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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. BOSTON SCIENTIFIC CORPORATION, a Delaware Corporation, Defendant.	Case No. 3:16-cv-06266 **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 Boston Scientific Corporation, a Delaware corporation ("BSC" 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 electrical 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 directed to the Patented Method, prosecuted by and on behalf of The Regents, including the two patents asserted

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

6. BSC 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," and other similar terms.

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

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

9. BSC 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 BSC Devices to perform the Patented Method. Moreover, BSC has actively induced, and continues to induce, medical professionals to use BSC 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 makes 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 BSC is a Delaware Corporation, with corporate headquarters in Marlborough, Massachusetts, 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 BSC because BSC's contacts with the State of California are significant and pervasive, and because BSC's contacts with California, as described in this Complaint, directly give rise to this dispute. BSC has multiple manufacturing facilities and offices in California, including at least one within this District, located in San Jose, San Jose County.

14. BSC 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 BSC Devices that are the subject of this action, throughout California. In doing so, BSC 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 BSC.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b) at least because BSC 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 electrical 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 development of the surgical procedures described above, doctors began to use catheters to ablate cardiac tissue to treat a variety of 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 electrical 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.

BSC'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 AFib 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. BSC was at all relevant times one of the largest manufacturers and distributors of cardiology-related devices, including devices used to treat AFib according to the Patented Method, and had performed extensive market research on the procedures and equipment used to treat AFib. BSC 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, BSC was sponsoring medical symposia at which leading cardiologists taught the use of BSC Devices to perform the Patented Method.

38. The Regents' Patents, and in particular the Asserted Patents, are widely cited in patent applications filed by BSC 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, BSC directly and through its wholly-owned subsidiary Boston Scientific Scimed, Inc., cited the '457 Patent in at least 49 patent applications. BSC directly and through its wholly-owned subsidiaries applied for and prosecuted at least 68 patent applications that cite one or both of the Asserted Patents as prior art. Thus, BSC maintains a thorough knowledge of all relevant facts, technologies, inventions, published research, and other developments relating to the Patented Method.

40. BSC also specifically discussed the Patented Method in its patent applications. For example, as set forth in the below reproduced excerpt from BSC's own U.S. Patent No. 7,435,248, BSC discussed the proposed utility of one of its claimed catheter inventions and confirmed that the Patented Method successfully isolated the pulmonary vein:

> One lesion that has proven to be difficult to form with conventional devices is the **circumferential lesion that is used to isolate the pulmonary vein and cure ectopic atrial fibrillation**. Lesions that isolate the pulmonary vein may be formed within the pulmonary vein itself or in the tissue surrounding the pulmonary vein. **Ablation of pulmonary veins is currently performed by placing a diagnostic catheter (such as . . . Boston Scientific Corporation's Constellation TM ECG catheter**) into the pulmonary vein to be treated, and then ablating the pulmonary tissue adjacent to the distal end of the selected diagnostic catheter with a standard, commercially available ablation catheter. The diagnostic catheter is used to determine if the lesion created by the ablation catheter has been successful in electrically isolating the pulmonary vein. (1:64-2:12 (emphasis added)).

41. The Regents also provided BSC additional notice of the Asserted Patents. On February 1, 2016, The Regents advised BSC in writing that BSC Devices were 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 informed BSC 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[al] pulses that cause atrial fibrillation."

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

BSC 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, BSC has marketed and sold multiple BSC Devices used by at least interventional cardiologists, EPs, and cardiothoracic surgeons, to perform the Patented Method in violation of the Asserted Patents. At all relevant times, BSC was aware that Doctors used BSC Devices to treat AFib and to perform the Patented Method.

44. BSC operates primarily in the United States, Europe and Asia Pacific. Upon information and belief, BSC employed approximately 25,000 people as of October 2016. BSC divides its business into several categories, including Cardiovascular, and Rhythm Management (which includes the sale of BSC Devices for treatment of AFib).

45. BSC's Electrophysiology Division, which is part of BSC's Rhythm Management division, encompasses a wide range of products that BSC designs, promotes, and sells to treat AFib. BSC's total worldwide sales of AFib treatment devices and equipment have ranged from $147 million to $248 million in each of the years 2010 through 2016.

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

- **Ablation Catheters**, including but not limited to: Blazer Temperature Ablation Catheter, Blazer Prime Temperature Ablation Catheter, Blazer II Temperature Ablation Catheter, Chilli II Cooled Ablation Catheter, and IntellaTip MiFi XP

Temperature Ablation Catheter.

- **Diagnostic Catheters**, including but not limited to: Blazer Dx-20 Bidirectional Duodecapolar Diagnostic Catheter, Polaris X Steerable Diagnostic Catheter, SteeroCath-Dx Bi-Directional Steerable Diagnostic Catheter, Woven Diagnostic Catheter Fixed Curve, WovenFlexie Diagnostic Catheter Fixed Curve, Viking / Viking Soft Tip Diagnostic Catheter Fixed Curve, Tango Stabilene Diagnostic Catheter Fixed Curve, Dynamic XT Diagnostic Catheter Steerable, Dynamic Tip Diagnostic Catheter Steerable, EP XT Diagnostic Catheter Steerable, Orbiter ST Diagnostic Catheter Steerable, and Radia Diagnostic Catheter Bidirectional Steerable.
- **Access Catheters**, including but not limited to: Zurpaz 8.5f Steerable Sheath, Direx Steerable Sheath, Channel Steerable Sheath, and TSX Transseptal Delivery System.
- **Mapping Catheters**, including but not limited to: Constellation Full Contact Mapping Catheter, and Orbiter PV Variable Loop Mapping Catheter.
- **Mapping Software**, including but not limited to: Rhythmia Mapping System.
- **Ablation Generators**, including but not limited to: Metriq Pump Cardiac Ablation System, and Maestro 4000 Cardiac Ablation System.

