IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

SNYDERS HEART VALVE LLC, Plaintiff, v. ST. JUDE MEDICAL S.C., INC., *et al.,* Defendants.	CIVIL ACTION NO. 4:16-cv-812-ALM **(Consolidated Lead Case)**
SNYDERS HEART VALVE LLC, Plaintiff, v. MEDTRONIC, INC.; MEDTRONIC COREVALVE LLC; MEDTRONIC VASCULAR GALWAY UNLIMITED; MEDTRONIC MEXICO S. DE R.L. DE C.V.; MEDTRONIC LOGISTICS LLC; and MEDTRONIC USA, INC.; Defendants.	CIVIL ACTION NO. 4:16-cv-813 **(Member Case)**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT AGAINST THE MEDTRONIC DEFENDNATS

Pursuant to Fed. R. Civ. P. 15(a)(2), and with the consent of the Medtronic defendants, Plaintiff Snyders Heart Valve LLC ("Snyders") files this amended complaint against Medtronic, Inc.; Medtronic CoreValve, L.L.C.; Medtronic Vascular Galway Unlimited; Medtronic Mexico S. de R.L. de C.V.; Medtronic Logistics LLC; and Medtronic USA, Inc. (collectively, "Defendants" or "Medtronic"), alleging, based on its own knowledge as to itself and its own actions and based on information and belief as to all other matters, as follows:

PARTIES

1. Snyders is a corporation formed under the laws of the State of Texas, with a principal place of business in Tyler, Texas.

2. Defendant Medtronic, Inc. is a corporation organized under the laws of the state of Minnesota with a principal place of business at Minneapolis, Minnesota. Defendant Medtronic, Inc. can be served with process by serving its registered agent: C T Corp System, 1999 Bryan St., Suite 900, Dallas, TX 75201.

3. [Reserved].

4. Defendant Medtronic CoreValve LLC is a limited liability corporation organized and existing under the laws of Delaware, with its principal place of business in Irvine, California. Medtronic CoreValve LLC can be served with process by serving The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, Delaware 19801.

5. [Reserved]

6. [Reserved]

7. [Reserved]

7.1 Defendant Medtronic Vascular Galway Unlimited is a company organized and existing under the laws of Ireland and having a principal place of business in Ireland.

7.2 Defendant Medtronic Mexico S. de R.L. de C.V. is a company organized under the laws of Mexico and has a principal place of business in Mexico.

7.3 Defendant Medtronic Logistics LLC is a Minnesota company with its principal place of business in Minnesota.

7.4 Defendant Medtronic USA, Inc. is a Minnesota company with its principal place of business in Minnesota.

JURISDICTION AND VENUE

8. This is an action for infringement of a United States patent arising under 35 U.S.C. §§ 271, 281, and 284–85, among others. This Court has subject matter jurisdiction of the action under 28 U.S.C. §1331 and §1338(a).

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b). Upon information and belief, Medtronic has transacted business in this district and has committed, by itself or in concert with others, acts of patent infringement in this district.

10. Medtronic is subject to this Court's specific and general personal jurisdiction pursuant to due process and/or the Texas Long Arm Statute, due at least to Medtronic's substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; and/or (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided to individuals in Texas and in this district.

DR. SNYDERS AND HIS INVENTION

11. Robert V. Snyders, M.D. is an accomplished physician having practiced clinical medicine for over forty years. Dr. Snyders has over 30 years of experience in cardiovascular device design, prototyping and pre-clinical studies and has been awarded six United States patents and several international patents related to medical devices (asserted patents in bold):

a. U.S. Patent No. 6,821,297 ("Artificial heart valve, implantation instrument and method therefor")

b. U.S. Patent No. 6,540,782 ("Artificial heart valve")

c. U.S. Patent No. 6,095,968 ("Reinforcement device")

d. U.S. Patent No. 5,256,132 ("Cardiac assist envelope for endoscopic application")

e. U.S. Patent No. 5,169,381 ("Ventricular assist device")

f. U.S. Patent No. 4,690,134 ("Ventricular assist device")

12. Dr. Snyders is the sole inventor of U.S. Patent Nos. 6,540,782 (the "'782 Patent) and 6,821,297 (the "'297 Patent") (collectively, the "Patents-in-Suit").

