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THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, a California Corporation, Plaintiff, v. ST. JUDE MEDICAL, INC., a Minnesota Corporation, Defendant.	Case No. 3:16-cv-6210 **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiff The Regents of the University of California ("The Regents" or "Plaintiff"), by and through its undersigned counsel, complains and alleges against St. Jude Medical, Inc., a for-profit medical device company ("SJM" or "Defendant"), as follows:

BACKGROUND AND NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and specifically § 271, for Defendant's infringement of The Regents' patents covering the now-standard and universally utilized method of treating atrial fibrillation.

2. Atrial fibrillation (also referred to as "AFib" or "AF") is the most common type of abnormal heart rhythm. AFib can be an extremely serious condition that severely limits physical activities and significantly increases the risk of other serious heart diseases, stroke, and death. It is estimated that five million people in the United States suffer from AFib currently, and that this number will reach up to 12 million people by 2050. Approximately 450,000 new cases of AFib are diagnosed in the U.S. alone each year. These figures are expected to increase as the population ages.

3. Atrial fibrillation is caused by irregular electrical activity that is triggered typically from locations in the pulmonary veins, or near the entrance of the pulmonary veins in the left atrium of the heart. Absent appropriate treatment, the erratic electrical pulses travel from the pulmonary vein into the left atrium, wherein they trigger the onset of AFib, which causes erratic heart muscle contractions and decreases the effectiveness of the heart's ability to pump blood through the patient's body.

4. Medical researchers spent decades attempting to develop safe and effective non-pharmacologic treatment methods. Michael D. Lesh MD, a professor of medicine and a cardiac electrophysiologist at the University of California, San Francisco (or "UCSF"), finally solved the problem by inventing the first safe and reliable minimally invasive method of treating AFib.

5. The treatment method invented by Dr. Lesh (the "Patented Method") involves the formation of a circumferential conduction block at a location where a pulmonary vein extends from the heart's left atrium. The resulting conduction block is intended to block electric pulses originating within or near the pulmonary vein(s) and to prevent them from entering the left atrium and triggering atrial fibrillation. Dr. Lesh filed several related patent applications, prosecuted by and on behalf of The Regents, directed to the Patented Method,

including the two patents asserted in this action. All of these patents are duly assigned to The Regents (collectively, "The Regents' Patents").

6. SJM and the relevant medical community have, at all relevant times, consistently referred to the Patented Method as "pulmonary vein isolation," "PVI," "circumferential PVI," circumferential conduction block, and/or electrical isolation of the pulmonary veins.

7. The Patented Method has proven highly successful in treating atrial fibrillation. During the early 2000's, relevant medical professionals, such as doctors, cardiologists, cardiac electrophysiologists, and thoracic and cardiac surgeons, universally adopted the Patented Method as the accepted non-pharmacologic method of treating AFib, either alone, or in combination with other therapy.

8. Defendant SJM has, at all relevant times, been one of the major manufacturers of medical devices and related equipment used to treat AFib. SJM manufactures, markets, and sells a wide range of medical devices and related equipment (collectively, "SJM Devices") that are used to perform the Patented Method to treat AFib.

9. SJM has, at all relevant times, been aware of The Regents' Patents, including the two patents asserted in this action, and is well aware of the widespread use of SJM Devices to perform the Patented Method. Moreover, SJM has actively induced, and continues to induce, medical professionals to use SJM Devices specifically to practice the Patented Method.

THE PARTIES

10. Plaintiff The Regents is a California corporation, with a principal place of business in Oakland, California. The Regents make up the governing board of the University of California. The Regents maintains a principal, and world-renowned, medical research facility, the University of California, San Francisco, in the City and County of San Francisco. All actions are done in The Regents' name, including owning property such as patents and other intellectual property, and entering into contracts.

11. Defendant SJM is a for-profit Minnesota Corporation, with corporate headquarters in St. Paul, Minnesota, and with numerous manufacturing facilities and management offices located in California, including in this District.

JURISDICTION AND VENUE

12. This Court has original and exclusive subject matter jurisdiction over this controversy pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over SJM because SJM's contacts with the State of California are significant and pervasive, and because SJM's contacts with California, as described in this Complaint, directly give rise to this dispute. SJM has multiple manufacturing facilities and offices in California, including at least one within this District, located in Sunnyvale, Santa Clara County.

14. SJM has conducted substantial business with individuals, hospitals, and other medical institutions and facilities throughout the State of California, including in this District, and it actively promotes and sells its medical devices and equipment, including the SJM Devices that are the subject of this action, throughout California. In doing so, SJM regularly transacts business throughout the state, and in this District, in violation of the Asserted Patents, as alleged in this Complaint. Accordingly, this Court may properly exercise personal jurisdiction over SJM.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b) at least because SJM resides in this District, has a regular and established place of business in this District, and has committed acts of infringement in this District.

INTRA-DISTRICT ASSIGNMENT

16. This is an intellectual property action to be assigned on a district-wide basis pursuant to Civil Local Rule 3-2(c).

THE ASSERTED PATENTS

17. On December 26, 2000, the United States Patent and Trademark Office ("USPTO") duly issued United States Patent No. 6,164,283 ("the '283 Patent"), entitled "DEVICE AND METHOD FOR FORMING A CIRCUMFERENTIAL BLOCK IN A PULMONARY VEIN." The Regents owns by assignment all rights, title, and interest in the '283 Patent. A true and correct copy of the '283 Patent is attached hereto as Exhibit 1.

18. On January 7, 2003, the USPTO duly issued United States Patent No. 6,502,576 ("the '576 Patent"), entitled "DEVICE AND METHOD FOR FORMING A

CIRCUMFERENTIAL BLOCK IN A PULMONARY VEIN." The Regents owns by assignment all rights, title and interest in the '576 Patent. A true and correct copy of the '576 Patent is attached hereto as Exhibit 2.

