

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS**

TROY R. NORRED, M.D.,)	
)	
Plaintiff,)	
)	
v.)	Case No. 13-cv-2061 EFM/DJW
)	
MEDTRONIC, INC.,)	DEMAND FOR JURY TRIAL
MEDTRONIC VASCULAR, INC.,)	
MEDTRONIC COREVALVE, LLC.,)	
COREVALVE, INC., ROB MICHIELS and)	
DANIEL LEMAITRE,)	
)	
Defendants.)	

COMPLAINT

Plaintiff Troy R. Norred, M.D., through his undersigned attorneys of record, file this Complaint against Defendants Medtronic, Inc., Medtronic Vascular, Inc., Medtronic CoreValve, LLC, CoreValve, Inc., Rob Michiels and Daniel Lemaitre (collectively “Defendants”), and states and alleges as follows:

INTRODUCTION

1. This is a lawsuit for patent infringement.
2. This lawsuit stems from the flagrant theft of valuable intellectual property belonging to Dr. Troy R. Norred (“Dr. Norred” or “Plaintiff”).
3. This intellectual property consists of the specifications for a unique type of percutaneous aortic valve.
4. This percutaneous aortic valve is a life-saving surgical device that can be implanted in cardiac patients suffering from aortic stenosis or aortic regurgitation to help regulate blood flow in the heart.

5. Dr. Norred developed the specifications for this valve through years of painstaking research and experimentation, ultimately securing a United States Patent.

6. In complete disregard for Dr. Norred's intellectual property rights, Defendant CoreValve, Inc. ("CoreValve") put forth Dr. Norred's invention as its own, seeking to profit from Dr. Norred's efforts without giving him credit or compensation.

7. Defendant Medtronic, Inc. ("Medtronic") subsequently acquired CoreValve and continued these development efforts through its subsidiary, Defendant Medtronic Vascular, Inc. ("Medtronic Vascular"), despite lack legal rights to this property.

8. Defendants' actions have infringed and continue to infringe on Dr. Norred's patent.

9. Accordingly, at a minimum, Dr. Norred seeks a reasonable royalty, together with such other and further relief is available under 35 U.S.C. § 285.

PARTIES

10. Plaintiff Norred is a cardiologist residing in Ada, Oklahoma. Dr. Norred is the inventor of a replacement aortic valve designed to be placed percutaneously via a catheter and stent system.

11. Defendant Medtronic is a public corporation organized under the laws of the State of Minnesota with a principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432. Medtronic touts itself as the world's largest independent medical technology company. Cardiovascular is Medtronic's third-largest business, accounting for \$3.18 billion in revenue in fiscal year 2011. Medtronic's shares trade on the New York Stock Exchange under the ticker symbol, MDT

12. Defendant Medtronic Vascular is a private corporation organized under the laws of the State of Delaware with its place of business at 3576 Unocal Place, Santa Rosa, California 95403. Medtronic Vascular designs and develops technologies for coronary, peripheral and neurovascular indications. Medtronic Vascular operates as a subsidiary of Medtronic. Medtronic Vascular can be served through its registered agent C T Corporation System Inc., 100 S. 5th Street, #1075, Minneapolis, MN 55402.

13. Defendant Medtronic CoreValve LLC (“Medtronic CoreValve”) is a limited liability company organized under the laws of the State of Delaware with a principal place of business at 1 Jenner #100, Irvine, CA 92618. Medtronic CoreValve develops, markets, and manufactures catheter-based aortic valve replacement products for cardiac care to patients and healthcare professionals in the United States and internationally.

14. Defendant CoreValve was a private corporation organized under the laws of the State of Delaware with a principal place of business at 1 Jenner #100, Irvine, CA 92618. CoreValve was founded in 2001 in Paris, France to develop the ideas of Dr. Jacques Seguin, a French cardiac surgeon who invented a technique for implanting a heart valve through a catheter. CoreValve discovered, however, that its catheter was too wide to be useful to many patients. In or about 2004, CoreValve moved to Irvine, California area to attempt to develop a smaller catheter. CoreValve operated as an independent company until 2009, when it was purchased by Medtronic and became Medtronic CoreValve. On information and belief, Medtronic CoreValve succeeded to all liabilities of CoreValve, known or unknown, and monies were set aside as part of the transaction to cover these liabilities.