13. Dr. Snyders' named his valve the "Funnel Valve" due to its resemblance to that particular geometric shape. The Funnel Valve allowed rapid deployment of a bioprosthetic heart valve without the need for conventional, invasive surgery.

14. Dr. Snyders submitted his Funnel Valve design to Medtronic's Chris Coppin, M.D., Ph.D., Senior Research Manager. In May 2000, Dr. Coppin noted that Dr. Snyders' "funnel valve design is quite ingenious" and that "there is no other product on the market that even comes close to," being able to "be deployed by minimally invasive means for urgent…use in patients that are too unstable for open heart surgery."

15. In mid-2001, Dr. Snyders tested the Funnel Valve with several renowned physicians including Dr. Mehmet Oz, Dr. Paul DiGiorgi, Dr. Neel Joshi, and Dr. Alessandro Barbone at Columbia Presbyterian Medical Center. The physicians at Columbia Presbyterian determined that the funnel valve was "a promising design for potential transluminal valve replacement."

16. The Funnel Valve also underwent tests at the Heineman Medical Research Laboratories in early 2002. During those tests, Dr. Mano Thubrikar, Ph.D., Associate Director, Biomedical Engineering, determined that the Funnel Valve was "ingenious" and that it was the only valve he had "seen so far, which can be implanted using a catheter-based technology."

17. Based on his revolutionary concept and design, Dr. Snyders was awarded the Patents-in-Suit by the United States Patent and Trademark Office.

ALLEGATIONS COMMON TO ALL CLAIMS

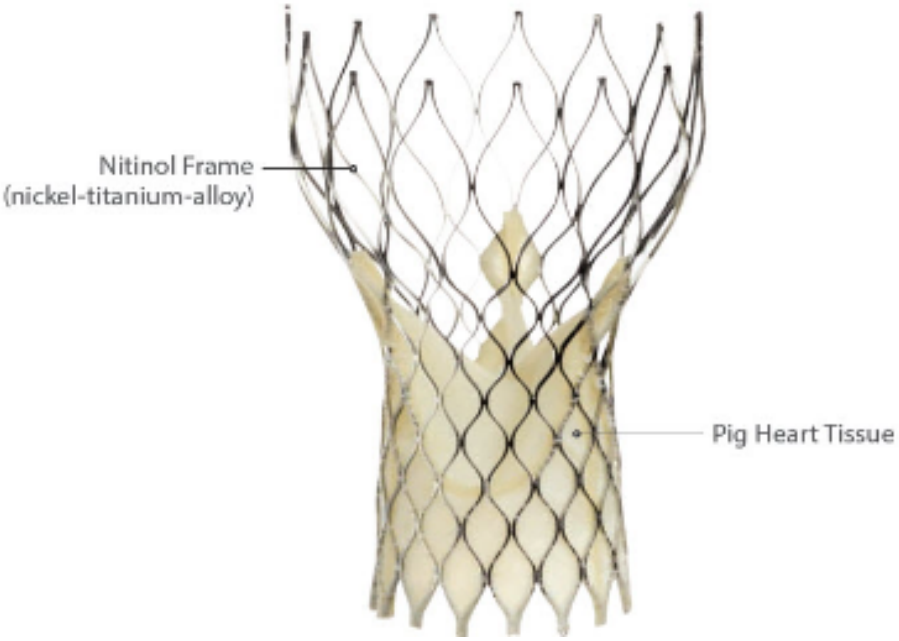
18. Medtronic has made, had made, used, imported, provided, supplied, distributed, sold, and/or offered for sale artificial heart valves and corresponding delivery systems, including the CoreValve, CoreValve Evolut, CoreValve Evolut R, and EnVeo R.