19. The '283 and '576 Patents are referred to collectively as the "Asserted Patents."

BACKGROUND OF ATRIAL FIBRILLATION

20. Atrial fibrillation is a type of cardiac arrhythmia that causes an abnormally fast and irregular heart rate. In patients with normal sinus rhythm, the heart is electrically excited to beat in a synchronous, patterned fashion. In patients with a cardiac arrhythmia, however, abnormal regions of cardiac tissue emit erratic electric signals, disrupting the synchronous beating cycle associated with normally conductive tissue in healthy patients.

21. Atrial fibrillation occurs in the upper chambers of the heart (*i.e.*, atria). In healthy individuals, the heart's atrial and ventricular chambers (*i.e.*, the lower chambers of the heart) contract in a coordinated fashion, with a normal sinus heart rate between 60 and 100 beats per minute.

22. In patients with AFib, however, the atrial chambers receive such fast and erratic electrical stimulation that they can only quiver and are unable to actively pump blood from the atria to the ventricles. During AFib, the two atria of the heart "beat" between 350 and 600 times per minute. When this occurs, the atrioventricular node, a part of the electrical pathway between the atria and the ventricles, becomes overloaded with electrical impulses trying to get to the ventricles. As a result, the normal coordination between the atria and ventricles is lost, ventricles develop an irregular heart rhythm, and pumping efficacy is decreased.

23. As a result of blood not being pumped effectively to the ventricles, blood can pool in the atria, posing a serious health risk. The pooling of blood can lead to coagulation and clotting. Strokes occur when a blood clot travels from the atrium, through the arterial system, to the brain. People with AFib are five times more likely to suffer a stroke than patients without AFib, and more than 15% of all strokes occur in patients with AFib. Once AFib is diagnosed, however, treatment can reduce the risk of stroke.

24. In some patients, the risk of stroke may be reduced with blood thinners to prevent

the blood from clotting, and with anti-arrhythmic drugs to restore normal sinus rhythm. These drugs often have serious side effects, such as severe bleeding, dizziness, nausea, bruising, fatigue, lung disease, and ventricular arrhythmias. Further, these drugs often do not prevent further episodes of AFib. If drugs are not effective or well tolerated by a patient, the treatment options include highly invasive open heart surgery or a cardiac ablation procedure, the evolution of which is described more fully below.

DR. MICHAEL LESH INVENTS THE PATENTED METHOD TO TREAT ATRIAL FIBRILLATION

25. Early non-pharmacologic approaches to treat atrial fibrillation were surgical, and involved a complex pattern of surgical incisions in both the left and right atria. The resulting scarred tissue was non-conductive and hence had the potential to block the erratic electrical pulses thought to cause AFib.

26. The early surgical efforts were reported as having some success in treating patients, but these open heart surgeries were highly invasive with the heart stopped, the chest opened, and the patient placed on a heart-lung machine. They also required a long recovery period, tended to render the left atrium non-functional, and had a high risk of death.

27. In parallel with the developments of the surgical procedures described above, doctors began to use catheters to ablate cardiac tissue to treat a variety of other cardiac arrhythmias. Catheter ablation is a much less invasive procedure than surgery and is performed by cardiac electrophysiologists ("EPs") in a catheterization lab. EPs are board-certified cardiologists with additional training in treating cardiac arrhythmias. In a catheter ablation procedure, the EP inserts multiple specialized catheters into the patient's veins and arteries. The EP generally guides the catheters into the right atrium of the patient's heart. For procedures involving the left atrium, the EP uses a special catheter to puncture the intra-atrial septum (*i.e.*, the wall separating the left and the right atria) to access the patient's left atrium, where the desired tissue can be ablated.

28. In the early 1990s, EPs began using catheter ablation in an attempt to treat AFib by mimicking the surgical procedures described above. These catheter procedures typically involved

the creation of linear patterns of non-conductive tissue from the inside wall of the heart with a goal to create lesions that were transmural (*i.e.*, through the wall from inside to out). In addition, the lesions needed to be continuous (or nearly so) with no gaps. Because they took many hours to complete, these procedures were very stressful for patients and resulted in safety complications such as perforations of the atrium and excessive radiation exposure.

29. In the mid-1990s, research established that approximately 90% of the erratic electrical pulses triggering AFib originated somewhere in the pulmonary veins. Thereafter, treating EPs attempted to cure AFib by locating and ablating the point or points (focus or foci) of origination of the erratic electrical signals within the pulmonary veins.

30. These procedures were of limited success because the exact locations of the originating foci are difficult to identify. In addition, there are often multiple originating foci within each pulmonary vein, causing this methodology to be extremely time-consuming. The procedure also posed safety concerns, the most serious of which was stenosis of the pulmonary veins due to excessive scarring. This stenosis blocked oxygen transmission in the blood, and could lead to serious lung problems and even death.

31. Dr. Lesh invented the solution to this life threatening problem. The Patented Method is directed to forming a circumferential conduction block at a location where a pulmonary vein extends from a patient's left atrium. The resulting circumferential conduction block prevents electric pulses originating from within or near the pulmonary vein from entering the left atrium and causing AFib. This allows treatment of AFib without having to identify, locate, or ablate the triggering foci within each pulmonary vein. At the same time, it reduces the risk of complication posed by previously-employed methods of treatment.