15. Defendant Rob Michiels (“Michiels”) was an investor and consultant in CoreValve, and on information and belief, served as its President and Chief Operating Officer from sometime in 2004 until sometime in 2009.

16. Defendant Daniel Lemaitre (“Lemaitre”) succeeded Michiels as President of CoreValve and was serving in that capacity at the time CoreValve was purchased by Medtronic.

JURISDICTION AND VENUE

17. This is a patent infringement action brought under the patent laws of the United States, 35 U.S.C. Section 1, *et seq.* Dr. Norred seeks damages for patent infringement and an injunction preventing Defendants from making, using, selling, offering to sell, importing, or inducing others to use Dr. Norred’s patented technology without his permission.

18. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

19. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of conducting business within this State and this District by, among other things, conducting clinical trials of the Medtronic CoreValve percutaneous aortic valve.

20. Venue in this district is proper under 28 U.S.C. §§ 1391 and 1400 because a substantial part of the events giving rise to the claims asserted herein occurred in this District, and Defendants have committed acts of infringement in this District.

FACTUAL BACKGROUND

Dr. Troy R. Norred and the Percutaneous Aortic Valve

21. Dr. Troy Norred was born in 1967 in Norman Oklahoma. He attended college at East Central Oklahoma from 1986 through 1990, earning a Bachelor of Science in Biology. He attended medical school at the University of Oklahoma College of Medicine from 1990 through 1995, graduating with a Doctor of Medicine. He served his internship and then residency in

internal medicine at the University of Oklahoma Health Science Center, his cardiology fellowship at the University of Missouri, and his interventional cardiology fellowship at Louisiana State University New Orleans. He is currently in private practice in Ada, Oklahoma as a board certified cardiac surgeon.

22. The idea for the percutaneous aortic valve came during Dr. Norred's residency. An 83-year-old patient of Dr. Norred was diagnosed with aortic stenosis. Dr. Norred knew that his patient needed an aortic valve replacement, but he also knew that his patient could not survive the open-heart surgical procedure necessary to replace the diseased aortic valve. Dr. Norred watched helplessly as his patient's health continued to decline and eventually his patient passed away.

23. Dr. Norred was determined find another way to treat elderly patients with aortic stenosis that could not survive the trauma of open-heart surgery.

24. In 1999, Dr. Norred began working on his concept to develop a percutaneous placement technique and aortic valve that would mimic the function of the native aortic valve and avoid problems associated with the then-current methods for surgical replacement.

25. Dr. Norred researched the physiological and mechanical aspects of the aorta and aortic valve, and conducted experiments to prove his concept.

26. Dr. Norred created a large mock-up using chicken wire and other materials from a local hardware store. He gathered porcine samples (aortic valves and aortas) to develop the outline of the stented valve. He utilized both stainless steel stent and Nitinol® tubing cut into a stent to suture porcine valves onto. Then he had a glass aorta blown into shape to place the stented models into. He connected a pump to cycle blood through this blown glass model to

simulate the natural flow of the aorta/valve complex. Finally, he implanted the valve system into an extracted pig aorta.

27. In May 2000, with his invention solidified, Dr. Norred took steps to obtain a patent. He met with patent attorneys and filed a patent application on November 14, 2000.

28. On November 19, 2002, United States Patent No. 6,482,228 (“the ‘228 patent”) entitled, “Percutaneous Aortic Valve Replacement” issued to Dr. Norred. A true and correct copy of the ‘228 Patent is attached hereto as Exhibit A.

29. Dr. Norred owns all right, title and interest to the ‘228 Patent, including the right to sue for past, present and future infringements.

30. The ‘228 Patent is valid and enforceable.

Dr. Norred’s Meetings With The Infringers

31. In September 2003, Dr. Norred attended the Transcatheter Cardiovascular Therapeutics Conference in Washington, DC.

32. Representatives from CoreValve were present at this conference and presented a surgical device called the Percutaneous ReValving System (the “ReValving System”).