CoreValve Aortic Valve Replacement

The CoreValve heart valve is another option for people with severe AS. It does not require open heart surgery. It is implanted using an artery that leads to the heart.

The CoreValve heart valve is made from pig heart tissue. This tissue valve is held by a metal frame. It is designed to work like your own heart valve.

Your physician may refer to the CoreValve heart valve by a different name. CoreValve and Evolut R are names for different models of the CoreValve heart valve.



19. Medtronic has also made, had made, used, imported, provided, supplied, distributed, sold, and/or offered for sale systems for delivery of the artificial heart valves, including the EnVeo R Delivery System and the CoreValve Delivery Catheter System (collectively with the heart valve products, the "accused products").

20. The accused products include a line of rapidly-deployable artificial heart valves that may be delivered to a patient' damaged heart valve through an artery in order to avoid invasive, open-heart surgery. The accused products also include a line of catheter delivery systems used to deliver the artificial heart valves to the patient's damaged heart valve through an artery.

21. Specifically, Medtronic's accused products include at least the following model numbers:

Bioprothesis Model	**Size**	**Catheter Model**	**Corresponding CLS Model**
CoreValve Evolut Bioprothesis			
MCS-P4-23-AOA	23 mm	DCS-C4-18FR-23	CLS-3000-18FR
CoreValve Bioprothesis			
MCS-P4-26-AOA	26 mm	DCS-C4-18FR	CLS-3000-18FR

MCS-P4-29-AOA	29 mm	DCS-C4-18FR	CLS-3000-18FR
MCS-P4-31-AOA	31 mm	DCS-C4-18FR	CLS-3000-18FR

Bioprothesis Model	**Corresponding LS Model**	**Corresponding Catheter Model**
EVOLUTR-23-US	LS-ENVEOR23US	ENVEOR-US
EVOLUTR-26-US	LS-ENVEOR2629US	ENVEOR
EVOLUTR-29-US	LS-ENVEOR2629US	ENVEOR

MEDTRONIC'S INFRINGEMENT OF U.S. PATENT NO. 6,540,782

22. On April 1, 2003, United States Patent No. 6,540,782 ("the '782 patent") was duly and legally issued by the United States Patent and Trademark Office for an invention entitled "Artificial Heart Valve." A copy of the '782 Patent is attached as Exhibit 1 hereto.

23. Snyders is the owner of the '782 patent with all substantive rights in and to that patent, including the sole and exclusive right to prosecute this action and enforce the '782 patent against infringers, and to collect damages for all relevant times.

24. By making, having made, using, importing, providing, supplying, distributing, selling or offering for sale the accused products, Medtronic has directly infringed (literally and/or under the doctrine of equivalents) at least claim 1 of the '782 patent.

25. Specifically, the accused products comprise an artificial heart valve including a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and downstream region of the damaged valve, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors.

26. The accused products include a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band.

27. The valve element of the accused products moves in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

28. Medtronic's infringement in this regard is ongoing.

29. Snyders has been damaged as a result of the infringing conduct by Medtronic alleged above. Thus, Medtronic is liable to Snyders in an amount that adequately compensates it for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

30. Snyders and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law for infringement of the '782 patent.

MEDTRONIC'S INFRINGEMENT OF U.S. PATENT NO. 6,821,297

31. On November 23, 2004, United States Patent No. 6,821,297 ("the '297 patent") was duly and legally issued by the United States Patent and Trademark Office for an invention entitled "Artificial Heart Valve, Implantation Instrument, and Method Therefor." A copy of the '297 Patent is attached as Exhibit 2 hereto.

32. Snyders is the owner of the '297 patent with all substantive rights in and to that patent, including the sole and exclusive right to prosecute this action and enforce the '297 patent against infringers, and to collect damages for all relevant times.

