IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ACADEMISCH ZIEKENHUIS LEIDEN d/b/a LEIDEN UNIVERSITY MEDICAL CENTRE, a Dutch public entity, Plaintiff, v. CARDIOMEMS, INC., a Delaware corporation, Defendant.	C.A. No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Academisch Ziekenhuis Leiden, acting under the name Leids Universitair Medisch Centrum, a Dutch public entity (hereinafter "LEIDEN UNIVERSITY MEDICAL CENTRE" or "LUMC"), through its counsel, brings this complaint and demand for jury trial against Defendant CardioMEMS, Inc. (hereinafter "CardioMEMS") and alleges as follows:

THE PARTIES

1. Plaintiff LUMC is a legal entity organized and existing under the laws of the Netherlands as Academisch Ziekenhuis Leiden, acting under the name Leiden University Medical Centre, and having its offices at Albinusdreef 2, (2333 ZA) Leiden, the Netherlands.

2. On information and belief, defendant CardioMEMS, Inc., is a corporation organized and existing under the laws of the state of Delaware and having a principal place of business at 387 Technology Circle NW, Suite 500, Atlanta, Georgia, 30313.

JURISDICTION AND VENUE

LUMC incorporates the previous paragraphs herein.

3. This is a civil action for patent infringement under the patent laws of the United States and, more specifically, under Title 35 U.S.C. §§271, 281, 283, 284 and 285. Jurisdiction in this Court is founded upon 28 U.S.C. §§1338(a) and 1331.

4. The venue is proper in this district pursuant to 28 U.S.C. §§1400(b) and 1391(b) and (c).

BACKGROUND OF PATENT AT ISSUE

5. LUMC is an academic hospital actively combining patient care with research, including in field of vascular surgery.

6. On August 14, 1998, Rijksuniversiteit Leiden filed a U.S. Non-Provisional Utility Application (United States Application Serial No. 09/134,746), claiming priority to European Patent Application 97202523.3, filed August 15, 1997. The United States Application issued as United States Patent 6,159,156 ("the '156 Patent") on December 12, 2000, a copy of which is attached hereto as Exhibit A.

7. The '156 Patent has not expired and is currently in full force and effect.

8. The '156 Patent was ultimately assigned to LUMC, who owns all rights, title and interest in the '156 Patent.

9. The '156 Patent includes four claims. Claim 1 is an independent claim and recites:

> A method for using a miniaturized pressure sensor and transponder attached thereto, comprising introducing said miniaturized pressure sensor and transponder into an aneurysmal sac of a human or animal.

Claim 4 depends directly from independent claim 1 and, therefore, includes all of the elements and elements of claim 1. Claim 4 recites:

> The method of claim 1, further comprising introducing said miniaturized pressure sensor and transponder into said aneurysmal sac with a catheter.

Claim 2 is an independent claim and recites:

> A method for measuring pressure in an aneurysmal sac of an artery of a human or animal body, comprising positioning a pressure sensor and a transponder attached to the pressure sensor in said aneurysmal sac, the transponder being arranged for wirelessly transmitting pressure data from the pressure sensor to detecting means outside said human or animal body.

Claim 3 depends directly from independent claim 2 and, therefore, includes all of the elements and elements of claim 2. Claim 3 recites:

> The method according to claim 2, wherein said positioning comprises introducing the pressure sensor and transponder into said artery by means of a catheter and further comprising introducing an endoprosthesis into said artery in a position over the pressure sensor and transponder, thus enclosing the pressure sensor and transponder within said aneurysmal sac, between the wall of said artery and said endoprosthesis.

10. CardioMEMS manufactures, offers for sale, and sells a device referred to as the EndoSure® Wireless AAA Pressure Measurement System (hereafter "EndoSure® System").

11. In CardioMEMS' website (www.cardiomems.com), under the "Patient Education" page, the Endosure® System is described as follows:

The EndoSure® Wireless AAA Pressure Sensor is inserted during the minimally invasive repair of abdominal aortic aneurysms (AAA) or thoracic aortic aneurysms (TAA), via a catheter into a patient's aneurysm sac. Due to their small size, durability, and lack of wires or batteries, the EndoSure sensors are designed to be permanently implanted into the aneurysm sac. As a result, the EndoSure system is intended to last for, and transmit data over, the lifetime of the patient without requiring repeated procedures.

