

**Appendix A-4**  
**Invalidity of U.S. 9,125,739 in View of Bessler, Leonhardt, Klint and Rygg or Cox**

The asserted claims of the '739 patent are anticipated or obvious over United States Patent No. 5,855,601 ("Bessler"), U.S. Patent No. 5,957,949 ("Leonhardt"), U.S. Patent Publication No. 2001/0044633 ("Klint"), U.S. Patent No. 4,213,950 ("Rygg"), U.S. Pat. No. 5,713,950 ("Cox"), alone or in combination with the knowledge of a person of ordinary skill in the art and/or in combination with one or more other references disclosed in Medtronic's Invalidity Contentions, including the references cited below.

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), and (c).

The citations provided below are exemplary and do not necessarily include each and every disclosure of the limitations of the asserted claims. Medtronic has endeavored to cite to the most relevant portions of the identified prior art, but other portions may be disclosed either expressly or inherently, and/or render obvious one or more limitations of the asserted claims. Thus, Medtronic reserves the right to rely on: (1) uncited portions of the identified prior art; (2) other prior art not identified herein; (3) references not cited in the state of the art (irrespective of whether such references themselves qualify as prior art to the asserted patents); (4) disclosures from the inventors or authors of the prior art references, or purveyors of prior art devices; and/or (5) expert testimony in the 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 not disclosed by the reference. When the chart indicates a particular reference discloses or embodies a limitation, the terms "discloses" and "embodies," and "disclosed" and "embodied" refer to explicit and/or inherent disclosure and/or obvious variations of the actual limitation. To the extent Medtronic asserts that a claim is indefinite, Medtronic has used its best efforts to reasonably interpret the claim and perform their duties in charting the prior art references.

Where Medtronic cites to a particular drawing or figure in the accompanying charts, the citation encompasses the drawing or figure, as well as any text associated with the drawing or figure. Similarly, where citations are made to text concerning a drawing or figure, the citation encompasses that drawing or figure. Certain identified prior art inherently disclose features of the asserted claims. Medtronic reserves the right to rely on inherency to demonstrate the invalidity of the asserted claims. Moreover, certain prior art references may inherently disclose certain features of the asserted claims as construed. Medtronic may rely on cited or uncited portions of the prior art, other documents, factual testimony, and expert testimony to demonstrate 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 asserted claims, either expressly or inherently, it would have been obvious to a person of ordinary skill in the art as of the time of the invention to modify the reference and/or to combine its teachings with other prior art references, including but not limited to the prior art references identified in Medtronic's invalidity contentions and the relevant sections of the claim charts for the asserted claims in a 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 under 35 U.S.C. (b) and (e).
2. Klint, which was filed on January 26, 2001, published on November 22, 2001, so it is prior art under 35 U.S.C. (b) and (e).
3. Rygg, which was filed on May 19, 1978, published on August 8, 1980, so it is prior art under 35 U.S.C. (e).
4. Cox, which was filed on November 1, 1993 and issued on February 3, 1998, so it is prior art under 35 U.S.C. (b) 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:	<p>To the extent this preamble is limiting, Bessler and Leonhardt disclose treat a native heart valve in a patient, the assembly for use in combination with the assembly comprising.”</p> <p>For example, Bessler discloses an assembly (an “artificial heart valve” assembly) for use in combination with a native heart valve in a patient:</p> <p style="padding-left: 40px;">The present invention relates to novel artificial heart valves. More specifically, the present invention relates to novel heart valves that are especially adapted for placement using minimally invasive surgical techniques and are especially useful and device useful for such placement.</p> <p>Bessler at col. 1, lines 7-11. Bessler further discloses that the artificial heart valve assembly in combination with a guidewire:</p> <p style="padding-left: 40px;">A guidewire 94 having a blunt end 95 is disposed through a lumen of a catheter 93 and is used to guide the distal end of the catheter to a desired site.</p>