33. By making, having made, using, importing, providing, supplying, distributing, selling or offering for sale the accused products, Medtronic has directly infringed (literally and/or under the doctrine of equivalents) at least claim 22 of the '297 patent.

34. The accused products comprise a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and downstream region of the damaged valve and the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region.

35. The accused products comprise a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame, said element having a convex upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in

which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and an opening extending through at least one of said frame and the flexible valve element.

36. Medtronic's infringement in this regard is ongoing.

37. Snyders has been damaged as a result of the infringing conduct by Medtronic alleged above. Thus, Medtronic is liable to Snyders in an amount that adequately compensates it for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

38. Snyders and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law for infringement of the '297 patent.

ADDITIONAL ALLEGATIONS REGARDING INDIRECT INFRINGEMENT

39. Medtronic has also indirectly infringed the Patents-in-Suit by inducing others to directly infringe the Patents-in-Suit. Medtronic has induced the end-users to directly infringe (literally and/or under the doctrine of equivalents) the Patents-in-Suit by directing or instructing doctors and technicians to insert the accused heart valves between a plurality of cusps of a damages heart valve in an infringing manner. Such steps by Medtronic include, among other

things, advising or directing doctors and technicians to use the accused products in an infringing manner; advertising and promoting the use of the accused products in an infringing manner; and/or distributing instructions and training videos that guide users to use the accused products in an infringing manner. Specifically, Medtronic's "Instructions for Use" for the CoreValve Transcatheter Aortic Valve Delivery Catheter System, Compression Loading System instructs the doctor to "insert the device over the 0.035-in (0.889-mm) guidewire and advance it." The instructions further instruct the doctor to "[a]dvance the device through the native valve," and "after attaining optimal catheter position, slowly turn the micro knob and begin to deploy the bioprothesis." Finally, the CoreValve instructions warn, "[i]mplantation of the CoreValve and CoreValve Evolut R systems should be performed only by physicians who have received Medtronic CoreValve training." Medtronic's inducement is ongoing.

40. Medtronic has sold, supplied, provided, offered for sale, and/or distributed, directly or through intermediaries, the infringing heart valves to doctors who conduct transcatheter aortic valve replacement on patients with damaged heart valves using the patented methods and apparatus.

41. Medtronic also indirectly infringes by contributing to the infringement of the Patents-in-Suit. Medtronic has contributed to the direct infringement of the Patents-in-Suit by the end-user of the accused products (doctors who place the accused heart valves into a patient's damaged heart valve). The accused heart valves are specially designed to be used in an infringing way and have no substantial uses other than ones that infringe the Patents-in-Suit. Medtronic knows that the accused products constitute a material part of the invention of one or more of the claims of the Patents-in-Suit and are not staple articles of commerce suitable for substantial non-infringing use. Medtronic's contributory infringement is ongoing.

42. Medtronic's actions are at least objectively reckless as to the risk of infringing a valid patent and this objective risk was either known or should have been known by Medtronic.

43. Medtronic's direct and indirect infringement of the Patents-in-Suit is, has been, and continues to be willful, intentional, deliberate, and/or in conscious disregard of Snyders' rights under the Patents-in-Suit.

44. Snyders has been damaged as a result of the infringing conduct by Medtronic alleged above. Thus, Medtronic is liable to Snyders in an amount that adequately compensates it for such infringements, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

45. Snyders and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law.

MEDTRONIC'S KNOWLEDGE OF THE PATENTS-IN-SUIT

46. Medtronic is, and has been, well aware of Dr. Snyder's pioneering work that led to the issuance of the Patents-in-Suit, as well as Dr. Snyder's application for, and the issuance of the Patents-in-Suit.

47. In May 2000, Dr. Coppin, Medtronic's Senior Research Manager "carefully read" Dr. Snyders' Funnel Valve disclosure including drawings, photo reproductions and four monographs submitted to Medtronic. Dr. Coppin also responded to communication from Dr. Snyders in which Dr. Snyders indicated that he had "recently filed for provisional patent protection." Dr. Coppin indicated that Dr. Snyders' "funnel valve design is quite ingenious" and that "there is no other product on the market that even comes close to," being able to "be deployed by minimally invasive means for urgent…use in patients that are too unstable for open heart surgery."

