739 in View of Bessler, Leonhardt and Rygg or Cox

The asserted claims of the '739 patent are anticipated or obvious over United States Patent No. 5,855,601 ("Bes Patent No. 5,957,949 ("Leonhardt"), U.S. Patent No. 4,218,782 ("Rygg") and/or U.S. Pat. No. 5,713,950 ("Cox combination with the knowledge of a person of ordinary skill in the art ("POSITA") and/or in combination with references disclosed in Medtronic's Invalidity Contentions, including other charted references.

Bessler was filed on June 21, 1996, published on January 5, 1999, so it is prior art under 35 U.S.C. § 102(a), (b)

The citations provided below are exemplary and do not necessarily include each and every disclosure of the lim Medtronic has endeavored to cite to the most relevant portions of the identified prior art, but other portions may either expressly or inherently, and/or render obvious one or more limitations of the asserted claims. Thus, Med right to rely on: (1) uncited portions of the identified prior art; (2) other prior art not identified herein; (3) refere state of the art (irrespective of whether such references themselves qualify as prior art to the asserted patents); (from the inventors or authors of the prior art references, or purveyors of prior art devices; and/or (5) expert testi context to or aid in understanding the prior art and the state of the art at the time of the alleged invention.

The lack of a citation for an element should not be deemed an admission that the element is not disclosed or is n reference. When the chart indicates a particular reference discloses or embodies a limitation, the terms "disclos "embodies," and "embodied" refer to explicit and/or inherent disclosure and/or obvious variations of the actual the extent Medtronic asserts that a claim is indefinite, Medtronic has used its best efforts to reasonably interpret their duties in charting the prior art references.

Where Medtronic cites to a particular drawing or figure in the accompanying charts, the citation encompasses th drawing or figure, as well as any text associated with the drawing or figure. Similarly, where citations are made concerning a drawing or figure, the citation encompasses that drawing or figure. Certain identified prior art inh features of the asserted claims. Medtronic reserves the right to rely on inherency to demonstrate the invalidity o Moreover, certain prior art references may inherently disclose certain features of the asserted claims as construe Medtronic may rely on cited or uncited portions of the prior art, other documents, factual testimony, and expert the inherency of certain features of the prior art to invalidate the asserted claims.

To the extent Colibri contends that the prior art reference does not disclose any particular limitation of the asser patent, either expressly or inherently, it would have been obvious to a person of ordinary skill in the art as of the invention to modify the reference and/or to combine its teachings with other prior art references, including but n art references identified in Medtronic's invalidity contentions and the relevant sections of the claim charts for th manner that renders such claims invalid as obvious.

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It would have been obvious under 35 U.S.C. § 103 to a person having ordinary skill in the art at the time of the invention to combine the teachings of Bessler with the following references:

1. Leonhardt, which was filed on May 1, 1997, published on September 28, 1999, so it is prior art und (b) and (e).
2. Rygg, which was filed on May 19, 1978, published on August 8, 1980, so it is prior art under 35 U. (e).
3. Cox, which was filed on November 1, 1993 and issued on February 3, 1998, so it is prior art under and (e).

	Claim language	Exemplary disclosure
1.pre	An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:	To the extent this preamble is limiting, Bessler and Leonhardt disclos treat a native heart valve in a patient, the assembly for use in combina the assembly comprising." For example, Bessler discloses an assembly to treat a native valve in > The present invention relates to novel artificial heart valves. M the present invention relates to novel heart valves that are esp for placement using minimally invasive surgical techniques ar and device useful for such placement. Bessler at col. 1, lines 7-11. Bessler further discloses that the artificia combination with a guidewire: > A guidewire 94 having a blunt end 95 is disposed through a pusher member 93 and is used to guide the distal end of the ca desired site. Bessler at col. 7, lines 35-38. Leonhardt discloses an assembly (an "a a native valve in a patient: > This invention relates to artificial valves, specifically percutaneously by a catheter. The artificial valve disclose