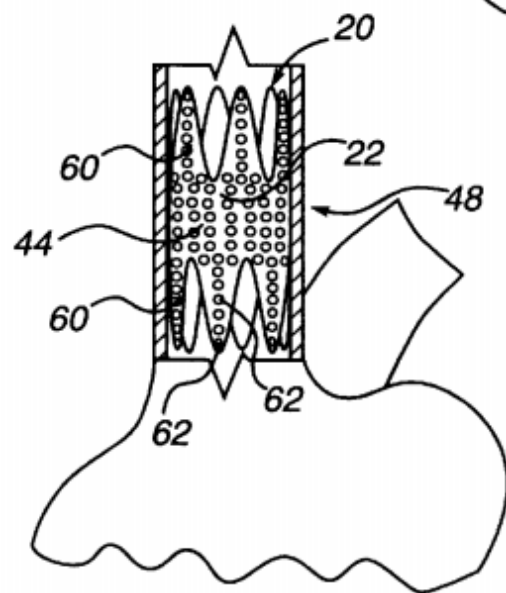
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		<p>Bessler at col. 7, lines 35-38. Leonhardt discloses an assembly to treat a patient:</p> <p style="padding-left: 40px;">This invention relates to artificial valves, specifically valves that are implanted percutaneously by a catheter. The artificial valve discloses a valve that can be used on existing valves such as are in the heart or esophagus, or may be used where fluid flow needs to be maintained in one direction only.</p> <p>Leonhardt at col. 1, lines 5-9. Leonhardt further discloses that the assembly is in combination with a guidewire:</p> <p style="padding-left: 40px;">If valve stent 20 is to be placed at mitral valve 14, entry may be made into the right internal jugular vein. A guide wire is advanced through the right internal jugular vein to the right atrium and interatrial septum 16. A catheter and needle combination (not shown) is advanced over the guide wire to the right atrium 16 and used to puncture septum 16 and access left atrium 18. The catheter is advanced into left atrium 18 and through mitral valve 14. The catheter and needle combination is removed.</p> <p>Leonhardt at col. 10, lines 22-30.</p> <p>A POSITA would have been motivated to combine Bessler and Leonhardt's mitral valve stent 20 for Bessler's valve 30 in a mitral valve replacement scenario in order to realize the advantages associated with Leonhardt's valve, including a) sealing to natural tissue to prevent microleaks [Leonhardt at 3:41-4:4]; b) a better shape with trumpet-like configuration for keeping valve stent in place on a mitral valve where parts of valve stent are on opposite sides of the valve and extends into ventricle; and c) reducing chance of thrombosis by having the valve covered by outer material (Leonhardt at 5:62-6:8).</p>
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1.a	<p>a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein</p>	<p>Leonhardt discloses “a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery, wherein.”</p> <p>For example, Leonhardt’s artificial valve is configured for transluminal percutaneous delivery:</p> <p style="padding-left: 40px;">This invention relates to artificial valves, specifically those configured for percutaneous delivery by a catheter. The artificial valve disclosed is different from existing valves such as are in the heart or esophagus, or may be used in situations where fluid flow needs to be maintained in one direction only.</p> <p>Leonhardt at col. 1, lines 5-9.</p> <p style="padding-left: 40px;">Stent 26 is a continuous super elastic nitinol wire having a proximal end. Both the distal end and the proximal end are formed into a cylindrical shape, both forming a cylinder wall 64 of six zig-zags 4. The distal end is pre-sized in diameter to be approximately thirty percent smaller than the largest diameter of the tissue against which stent 20 (FIG. 3) will seal. The overall length of stent 26 is also sufficient to maintain patency against fluid flow in the vessel in its deployed position, as well as completely support the biological valve (or synthetic valve) without causing valve 22 to suffer prolapse.</p> <p>Leonhardt at col. 4, line 66 – col. 5, line 10. Leonhardt’s stent member having an inner channel as shown in the drawing below:</p>
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**FIG. 3**

Leonhardt at FIG. 3.

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 malleable stent 24 enclosing deformable self-expanding stent 26 to which valve 14 is attached. Stent 26 biases the proximal and distal ends of valve 14 into conforming and sealingly fixed engagement with the tissue of vessel 14. The deployed valve stent 20 creates a patent one way flu

Leonhardt at col. 5, lines 42-52.

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