48. In December 2001, Medtronic's Dr. Coppin continued to express interest in Dr. Snyders' invention stating that he would be interested in seeing a video of the Funnel Valve testing and asking if they "could link up at one of the national cardiac surgery meetings."

49. Dr. Snyders also submitted his Funnel Valve design to Medtronic's Andy Campbell, P.E., Senior Director, Research and Development in December 2003. Mr. Campbell subsequently sent an email to Dr. Snyders thanking him "for spending the time to explain [his] design" and also letting Dr. Snyders know that he would take a look at his patents.

50. In November 2007, Dr. Snyders emailed Medtronic's Rob Michiels, President and Chief Operating Officer, and said he would like to present his Funnel Valve design to Mr. Michiels. Dr. Snyders further indicated in his email to Mr. Michiels that his Funnel Valve device is "under US and EU patents." Mr. Michiels responded to Dr. Snyders' email telling him that he had forwarded the information to Medtronic's patent counsel.

51. In January 2008, prior to Medtronic's acquisition of CoreValve, CoreValve's patent lawyer, Vito Canuso III, had been forwarded Dr. Snyders' correspondence with Medtronic's Mr. Michiels. By this time, there was some relationship between CoreValve and Medtronic as evidenced by their communication regarding Dr. Snyders' technology. CoreValve's patent lawyer, Vito Canuso III contacted Dr. Snyders and set up a teleconference discussing Dr. Snyders' Funnel Valve technology.

52. In February 2008, CoreValve's CEO, Dr. Jacques Seguin, M.D., Ph.D., confirmed that he had been copied on the messages between Medtronic's Mr. Michiels and CoreValve's patent lawyer, Mr. Vito Canuso III, and that he had "read with great attention your description of your invention."

53. In March 2008, Medtronic's Tim Laske, Vice President, Research and Development, had a teleconference with Dr. Snyders discussing his "idea" and agreeing to give Dr. Snyders "a wet lab presentation of the Funnel Valve," which occurred in April 2008.

54. Medtronic has had knowledge of the Patents-in-Suit since at least May 7, 2007, when Medtronic cited the Snyders' U.S. Patent Publication No. 2002/0123802 (the published application that led to the '297 Patent) in their own patent application No. 11/352,614.

55. Medtronic also has had knowledge of the Patents-in-Suit at least as of the date when it was notified of the filing of this action.

JURY DEMAND

Snyders hereby requests a trial by jury on all issues so triable by right.

PRAYER FOR RELIEF

Snyders requests that the Court find in its favor and against Medtronic, and that the Court grant Snyders the following relief:

a. Judgment that one or more claims of the '782 and '297 patents have been infringed, either literally and/or under the doctrine of equivalents, by Medtronic and/or all others acting in concert therewith;

b. A permanent injunction enjoining Medtronic and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in concert therewith from infringement, inducing infringement, or contributing to the infringement of the '782 and '297 patents;

c. Judgment that Medtronic accounts for and pay to Snyders all damages to and costs incurred by Snyders because of Medtronic's infringing activities and other conduct complained of herein;

d. That Medtronic's infringements be found to be willful, and that the Court award treble damages for the period of such willful infringement pursuant to 35 U.S.C. § 284;

e. That Snyders be granted pre-judgment and post-judgment interest on the damages caused by Medtronic infringing activities and other conduct complained of herein;

f. That this Court declare this an exceptional case and award Snyders its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and

g. That Snyders be granted such other and further relief as the Court may deem just and proper under the circumstances.

Dated: May 3, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that om May 3, 2017, I served the foregoing on all counsel of record by email.

/s/ Matthew J. Antonelli
Matthew J. Antonelli