To date, more than 3500 patients have been implanted with the EndoSure sensor.

* * * *

The EndoSure sensor uses radiofrequency, or RF, energy to transmit real-time pressure information to an external electronics module, which then communicates this information to the patient's physician. The EndoSure sensor does not require the patient to be exposed to contrast dye or radiation like a computerized tomography scan (CT scan) and is intended to minimize patient discomfort.

http://www.cardiomems.com/content.asp?display=patient+pb&view=endo sure

12. Under the "Medical Professionals" page of CardioMEMS' website, the Endosure® system is described as follows:

The EndoSure® Wireless AAA Pressure Measurement System is cleared by the FDA for the measuring of intrasac pressure during endovascular abdominal aortic aneurysm (AAA) repair and during endovascular thoracic aortic aneurysm repair (TAA). It serves as an adjunctive tool in the detection of intraoperative leaks of the stent graft during AAA repair.

The EndoSure sensor is inserted during the minimally invasive repair via a catheter into a patient's aneurysm sac and communicates pressure information to an external electronics module from inside the sac.

****

The EndoSure Wireless Pressure Measurement System is composed of two components: a miniaturized, wireless implantable sensor and an external electronics module. The external electronics module wirelessly communicates with our sensors to deliver vital patient data. Our wireless sensors are powered by RF energy delivered by an external electronics module and transmit real-time data without batteries.

The EndoSure sensor is designed and manufactured using microelectromechanical systems, or MEMS, technology, which enables the fabrication of millimeter-scale devices with internal features in the nanometer to micrometer range. MEMS technology allows the creation of sensors with measurement stability and energy efficiency.

The EndoSure sensor is approximately the size of a paperclip. It is a hermetically sealed circuit, encapsulated in fused silica and silicone, and is surrounded by a PTFE-coated nickel-titanium wire. Inside the fused silica is a micron scale cavity. Changes to the membrane of this cavity result in changes to the sensor's resonant frequency. These changes correlate to pressure changes. The sensor contains no batteries or internal power source, but is instead powered by RF-energy provided by a proprietary electronic antenna.

The EndoSure sensor comes pre-loaded in a one-piece 14 French delivery system that enables the physician to insert the sensor during the same procedure as the stent graft. Radiopaque markers assist the physician in delivery of the sensor by clearly defining the sensor location within the aneurysm sac between the stent graft and aortic wall. The EndoSure sensor is intended to be a permanent implant in the aneurysm sac.

The external electronics module consists of three parts: the internal signal processing electronics, or main unit, the antenna used to wirelessly communicate with the sensor, and the graphical user interface that displays the patient information. During a reading, the antenna is placed near the

implant site and communicates with the sensor by way of a RF signal that is generated and processed by the main unit.

The graphical user interface allows for system operation and data entry and displays information generated from the sensor. This information includes a pressure waveform and readings, such as mean pressure, systolic pressure, diastolic pressure, heart rate and cardiac output. By comparing pressure waveforms before and after deployment of the stent graft, the EndoSure system assists the physician in confirming traditional angiographic findings of successful stent graft placement. During the endovascular repair procedure, pre-exclusion and post-exclusion pressure measurements demonstrate the difference between an aneurysm sac that is exposed to circulation and one that is excluded.

http://www.cardiomems.com/content.asp?display=medical+mb&expand=ess.

13. True and correct copies of the "Patient Education" page and "Medical Professionals" webpages from CardioMEMS' website are attached hereto as Exhibit B.

14. CardioMEMS' EndoSure® System includes a sensor configured to be placed within an aneurysmal sac of a human to measure pressure therein. Therefore, the EndoSure® System would require "introducing [a] miniaturized pressure sensor and transponder into an aneurysmal sac of a human," as recited in claim 1 and/or "positioning a pressure sensor and a transponder attached to the pressure sensor in [an] aneurysmal sac [of a human or animal]," as recited in claim 2. Additionally, CardioMEMS teaches insertion of the EndoSure sensor during the repair procedure via a catheter into a patient's aneurysm sac, thus requiring "introducing said miniaturized pressure sensor and transponder into said aneurysmal sac with a catheter," as recited in claim 4.