32. Beginning in July 1997, Dr. Lesh filed several related patent applications disclosing and covering the Patented Method. The first of these patents was filed on July 3, 1997, and issued on January 11, 2000, as U.S. Patent No. 6,012,457 ("the '457 Patent") entitled "DEVICE AND METHOD FOR FORMING A CIRCUMFERENTIAL BLOCK IN A PULMONARY VEIN." The Regents owns by assignment all rights, title and interest in the '457 Patent. A true and correct copy of the '457 Patent is attached hereto as Exhibit 3.

33. The Asserted Patents claim direct priority from the '457 Patent. More specifically, the '576 Patent is a continuation and the '283 Patent is a continuation-in-part of the '457 Patent.

34. The Asserted Patents disclose and claim the Patented Method, as demonstrated in representative claim 1 of the '283 Patent:

> A method for treating atrial arrhythmia in a patient, comprising:
>
> forming a circumferential conduction block in a circumferential region of tissue at a location where a pulmonary vein extends from an atrium in the patient,
>
> wherein the circumferential conduction block formed is continuous along the circumferential region of tissue, and
>
> wherein the circumferential conduction block is formed without contacting the tissue with an ablative fluid medium.

35. The Patented Method can be performed using a variety of devices and in either a surgical or a less-invasive catheterization procedure. The Patented Method has been adopted by surgeons and surgical device companies, as well as by EPs and electrophysiology device companies.

SJM'S KNOWLEDGE OF THE PATENTED METHOD AND ASSERTED PATENTS

36. By the early 2000s, the Patented Method claimed in the Asserted Patents had become recognized as the most effective means of treating atrial fibrillation and had become the essential element of all ablation procedures to treat AFib. In fact, all doctors in the United States that perform catheter ablation procedures to treat AFib perform the Patented Method and infringe the Asserted Patents, including representative claim 1 of the '283 Patent.

37. SJM was one of the largest manufacturers and distributors of cardiology-related devices by the early 2000s and had performed extensive market research on the procedures and equipment used to treat AFib. SJM was aware of the Asserted Patents and knew that the Patented Method was the universally-adopted procedure for treating AFib. Indeed, by no later than 2006, SJM was sponsoring medical symposia at which leading cardiologists taught the use of SJM Devices to perform the Patented Method. And, in 2008, SJM conducted a clinical study outside of the United States called "STAR-AF: Substrate Versus Trigger Ablation for Reduction of Atrial

Fibrillation Trial." This study recognized, evaluated, and confirmed the effectiveness of the Patented Method.

38. The Regents' Patents, and in particular the Asserted Patents, are widely cited in patent applications filed by SJM and numerous other medical device companies. According to the USPTO's database, the '457 Patent has been cited as relevant prior art in more than 460 patents and patent applications published before 2013. The asserted '283 Patent is cited in more than 350 published U.S. patents, and the asserted '576 Patent is cited in more than 100 published U.S. patents.

39. According to the USPTO's database, SJM itself cited the '457 Patent in more than 40 applications that resulted in issued patents, and SJM applied for and prosecuted at least 31 U.S. patent applications that cite one or both of the Asserted Patents as prior art. Thus, SJM maintains a thorough knowledge of all relevant facts, technologies, inventions, published research, and other developments relating to the Patented Method.

40. SJM also specifically discussed the Patented Method in its patent applications. For example, as set forth in the below reproduced excerpt from SJM's own U.S. Patent No. 6,984,232, SJM discussed the proposed efficacy of one of its claimed catheter inventions in performing the "advantageous" Patented Method of forming a circumferential block by forming a "circumferential lesion" either "at the ostium of one or more of the pulmonary veins or within one or more of the pulmonary veins," blocking the electric signals originating from the pulmonary veins from entering the left atrium:

> [I]t may be advantageous to produce a **circumferential lesion at the ostium of one or more of the pulmonary veins or within one or more of the pulmonary veins**. Desirably, such a **circumferential lesion would electrically isolate a pulmonary vein from the left atrium completely blocking stray signals from traveling down the pulmonary vein and into the left atrium**. (4:61-67 (emphasis added)).
>
> During use, the active region [of the claimed catheter] is directed into contact with, for example, the wall of a pulmonary vein. Upon energization, the virtual electrode

> creates a **continuous lesion on an inner wall of the pulmonary vein, thereby electrically isolating the pulmonary vein from the left atrium**.
> (Abstract (emphasis added)).

41. The Regents also provided SJM additional notice of the Asserted Patents. On February 1, 2016, The Regents advised SJM in writing regarding the concern that SJM Devices are being marketed and sold to doctors for use in practicing the Patented Method as claimed in the Asserted Patents. The Regents' letter (attached hereto as Exhibit 4) specifically identified the Asserted Patents, and explained that they cover the Patented Method, which "involve[s] the use of various energy sources . . . to ablate heart tissue in a circumferential pattern around the pulmonary vein, disrupting the erratic electric pulses that cause atrial fibrillation."

42. Accordingly, SJM had actual knowledge of the Asserted Patents and that the Asserted Patents cover the Patented Method at all relevant times.

SJM MAKES, PROMOTES AND SELLS A WIDE RANGE OF CATHETERS AND OTHER MEDICAL DEVICES THAT DOCTORS USE TO PERFORM THE PATENTED METHOD

43. During the relevant time period, SJM has marketed and sold multiple SJM Devices used by at least interventional cardiologists, EPs, and cardiothoracic surgeons, (collectively, "Doctors"), to perform the Patented Method in violation of the Asserted Patents. At all relevant times, SJM was aware that Doctors used SJM Devices to treat AFib and to perform the Patented Method.

44. SJM operates primarily in the United States, Europe and Asia Pacific. Upon information and belief, SJM employed approximately 16,000 people as of January 2015. SJM divides its business into several categories: Atrial Fibrillation; Heart Failure; Neuromodulation; Traditional Cardiac Rhythm Management; and Cardiovascular.

