**Appendix A-10**
**Invalidity of U.S. 9,125,739 in View of Paniagua**

The asserted claims of the '739 patent are anticipated or obvious over United States Patent Publication No. 200
("Paniagua"), alone or in combination with the knowledge of a person of ordinary skill in the art ("POSITA") a
with one or more other references disclosed in Medtronic's Invalidity Contentions, including other charted refer

Paniagua was filed on July 10, 2004, published on May 26, 2005, and is prior art under 35 U.S.C. § 102(a), (b)
'739 patent is not entitled to any priority date earlier than April 15, 2014.

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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| | 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, Paniagua discloses "[a]n assembly valve in a patient, the assembly for use in combination with a guidewire, comprising."<br><br>For example,<br><br>The present invention comprises a percutaneously implantable valve device and a method of making same. The replacement h comprises a stent member made of stainless steel or self-exp biological tissue artificial valve means disposed within the inner member. An implantation and delivery system having a central p of a flexible hollow tube catheter that allows a metallic wire gui inside it. The endovascular stented-valve is created from a glu biocompatible tissue material which has two or three cusps tha permit unidirectional blood flow. The present invention also c method of making a replacement heart valve by taking a fragment tissue material and treating, drying, folding and rehydrating it i forms a two- or three-leaflet/cusp valve with the leaflets/cusps f thereby eliminating the extent of suturing required, providing im and function.<br><br>Paniagua at Abstract. |
| 1.a | a prosthetic heart valve including: a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal | Paniagua discloses "a prosthetic heart valve including: a stent member ha the stent member collapsible, expandable and configured for transluminal wherein."<br><br>For example, Paniagua's artificial valve includes a stent member (100) ha |

| | | |
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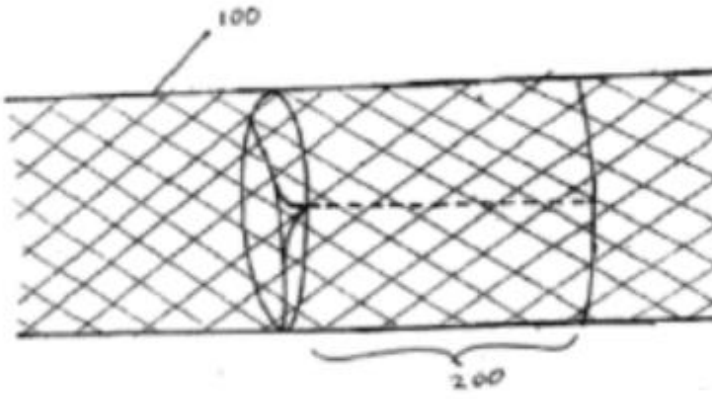
| | percutaneous delivery, wherein | The valve means 200 is then attached to the inner channel of the s by suturing the outer surface of the valve means' pericardium mat member.<br><br>Paniagua at paragraph [0049]. Paniagua further discloses that the stent mer expandable and configured for transluminal percutaneous delivery:<br><br>The present invention comprises a percutaneously implantable re valve and a method for making same. The artificial heart valve devi invention is capable of exhibiting a variable diameter between collapsed position and an expanded position. A preferred emb replacement heart valve device according to the present invention is 5. The replacement heart valve device comprises a stent member 1 valve means 200. The stent member 100 is preferably self-expa balloon-expandable stents can be used as well, and has a first polyg compressed or collapsed configuration and a second, larger polyg expanded configuration.<br><br>Paniagua at paragraph [0037]. The drawings below show the expanded and configurations of the stent:<br><br>  |

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| | | |
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| | | Paniagua at FIG. 5 (showing stent in the expanded configuration).<br>  <br>Paniagua at FIG. 6 (showing stent in the collapsed configuration). |
| 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 | Paniagua discloses "the stent member includes a tubular structure away fro flares at both ends in a trumpet-like configuration; and"<br><br>For example:<br><br>The stent used in a preferred embodiment of the present invention i a "shaped memory" alloy, nitinol, which is composed of nickel and wire is first fashioned into the desired shape for the device and then annealed. A meshwork of nitinol wire of approximately 0.008 inch into a tubular structure with a minimum central diameter of 20 min t Away from its central portion, the tubular structure flares markedly trumpet-like configuration. The maximum diameter of the flared en approximately 50 mm. The purpose of the stent is to maintain a s channel through the diseased cardiac valve following its implantati<br><br>Paniagua at paragraph [0041]. |
| 1.c | a valve means including two to four individual leaflets made of fixed pericardial tissue, | Paniagua discloses "a valve means including two to four individual leaflets pericardial tissue, wherein the valve means resides entirely within the inne member, and wherein no reinforcing members reside within the inner chan member" |

| | | |
|---|---|---|
| | wherein the valve means resides entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member | For example, Paniagua's artificial valve includes two to four individual lea pericardial tissue:<br><br>The present invention also comprises a method of making a replace device. In order to make the valve, the biocompatible tissue materi all the fat tissue and extra fibers are removed. Cleaning is preferab by using a hydromechanical force-based cleaning device to separate hydration with distilled water to remove unwanted layers. Once th completely clean, it is subjected to photo-mechanical compression, formed and placed in sequential solutions of isopropyl alcohol of ethanol of about 70-100% glycerol and gluteraldehyde preferably a of about 0.07-25% for about 36 hours, respectively. The mater photomechanically compressed to remove lipids and produce prote make the surface smoother and more compact and biocompatible molecular distance of collagen fibers. The exposure to light compression cause protein denaturation making the material str homogeneous and biocompatible. Gas sterilization can also be use tissue membrane material. The valve is formed by taking a flat she and folding it in such a way that forms a three-leaflet or desired r valve as shown in FIGS. 3A and 3B and/or FIGS. 9A, 9B and 9C. T pericardium material to create the cusps or leaflets reduces the e otherwise required, and resembles the natural form and function of t It also greatly reduces the risk of tearing of the cusps or leaflet integral to the valve rather than being attached by suturing.<br><br>Paniagua at paragraph [0046]. Paniagua further discloses that the valve me entirely within the inner channel of the stent member (100), and wherein n reside within the inner channel of the stent member:<br><br>The valve means 200 is then attached to the inner channel of the s by suturing the outer surface of the valve means' pericardium mat member. FIG. 7 depicts preferred suture points of one embodime invention: 3-point fixation or 6-point fixation at each border of |

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