15. Upon information and belief, CardioMEMS' teaches introducing the pressure sensor and transponder into said artery by means of a catheter and introducing an endoprosthesis into said artery in a position over the pressure sensor and transponder, so as to enclose the pressure sensor and transponder within said aneurysmal sac, between the wall of said artery and said endoprosthesis, as recited in claim 3.

16. As early as April 2007, CardioMEMS has been aware of the '156 Patent and has, on multiple occasions, exchanged communications with LUMC regarding the '156 Patent as it relates to the Endosure® System.

FIRST CAUSE OF ACTION

17. The allegations of the previous paragraphs are incorporated herein.

18. CardioMEMS has directly infringed and continues to directly infringe, either literally or under the Doctrine of Equivalents, the '156 Patent by making, using, selling, and/or offering to sell its EndoSure® System (see Exhibit B), said infringement being of at least Claims 1 through 4 of the '156 Patent, and being unlawful per 35 U.S.C. §271(a).

19. CardioMEMS has induced and/or contributed to the infringement of the '156 Patent and is continuing to induce and/or contribute to infringement of the '156 Patent by, among other acts, intentionally encouraging, causing, urging, and/or aiding others to directly infringe the '156 Patent, including, but not limited to, by offering to sell, selling, and/or otherwise providing others with instructions, information, and assistance for practicing the claimed invention..

20. All of the aforementioned infringing acts by CardioMEMS are without the permission, license, or consent of LUMC.

21. Upon information and belief, such acts of infringement by CardioMEMS have been, and continue to be, willful and deliberate, and LUMC reasonably believes that such acts of infringement will continue in the future unless enjoined by this Court.

22. By reason of its aforementioned acts of infringement, CardioMEMS has been unjustly enriched.

23. By reason of CardioMEMS' acts of infringement, LUMC has suffered and continues to suffer irreparable harm and damages, including, but not limited to lost profits,

damage to LUMC's goodwill and reputation, and diminution of the inherent value of the '156 Patent, in an amount to be determined at trial. CardioMEMS' infringement further irreparably harms LUMC by encouraging others to infringe.

24. As a result of the continuing harm to LUMC and the diminution of the value of the '156 Patent, LUMC has no adequate remedy at law for CardioMEMS' infringement of the '156 Patent.

PRAYER FOR RELIEF

WHEREFORE, LUMC prays:

(a) For a judgment holding CardioMEMS liable for infringement of the '156 Patent;

(b) For a preliminary and permanent injunction enjoining CardioMEMS , its officers, agents, servants, employees and attorneys, successors and assigns, and all other persons acting in concert or participation with CardioMEMS from further infringement of the '156 Patent;

(c) For an award to LUMC of his damages, and that such damages be trebled in view of the willful and deliberate nature of CardioMEMS' infringements;

(d) Awarding LUMC prejudgment interest on any amounts of actual damages;

(e) That this be declared an exceptional case, and that LUMC be awarded his attorneys' fees;

(f) For an award of LUMC costs of this action; and

(g) For such other further relief to which this court deems LUMC may be entitled in law and in equity.

DEMAND FOR JURY TRIAL

LUMC, under Rule 38 of the Federal Rules of Civil Procedure, requests a trial by jury of any issues so triable by right.

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

John W. Shaw (No. 3362)
Monté T. Squire (No. 4764)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19899-0391
(302) 571-6600
jshaw@ycst.com
msquire@ycst.com

Attorneys for Plaintiff Leiden University Medical Centre

OF COUNSEL

Edgar R. Cataxinos
TRASKBRITT, PC
230 South 500 East, Suite 300
P.O. Box 2550
Salt Lake City, Utah 84110
(801) 532-1922
ercataxinos@traskbritt.com

Dated: December 21, 2010