45. SJM's "Atrial Fibrillation" Division encompasses a wide range of products that SJM designs, promotes, and sells to treat AFib. SJM's total worldwide sales of AFib treatment devices and equipment have ranged from $710 million to $1.1 billion in each of the years 2010 through 2016. SJM has reported U.S. annual sales of its atrial fibrillation products as ranging from $411 million to $600 million annually over the same period.

46. When promoting SJM Devices for treatment of AFib, SJM understands, and the relevant medical community understands, that it is promoting the SJM Devices to be used specifically to perform the Patented Method. During the relevant time period, SJM has marketed and sold a number of ablation catheters specifically for use by Doctors to perform the Patented Method. These include, but are not limited to, the following:

- TactiCath Quartz Contact Force Ablation Catheter
- Cool Path Duo Ablation Catheters
- FlexAbility Ablation Catheter
- Safire BLU Duo Irrigated Ablation Catheters
- Therapy Ablation Catheters (various sizes)
- Therapy Bi-directional Ablation Catheters
- Therapy Cool Path Ablation Catheter (various sizes)
- Therapy Dual-8 Ablation Catheter

47. SJM has also marketed, advertised, and sold other types of SJM Devices to perform the Patented Method, including: navigational and mapping catheters, such as SJM's Reflexion High Density Mapping Catheter, Reflexion Spiral EP, and Inquiry AFocus II Double Loop catheters; related cardiac mapping and diagnostic equipment such as SJM's EnSite Mapping System, EnSite Velocity, NavX, Array, Derexi Integration Module, Ensite Contact Display, and MediGuide Integration; equipment such as radio frequency (RF) and other power generators that are coupled with the ablation catheters and supply the heat (or other energy) needed to ablate targeted cardiac tissue.

48. Additional SJM Devices used to perform the Patented Method include, but are not limited to, guiding catheters, catheter sheaths, access devices, and other complementary devices used by Doctors to perform the Patented Method.

49. Numerous SJM Devices, including many listed above, are specifically designed for and used by Doctors only in and as a material part of performing the Patented Method. With knowledge of the Asserted Patents, SJM has knowingly promoted such SJM Devices as specifically designed for the purpose of being used by Doctors in performing the Patented

Method. These particular SJM Devices, which have no substantial non-infringing uses, include but are not limited to:

- Mapping Catheters, including the Reflexion Spiral EP Catheters, the Reflexion Spiral Variable Radius Loop Bi-Directional Catheters, the Reflexion HD High Density Loop Bi-Directional Catheters, the Inquiry AFocus Catheters, the Inquiry AFocus II Catheters, the Inquiry AFocus II Double Loop Catheters, the Inquiry AFocus II EB Catheters, and the Inquiry Optima Catheters.
- Introducers, including the Agilis NxT Steerable Introducers, the Fast-Cath Guiding Introducer Swartz Reduced Radius SRR Series, and the Fast-Cath Guiding Introducers Swartz SR Series, the Swartz Braided Transseptal Guiding Introducers SL Series, and the Swartz Braided Transseptal Guiding Introducers LAMP Series.

50. In a 2010 shareholder presentation, Jane J. Song, then president of SJM's Atrial Fibrillation Division, explained that "[w]e have the broadest AF product portfolio in the industry," and that "[o]ur AF business includes all devices used in catheter procedures performed in the EP cath[eter] lab." The presentation included a "Key Product Overview" identifying the following SJM Devices, which were promoted by SJM to perform the Patented Method:

- Cardiographic Mapping Systems, including the EnSite Mapping System, the EnSite Velocity, the NavX, the Array, the Derexi Integration Module, the Ensite Contact Display, and the MediGuide Integration.
- Mapping Catheters, including the Reflexion HD, the Reflexion Spiral EP Catheters, and the Inquiry AFocus II Double Loop.
- Ablation Catheters, including the Safire BLU and Cool Path, the Safire BLU Duo and Cool Path Duo, the Cool Flex, and the Livewire.
- Access and guidance devices, including: Agilis NxT Steerable Introducer, Swartz Braided Left Atrial Multipurpose Transseptal Guiding Introducers.
- Complementary technologies, including SJM's Confirm Implantable Cardiac Monitor, the EP-WorkMate Recording System, and the EnSite Contact. Notably, one of the touted benefits of this device was its "[s]ignificant increase of first pass

pulmonary vein isolation."

51. Since 2010, SJM has updated and expanded its pre-existing lines of SJM Devices and has continued to develop, promote, market, and sell additional products for use in performing the Patented Method. These include:

- Additional cardio mapping systems, including the EnSite Precision mapping module.
- Additional diagnostic and mapping catheters, including the Inquiry Optima, the Reflexion Spiral Variable Radius, the Reflexion HD High Density, the ViewFlex, and the ViewMate.
- Ablation Catheters, including the TactiCath Quartz Contact Force; the FlexAbility.
- Access and Guidance devices, including the Fast-Cath Hemostasis Introducer.

52. At all relevant times, Doctors have used SJM Devices to perform the Patented Method in the United States in violation of the Asserted Patents. SJM has at all relevant times promoted, marketed, and advertised the SJM Devices to be used by Doctors to perform the Patented Method. SJM was aware of and intended Doctors to use the SJM Devices to specifically perform the Patented Method in violation of the Asserted Patents.

SJM'S INFRINGEMENT OF THE ASSERTED PATENTS

53. At all relevant times, SJM has induced and contributed to the infringement of the Asserted Patents. With actual knowledge of the Asserted Patents, SJM actively encouraged Doctors to use SJM Devices to perform the Patented Method with specific intent to infringe the Asserted Patents. With actual knowledge of the Asserted Patents, SJM sold SJM Devices that have no substantial non-infringing uses, contributing to the infringement of the Asserted Patents by Doctors.