33. The ReValving System was strikingly similar to the invention claimed in the ‘228 Patent, and indeed, appeared to be rough copy.

34. Dr. Norred spoke to the then-Vice President of Marketing of CoreValve to discuss his valve and CoreValve’s ReValving System.

35. After the conference, Dr. Norred called Defendant Michiels, the then-President of CoreValve, to discuss his infringing product.

36. Dr. Norred told Mr. Michaels that CoreValve needed a license for its ReValving System. Defendant Michiels did not deny a license was necessary. On the contrary, Defendant

Michiels explained that CoreValve was a small company, and that Dr. Norred should wait to discuss licensing until CoreValve grew in size to the point that it could support the licensing fees associated with the '228 Patent.

37. Dr. Norred was not persuaded. He sent a follow-up letter to Defendant Michiels enclosing a copy of the '228 Patent and urging CoreValve to enter into licensing discussions immediately. CoreValve did not respond to this letter.

38. Dr. Norred waited several months then sent another letter to CoreValve. Again, CoreValve did not respond.

39. Medtronic purchased CoreValve in 2009. At the time of the purchase, Defendant Lemaitre was President of CoreValve.

40. CoreValve and Lemaitre both knew about Dr. Norred's claim regarding the '228 Patent.

41. On information and belief, CoreValve and Lemaitre disclosed this information to Medtronic, and this information informed the terms of this transaction.

42. After this transaction was completed and CoreValve became Medtronic CoreValve, Dr. Norred contacted Medtronic to introduce himself and explain the issue that had arisen regarding the PRV System and the '228 Patent.

43. Medtronic was initially receptive to this inquiry.

44. From November 2009 through December 2010, Dr. Norred and Medtronic engaged in extensive discussions regarding licensing of the '228 Patent.

45. Medtronic ended these discussions without explanation in December 2010, refusing further communication.

46. On information and belief, and as described herein, Defendants Michiels and Lemaitre actively and knowingly participated in the furtherance of the infringement of the '228 Patent by, among other things, inducing CoreValve to infringe. Equity demands that these corporate officers be held liable for the infringement.

47. On information and belief, and as described herein, Defendants Medtronic, Medtronic Vascular, Medtronic CoreValve and CoreValve acted in concert with one another in the furtherance of the infringement of the '228 Patent. Equity demands that these corporate entities be held jointly and severally liable for the full extent of the wrongdoing.

COUNT I: PATENT INFRINGEMENT

48. Dr. Norred incorporates by reference the foregoing allegations as if fully set forth herein.

49. On information and belief, Defendants have committed and/or are continuing to commit direct acts of infringement of the '228 Patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, and/or importing percutaneous aortic valves that infringe the '228 Patent, without license or authority from Dr. Norred, including but not limited to a device that Defendants have made, used, sold, offered to sell, and imported under the name of "CoreValve Percutaneous Aortic Valve Implantation System" or CoreValve ReValving System."

50. The '228 Patent discloses and claims, among other things, an aortic valve adapted to be placed percutaneously for regulating blood flow through a channel of an aorta.

51. Dr. Norred has been damaged as a direct result of the infringement of the '228 Patent. Dr. Norred will continue to be damaged unless further infringement is enjoined.

52. Dr. Norred is entitled under 35 U.S.C. § 284 to an award of damages adequate to compensate Dr. Norred for Defendants' infringement of the '228 Patent. Dr. Norred is entitled

to in no event less than a reasonable royalty for the infringement and use made of the invention of the '228 Patent by Defendants, all together with interest and costs.

53. Defendants continued to infringe the '228 Patent after being put on notice by Dr. Norred.

54. On information and belief, Defendants' past and continuing infringement of the '228 Patent has been and continues to be deliberate and willful.

55. Defendants' conduct warrants an award of treble damages pursuant to 35 U.S.C. § 284.

56. Moreover, this is an exceptional case that entitles Dr. Norred to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II: CONTRIBUTORY PATENT INFRINGEMENT

57. Dr. Norred incorporates by reference the foregoing allegations as if fully set forth herein.

58. Defendants have engaged in clinical trials in which the infringing valve systems are provided to doctors and others with detailed instructions, information, and training on how to use the infringing system in an infringing manner. Defendants' acts constitute inducement to infringe the '228 patent whenever doctors or others use Medtronic's infringing systems in an infringing manner.