		existing valves such as are in the heart or esophagus, or may fluid flow needs to be maintained in one direction only. Leonhardt at col. 1, lines 5-9. Leonhardt further discloses that the a referred to in Leonhardt as valve stent 20, is used in combination w If valve stent 20 is to be placed at mitral valve 14, entry may the right internal jugular vein. A guide wire is advanced thro to the right atrium and interatrial septum 16. A cath combination (not shown) is advanced over the guide wire to 16 and used to puncture septum 16 and access left atrium 1 is advanced into left atrium 18 and through mitral valve 14 and needle combination is removed. Leonhardt at col. 10, lines 22-30. A POSITA would have been motivated to combine Bessler and Leo Leonhardt's mitral valve stent 20 for Bessler's valve 30 in a mitral scenario in order to realize the advantages associated with Leonhard sealing to natural tissue to prevent microleaks [Leonhardt at 3:41-4 better shape with trumpet-like configuration for keeping valve stent of a mitral valve where parts of valve stent are on opposite sides of extends into ventricle; and c) reducing chance of thrombosis by hav covered by outer material (Leonhardt at 5:62-6:8).
1.a	a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein	Leonhardt discloses "a prosthetic heart valve including: a stent mem channel, the stent member collapsible, expandable and configured f percutaneous delivery, wherein." For example, Leonhardt's artificial valve is configured for translum percutaneous delivery:

		This invention relates to artificial valves, specifical percutaneously by a catheter. The artificial valve disclo existing valves such as are in the heart or esophagus, or may fluid flow needs to be maintained in one direction only. Leonhardt at col. 1, lines 5-9. Leonhardt discloses a replacement he member that is collapsible and expandable: Stent 26 is a continuous super elastic nitenol wire having a proximal end. Both the distal end and the proximal end identical, both forming a cylinder wall 64 of six zig-zags 4 end is pre-sized in diameter to be approximately thirty perce diameter than the largest diameter of the tissue against whi 20 (FIG. 3) will seal. The overall length of stent 26 is als sufficient to maintain patency against fluid flow in the vesse position, as well as completely support the biological valve synthetic valve) without causing valve 22 to suffer prolapse Leonhardt at col. 4, line 66 – col. 5, line 10. Also refer to FIG. 4 to identify elements in the following valve 14 has been prepared for deployment by valvuloplasty and fistulas if necessary. Valve stent 20 comprises a mallea 24 enclosing deformable self-expanding stent 26 to which 22 is attached. Stent 26 biases the proximal and distal ends into conforming and sealingly fixed engagement with the tiss 14. The deployed valve stent 20 creates a patent one way flu Leonhardt at col. 5, lines 42-52. Leonhardt's stent member 26 inclu shown in the drawing below:

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		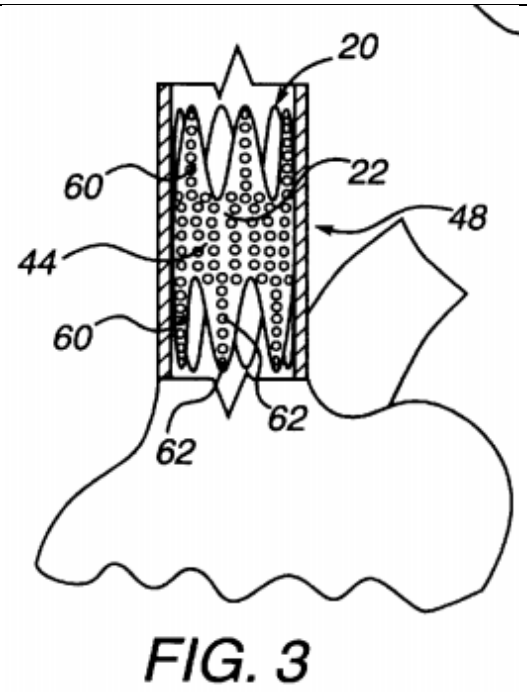 FIG. 3 Leonhardt at FIG. 3.
1.b	the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and	Leonhardt discloses "the stent member includes a tubular structure portion that flares at both ends in a trumpet-like configuration; and" For example: Where other vessels or passages leave the vessel receiving placement site, or when valve stent 20 must flair at one shown in FIG. 2, graft material 24 may be cut out betwee distensible fingers 46 formed by zig-zags 40 of stent 26. Dist form a conical tip when compressed together which facilita stent 20 in the deployment catheter (FIG. 5) prior to the retrieval after deployment is necessary. Valve stent 20 may b

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