54. SJM's intent to market and promote the SJM Devices to perform the Patented Method, and thus induce and contribute to the infringement of the Asserted Patents by Doctors, is highlighted by its 2010 statement to investors, explaining that "[a]fter heart failure, atrial fibrillation represents the largest unmet clinical need in cardiovascular medicine today. Significant opportunities exist . . . . We have the Broadest Product Portfolio in the industry and

are the best positioned company to address AFib market requirements." *See* Exhibit 5, relevant excerpts of SJM's 2010 Investor Presentation, at 119 (emphasis added).

Seminars and Tradeshows Using SJM Devices to Perform the Patented Method

55. Since as early as 2005, SJM has sponsored courses that teach the Patented Method. For example, SJM sponsors a course taught by Dr. Carlo Pappone, the Founder and Director of the Arrhythmology Academy at the San Raffaele University-Hospital in Milan, Italy (the "Academy"). The Academy is recognized for promoting and teaching advances in cardiac electrophysiology techniques through interactive discussions with the attending physicians, during meetings, lectures, and live procedure demonstrations performed by Dr. Pappone. The Academy's training programs are attended annually by medical professionals from around the world, including U.S.-based Doctors.

56. SJM sponsored its conferences at the Academy with the knowledge and intent that Dr. Pappone would teach doctors, during live procedure demonstrations, how to use SJM Devices to perform the Patented Method to treat patients with AFib. SJM intends its promotion of SJM Devices at these conferences to induce U.S. Doctors to use SJM Devices to practice the Patented Method in the United States.

57. SJM has frequently invited and sponsored U.S.-based Doctors to attend these seminars. In addition to maintaining its website, the Academy publishes a series of YouTube videos demonstrating how to use SJM Devices to perform the Patented Method. Upon information and belief, the production of these YouTube videos was paid for by SJM. A downloaded version of one such video is attached hereto on a DVD as Exhibit 6.

58. SJM has additionally sponsored a wide variety of medical professional trade shows, such as cardiology and electrophysiology conferences, to promote the use of SJM Devices to perform the Patented Method to Doctors.

59. SJM's sponsorship includes: paying lecture fees to encourage prominent speakers to teach Doctors how SJM Devices can be used to perform the Patented Method; renting booths and convention hall demonstration areas where SJM sales representatives network with Doctors and provide marketing materials that teach and promote the use of SJM Devices to perform the

Patented Method; and hosting invitation-only events or lectures extoling the use and benefits of SJM Devices for performing the Patented Method.

60. SJM sponsors and exhibits its SJM Devices at major U.S.-based conferences including the annual meetings of the American Heart Association, the Heart Rhythm Society, and the American College of Cardiology, as well as the Annual International Atrial Fibrillation Symposium. Several thousand Doctors attend these conferences, where they are introduced to SJM Devices and receive demonstrations, instructions, and promotional materials regarding the use of SJM Devices to perform the Patented Method.

61. SJM engages in the same promotion and teaching of the use of SJM Devices for performing the Patented Method at major cardiology conferences overseas, including annual meetings of the European Society of Cardiology and the CardioStim Conference held once every two years in either Nice, France or other cities. SJM is well aware that many U.S.-based Doctors attend these overseas conferences, and SJM intends its promotion of SJM Devices at these events to induce U.S. Doctors to use SJM Devices to practice the Patented Method in the United States. A downloaded version of one such video showing the promotion of SJM Devices to perform the Patented Method is attached hereto on a DVD as Exhibit 7.

62. Starting no later than 2010, SJM additionally offered and provided in-person training classes teaching Doctors to use SJM Devices to perform the Patented Method. Upon information and belief, SJM paid AFib experts to teach these training classes. One example of such class, paid for and promoted by SJM, was called "CAB Physician Training Seminar for Electrophysiologists." The specific purpose of this class was to teach advanced techniques that improve ablation procedure speed, proficiency, and clinical results.

63. By no later than 2013, SJM also opened the first of three U.S. teaching facilities to instruct Doctors how to use SJM Devices to perform the Patented Method. SJM opened one of these facilities in Sylmar, California. At these centers, SJM provides a "Virtual Reality Simulation" to teach Doctors how to perform "supraventricular ablation and transseptal procedures." SJM knows that the Patented Method is the primary known and commonly utilized "supraventricular ablation and transseptal procedure."

64. SJM also employs an extensive network of sales representatives who are trained to market SJM Devices to Doctors. Upon information and belief, SJM's sales representatives are taught about the Patented Method and are trained to demonstrate and otherwise promote SJM Devices as effective tools for performing the Patented Method through, for example, inviting Doctors to SJM-sponsored training programs, and the distribution of printed publications or other marketing materials.

SJM's Use of Medicare Reimbursement Guides to Promote the Use of SJM Devices to Perform the Patented Method

65. While SJM's customers such as Doctors, hospitals, or other individuals and entities purchase SJM Devices, they generally seek reimbursement from the patients' insurers or Medicare for the charged expense of performing the Patented Method to treat AFib. The reimbursed medical service fee includes charges for the SJM Devices used in the procedure, many of which are one-time use catheters costing in excess of one thousand dollars ($1,000.00).

66. In addition to its other promotional activities, SJM has provided its customers with reimbursement support for SJM Devices beginning as early as 2010. In particular, SJM has provided its customers a Medicare reimbursement guide for cardiac electrophysiology services, including for treatment of AFib. SJM's reimbursement billing guide provides Doctors with information on how to get reimbursed for performing the Patented Method under the Medicare billing code for "Comprehensive electrophysiologic evaluation . . . including treatment of atrial fibrillation by ablation by pulmonary vein isolation (PVI)." A copy of SJM's 2013 Hospital Reimbursement Guide is attached hereto as Exhibit 8.