59. Defendants provide material components for the infringing system such that whenever said infringing system is sold, offered for sale, and/or imported into the United States Defendants are liable for contributory infringement of the '228 patent.

60. Defendants' activities have been without express or implied license from Plaintiffs.

61. Defendants' actions in infringing the '228 patent have been, and continue to be, willful, deliberate, and/or in conscious disregard of the rights of Dr. Norred, making this an exceptional case within the meaning of 35 U.S.C. § 285.

62. As a result of the infringement of the '228 Patent, Dr. Norred has been damaged, will be further damaged, and it entitled to be compensated for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

63. Defendants' infringing activities have caused, and will continue to cause, Dr. Norred irreparable harm for which there is no adequate remedy at law.

WILLFUL INFRINGEMENT

64. Dr. Norred incorporates by reference their foregoing allegations as if fully set forth herein.

65. On information and belief, Defendants' past and continuing infringement of the '228 Patent has been deliberate and willful. Their conduct warrants an award of treble damages pursuant to 35 U.S.C. § 284. Moreover, this is an exceptional case as set forth in 35 U.S.C. § 285 warranting an award of attorney's fees.

DEMAND FOR JURY TRIAL

Dr. Norred demands trial by jury on all issues so triable. Dr. Norred designates Kansas City as the place of trial.

PRAYER FOR RELIEF

WHEREFORE, Dr. Norred respectfully prays that this Honorable Court enter relief as follows:

- A. A judgment that Medtronic has infringed the '228 Patent;
- B. A judgment that Medtronic Vascular has infringed the '228 Patent;

- C. A judgment that Medtronic CoreValve has infringed the '228 Patent;
- D. A judgment that CoreValve has infringed the '228 Patent;
- E. A judgment that Michiels has infringed the '228 Patent;
- F. A judgment that Lemaitre has infringed the '228 Patent;
- G. A judgment that Medtronic has induced others to infringe the '228 patent;
- H. A judgment that Medtronic Vascular has induced others to infringe the '228 Patent;
- I. A judgment that Medtronic CoreValve has induced others to infringe the '228 patent;
- J. A judgment that CoreValve has induced others to infringe the '228 Patent;
- K. A judgment that Michiels has induced others to infringe the '228 Patent;
- L. A judgment that Lemaitre has induced others to infringe the '228 Patent;
- M. A judgment and order permanently restraining and enjoining Medtronic and its officers, directors, agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with or under or through them, from making, using, selling, offering for sale, or importing any systems or products that infringe one or more claims of the '228 patent, or otherwise directly or indirectly committing further acts of infringement of that patent;
- N. A judgment and order permanently restraining and enjoining Medtronic Vascular and its officers, directors, agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with or under or through them, from making, using, selling, offering for sale, or importing any systems or products that infringe one or more claims of the '228 patent, or otherwise directly or indirectly committing further acts of infringement of that patent;
- O. A judgment and order permanently restraining and enjoining Medtronic CoreValve

and its officers, directors, agents, servants, employees, attorneys, subsidiaries, affiliates, and all those acting in concert with or under or through them, from making, using, selling, offering for sale, or importing any systems or products that infringe one or more claims of the '228 patent, or otherwise directly or indirectly committing further acts of infringement of that patent;

P. A judgment and order requiring Defendants to pay damages to Dr. Norred adequate to compensate them for Defendants' wrongful infringing acts in accordance with 35 U.S.C. § 284;

Q. A judgment and order requiring Defendants to pay increased damages up to three times, in view of their willful and deliberate infringement of the '228 Patent;

R. A finding in favor of Dr. Norred that this is an exceptional case under 35 U.S.C. § 285 and an award of Dr. Norred his costs, including reasonable attorney's fees and other expenses incurred in connection with this action;

S. A judgment and order requiring Defendants to pay Dr. Norred pre-judgment interest under 35 U.S.C. § 284 and post-judgment interest under 28 U.S.C. § 1961 on all damages awarded; and

T. Such other and further relief as the Court deems just and appropriate.

Respectfully submitted,

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