67. In providing this reimbursement support, SJM specifically intends to and actively induces Doctors to use SJM Devices to perform the Patented Method in violation of the Asserted Patents.

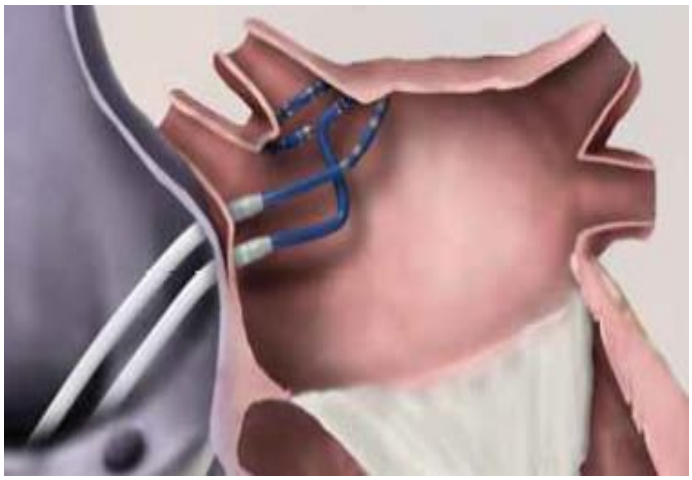
SJM's Use of Literature and Brochures to Promote SJM Devices to Perform the Patented Method

68. Promotion and marketing of SJM Devices to perform the Patented Method is further accomplished by providing literature and brochures to Doctors for their own education, or

for distribution to their patients. SJM routinely provides literature and brochures to Doctors to promote the use of SJM Devices to perform the Patented Method. These materials serve the dual purpose of reinforcing to Doctors that SJM Devices can be used to perform the Patented Method, and to encourage patients to ask Doctors about the use of SJM Devices to perform the Patented Method.

69. For example, beginning no later than 2008, SJM published and widely distributed through Doctors a patient-focused handbook teaching the use of catheter ablation to treat AFib. This handbook, a copy of which is attached here as Exhibit 9, demonstrated and promoted the use of certain SJM Devices to perform the Patented Method, using SJM's ablation catheters and a circular "mapping catheter," which is specifically for use in the performance of the Patented Method.

70. In particular, the handbook included the illustration shown below, which shows the use of a mapping and ablation catheter positioned to perform a circumferential lesion at a location where a pulmonary vein extends from the left atrium, as taught and claimed in the Asserted Patents. *See id.* at 9. SJM Devices, such as those shown below, are designed and used to perform the Patented Method.



Publication and Dissemination of Journal Articles and Other Materials Touting the Use of SJM Devices in Medical Studies

71. It is well understood by medical device manufacturers, such as SJM, that

sponsoring, promoting, and publicizing the fact and results of clinical trials in which their medical devices are used to perform a certain procedure is a very effective means of marketing the use of their medical devices to medical professionals and hospitals alike. Over the years, SJM has sponsored, promoted, and publicized numerous medical studies in which SJM Devices were used to perform the Patented Method, with the purpose and intent of specifically teaching and inducing Doctors to use the SJM Devices to perform the Patented Method in violation of the Asserted Patents.

72. As just one example, in August 2008, SJM sponsored and promoted a major study, not designed for submission to the FDA for approval, called the "STAR-AF: Substrate Versus Trigger Ablation for Reduction of Atrial Fibrillation Trial" ("STAR-AF"). The SJM Devices used in this study, and promoted by SJM for use in performing the Patented Method, were products already on the market in the United States. The SJM Devices included, but were not limited to, the SJM Ensite NavX, Therapy Cool Path, and Therapy Dual 8 devices. SJM's study confirmed the Patented Method's effectiveness in treating AFib.

73. SJM actively promoted its STAR-AF study and the use of its SJM Devices to perform the Patented Method to Doctors in numerous ways. For example, SJM released multiple news reports promoting this study, both on its website and directly to industry media. One news release from May 14, 2009, is attached hereto as Exhibit 10.

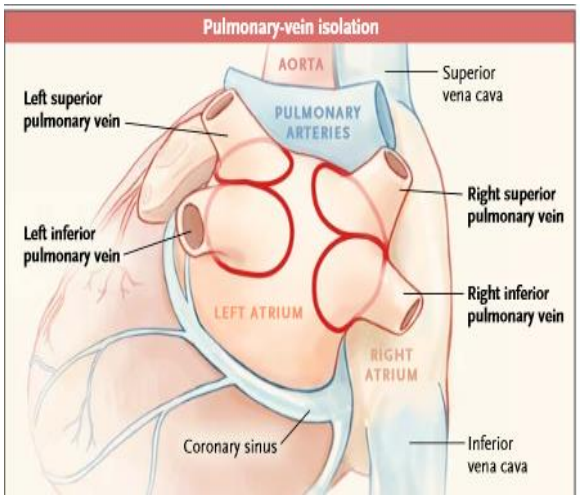
74. SJM also paid researchers to write and publish journal articles and abstracts which claimed that SJM Devices could be used to perform the Patented Method for effectively treating AFib. An example of one such journal article is attached hereto as Exhibit 11. Finally, SJM described the results of the STAR-AF study on its corporate website, a page of which is attached hereto as Exhibit 12. This website included a "Contact" link, encouraging visiting medical professionals to contact SJM representatives to discuss the study, learn more about the use of SJM Devices to perform the Patented Method, or purchase SJM Devices to perform the Patented Method.

75. Medical device manufacturers, including SJM, are actively involved in planning, editing, and approving journal articles before they are submitted to medical journals for

publication. The purpose of these reports, journal articles, abstracts, website promotions, and the presentations given at the medical conferences referenced above was to induce Doctors to use SJM's Devices to perform the Patented Method as claimed in the Asserted Patents. SJM thus specifically intended and encouraged Doctors to purchase SJM Devices and to use them to perform the Patented Method in violation of the Asserted Patents.

76. Before the STAR-AF study had concluded, SJM initiated and funded a second larger AFib treatment study, called the "STAR-AF II" study in November 2010. The stated purpose of the STAR-AF II study was to test the hypothesis that combining the Patented Method with more complex lesions would offer a higher success rate than the Patented Method alone, as SJM promoted the use of its devices on the web site clinical trials.gov, attached as Exhibit 13. As with the STAR-AF study, the researchers used multiple SJM Devices.

77. The STAR-AF II study concluded that the Patented Method was at least as effective alone in treating AFib as by adding additional lesion sets. SJM marketed this STAR-AF II study and its conclusions regarding the Patented Method's effectiveness at treating AFib by sponsoring multiple journal articles in industry-leading journals, examples of which are attached hereto as Exhibits 14 and 15. One article (Exhibit 14 at 3), included the below-reproduced illustration which depicts and promotes performance of the Patented Method using SJM Devices.



78. SJM similarly sponsored, paid for, and heavily promoted other clinical trials in which SJM Devices—that were already approved and on the market—were used to perform the

Patented Method. As with the STAR-AF and STAR-AF II studies, SJM has sponsored, published, or otherwise widely disseminated publications, "educational brochures," and multiple news reports both through its website and in medical industry media, thereby promoting its other studies and the use of SJM Devices to treat AFib using the Patented Method.

79. The purpose and effect of SJM's publications was to inform Doctors that they could and should use SJM Devices to perform the Patented Method to treat AFib. SJM knows and intends that Doctors reading these promotional materials at conferences and meetings will learn that SJM Devices are designed to perform the Patented Method. SJM thus induces Doctors to purchase and/or use SJM Devices to perform the Patented Method.

Promoting SJM Devices to Perform the Patented Method Through Product Catalogs and Labels

80. During the relevant time period, SJM further distributed a catalog of SJM Devices used to treat AFib. SJM's catalog is entitled "Atrial Fibrillation Division U.S. Product Catalog." The catalog lists all of the SJM Devices approved and on the market for use in the United States, and sold and offered for sale by SJM for treatment of AFib, *i.e.*, using the Patented Method.

81. SJM, as well as Doctors and other customers that used this catalog to make purchasing decisions, knew that the universally-adopted method to treat AFib using SJM Devices was the Patented Method. SJM published this catalog to the medical community with the knowledge and intent to induce Doctors to use the SJM Devices to perform the Patented Method.

82. In August 2013, SJM also acquired Endosense, which manufactured, promoted, and sold a tissue pressure-sensing ablation catheter called the TactiCath. SJM sought FDA approval for the TactiCath ablation catheter specifically for treatment of AFib. The FDA granted approval of the TactiCath in October 2014. The product's FDA-approved label specifically instructs Doctors that the TactiCath is approved for treatment of paroxysmal atrial fibrillation.

83. As alleged above, the Patented Method is the primary non-pharmacologic treatment for paroxysmal AFib. On its website, SJM advertises that one of the primary benefits of using the TactiCath ablation catheter is that it "[i]mprove[s] pulmonary vein (PV) isolation," *i.e.*, it is for use in performing the Patented Method. At all relevant times, SJM has actively and

intentionally promoted and advertised the use of the TactiCath, other SJM Devices, and related equipment to Doctors to be used according to and for infringement of the Patented Method.

84. SJM's marketing activities alleged herein were performed for the commercial purpose of selling SJM Devices, and were not reasonably related to the development and submission of information necessary to obtain regulatory approval from the FDA; nor were they directed to the collection of information or data necessary for filing an application with the FDA for approval to market any SJM Device. The SJM Devices were FDA approved and on sale in the United States before SJM engaged in its infringing activities, alleged herein, by marketing and promoting the SJM Devices with knowledge and intent that Doctors would use the SJM Devices to perform the Patented Method.

85. On February 1, 2016, The Regents wrote to SJM and advised it of The Regents' concern that SJM Devices were being marketed and sold to Doctors for use in practicing the Patented Method. SJM did not change its marketing or promotional practices. SJM waited until June 13, 2016, to provide a substantive response to The Regents' letter, at which time it wrongfully asserted that it was not promoting any SJM Devices for use in a manner that infringes the Asserted Patents.

COUNT I: INFRINGEMENT OF THE '283 PATENT

86. Plaintiff re-alleges here all of the allegations set forth in paragraphs 1-85 above.

87. At all relevant times, SJM had knowledge of the '283 Patent and the Patented Method.

88. SJM induces others to infringe and/or contributorily infringes one or more claims of the '283 Patent, either literally or under the doctrine of equivalents.

89. Claim 1 of the '283 Patent recites:

> A method for treating atrial arrhythmia in a patient, comprising:
>
> forming a circumferential conduction block in a circumferential region of tissue at a location where a pulmonary vein extends from an atrium in the patient,
>
> wherein the circumferential conduction block formed is continuous along the circumferential region of tissue, and

> wherein the circumferential conduction block is formed without contacting the tissue with an ablative fluid medium.

90. The use of SJM Devices by Doctors to perform the Patented Method on patients with AFib satisfies each and every limitation of claim 1 of the '283 Patent.

91. At all relevant times, SJM knowingly encouraged and intended Doctors to use SJM Devices to perform the Patented Method on patients who have been diagnosed with AFib, in violation of claim 1.

92. Upon information and belief, both by manufacturing SJM Devices to be used in a manner that SJM knows infringes the '283 Patent, and by encouraging Doctors and/or customers to use SJM Devices in a manner that SJM knows infringes the '283 Patent, SJM is inducing infringement of the '283 Patent by Doctors and/or customers in violation of 35 U.S.C. § 271(b). For example, SJM's marketing and promotional materials tout the use of SJM Devices to perform the Patented Method within the scope of at least claim 1 of the '283 Patent.

93. A subset of SJM Devices sold by SJM, as set forth in paragraph 49, are material to performing the Patented Method, according to claim 1 of the '283 Patent.

94. This subset of SJM Devices is not a staple article, commodity of commerce, or suitable for substantial non-infringing uses. Moreover, by its actual knowledge of the '283 Patent, SJM knew that a subset of SJM Devices are especially made or especially adapted for use in a manner that infringes the '283 Patent. Accordingly, SJM's sale of the subset of SJM Devices set forth in paragraph 49 contributes to the infringement of the '283 Patent by Doctors and/or customers in violation of 35 U.S.C. § 271(c).

95. SJM has profited and will continue to profit from its infringement of the '283 Patent.

96. SJM's infringement of the '283 patent has caused and will continue to cause The Regents substantial monetary harm, for which The Regents is entitled to receive compensatory damages in an amount to be determined at trial, but in no event less than a reasonable royalty.

97. Further, SJM's infringement of the '283 Patent has been willful, deliberate, and with full knowledge that the use of SJM Devices infringes the '283 Patent, justifying an increase

in the damages to be awarded to The Regents up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

98. SJM's willful infringement of the '283 Patent, among other actions, renders this an exceptional case, justifying the award to The Regents of its reasonable attorney fees, in accordance with 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '576 PATENT

99. Plaintiff re-alleges here all of the allegations set forth in paragraphs 1-98 above.

100. At all relevant times, SJM had knowledge of the '576 Patent and the Patented Method.

101. SJM induces others to infringe and/or contributorily infringes one or more claims of the '576 Patent, either literally or under the doctrine of equivalents.

102. Claim 12 of the '576 Patent recites:

> A method for treating atrial arrhythmia in a heart of a patient, wherein the patient includes a plurality of pulmonary veins and each pulmonary vein extends from a unique location in an atrium of the heart, the method comprising:
>
> ablating a first ablation lesion that substantially circumscribes only one of the locations; and
>
> ablating a second ablation lesion that substantially circumscribes only a different one of said locations.

103. The use of SJM Devices by Doctors to perform the Patented Method on patients with AFib satisfies each and every limitation of claim 12 of the '576 Patent.

104. At all relevant times, SJM knowingly encouraged and intended Doctors to use SJM Devices to perform the Patented Method on patients who have been diagnosed with AFib, in violation of claim 12.

105. Upon information and belief, both by manufacturing SJM Devices to be used in a manner that SJM knows infringes the '576 Patent, and by encouraging Doctors and/or customers to use the SJM Devices in a manner that SJM knows infringes the '576 Patent, SJM is inducing infringement of the '576 Patent by Doctors and/or customers in violation of 35 U.S.C. § 271(b). For example, SJM's marketing and promotional materials tout the use of SJM Devices to perform

the Patented Method within the scope of at least claim 12 of the '576 Patent.

106. A subset of SJM Devices sold by SJM, as set forth in paragraph 49, are material to performing the Patented Method, according to claim 12 of the '576 Patent.

107. This subset of SJM Devices is not a staple article, commodity of commerce, or suitable for substantial non-infringing uses. Moreover, by its actual knowledge of the '576 Patent, SJM knew that a subset of SJM Devices are especially made or especially adapted for use in a manner that infringes the '576 Patent. Accordingly, SJM's sale of the subset of SJM Devices set forth in paragraph 49 contributes to infringement of the '576 Patent by Doctors and/or customers in violation of 35 U.S.C. § 271(c).

108. SJM has profited and will continue to profit from its infringement of the '576 Patent.

109. SJM's infringement of the '576 Patent has caused and will continue to cause The Regents substantial monetary harm, for which The Regents is entitled to receive compensatory damages in an amount to be determined at trial, but in no event less than a reasonable royalty.

110. Further, SJM's infringement of the '576 Patent has been willful, deliberate, and with full knowledge that the use of SJM Devices infringes the '576 Patent, justifying an increase in the damages to be awarded to The Regents up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

111. SJM's willful infringement of the '576 Patent, among other actions, renders this an exceptional case, justifying the award to The Regents of its reasonable attorney fees, in accordance with 35 U.S.C. § 285.

PRAYER FOR RELIEF

Wherefore, The Regents of the University of California respectfully requests that the Court enter a judgment as follows:

A. That SJM has infringed the Asserted Patents;

B. Awarding The Regents damages, including enhanced damages, pursuant to 35 U.S.C. § 284, for SJM's infringement of the Asserted Patents, in an amount to be determined at trial, but in no event less than a reasonable royalty;

C. Awarding The Regents pre-judgment and post-judgment interest to compensate The Regents for the damages it has sustained;

D. Awarding The Regents all of its costs and disbursements incurred in bringing this action;

E. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding The Regents its reasonable attorney fees, costs, and expenses; and

F. Awarding The Regents any further relief the Court deems just and proper.

Dated: October 26, 2016

Respectfully submitted,

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DEMAND FOR JURY TRIAL

The Regents of the University of California hereby requests a trial by a jury on all issues so triable.

Dated: October 26, 2016

Respectfully submitted,

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