47. Numerous BSC Devices, including many listed above, are specifically designed for and used by Doctors only as a material part of performing the Patented Method. With knowledge of the Asserted Patents, BSC has knowingly promoted such BSC Devices as specifically designed for the purpose of being used by Doctors to perform the Patented Method. These particular BSC Devices, which have no substantial non-infringing uses, include but are not limited to:

- **Access Catheters**, including but not limited to: Zurpaz 8.5f Steerable Sheath, Direx Steerable Sheath, and TSX Transseptal Delivery System.
- **Mapping Catheters**, including but not limited to: Orbiter PV Variable Loop Mapping Catheter.

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

BSC'S INFRINGEMENT OF THE ASSERTED PATENTS

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

Seminars and Tradeshows Using BSC Devices to Perform the Patented Method

50. Since as early as 2005, BSC has sponsored courses that teach the Patented Method. For example, BSC 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.

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

52. BSC 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 perform the Patented Method. Upon information and belief, the production of these YouTube videos was paid for by BSC. A downloaded version of one such video on a DVD is attached hereto as Exhibit 5.

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

54. BSC's sponsorship includes: paying lecture fees to encourage prominent speakers to teach Doctors how BSC Devices can be used to perform the Patented Method; renting booths and convention hall demonstration areas where BSC sales representatives network with Doctors and provide marketing materials that teach and promote the use of BSC Devices to perform the Patented Method; and hosting invitation-only events or lectures extolling the use and benefits of BSC Devices for performing the Patented Method.

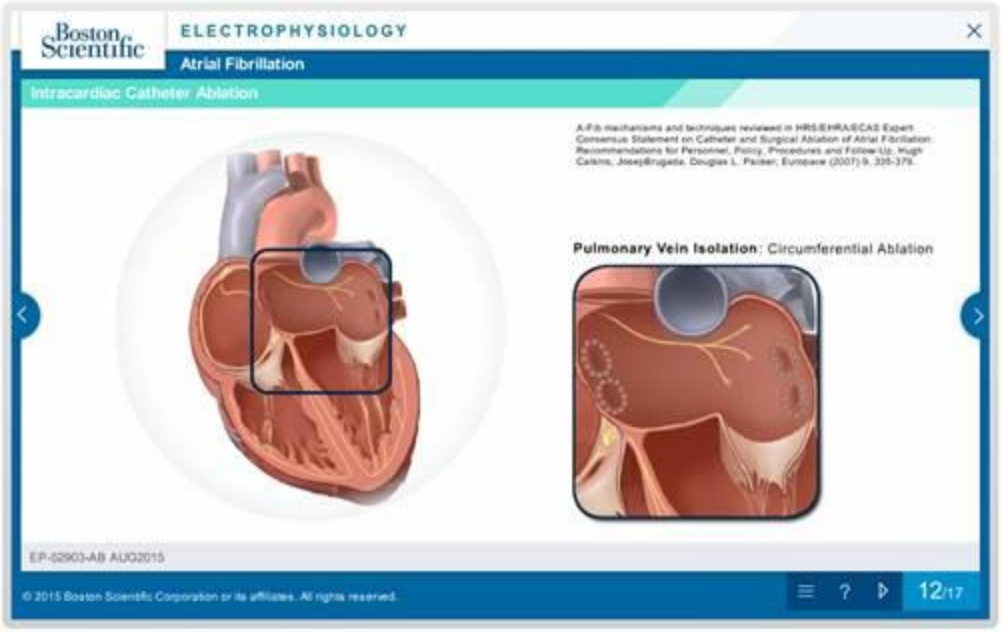
55. BSC promotes and exhibits its BSC Devices at major U.S.-based conferences including the annual meetings of the American Heart Association, the Heart Rhythm Society, the American College of Cardiology, and the Annual International Atrial Fibrillation Symposium. Several thousand Doctors attend these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

56. For example, one brochure BSC distributed at the Heart Rhythm Society's annual meeting in San Francisco, attached hereto as Exhibit 6, teaches Doctors to use the BSC Rhythmia mapping system, BSC's Intellatip MiFi (MicroFidelity) ablation catheter, and BSC's Orion diagnostic catheter to perform the Patented Method to treat AFib. The brochure concludes that "[u]sing the Rhythmia™ mapping system to perform AFib ablation is an effective, rapid way ***to aid in PVI*** . . . Because the Orion™ catheter basket can be collapsed and expanded, it can navigate into [Pulmonary Vein] branches as easily as a standard ablation catheter." *Id*. at 10 (emphasis added).

57. BSC engages in the same promotion and teaching of the use of BSC 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 Nice, France, or other cities. BSC is well aware that many U.S.-based Doctors attend these overseas conferences, and BSC intends its promotion of BSC Devices at these events to induce U.S. Doctors to use BSC Devices to practice the Patented Method in the United States.

58. BSC further offers live and web-based training programs that teach Doctors to use the BSC Devices to perform the Patented Method. For example, the following illustration is from a video course directed at "allied health professionals" that depicts the circumferential lesions formed after an EP performs the Patented Method. The course begins by teaching the health professionals why AFib is harmful, what causes AFib, and concludes by teaching how to treat AFib using the Patented Method, which is the primary treatment for AFib.



59. BSC operates at least one U.S. teaching facility in St. Paul, Minnesota, at which it instructs Doctors how to use BSC Devices to perform the Patented Method. According to BSC's promotional material, attached hereto as Exhibit 7, BSC provides a "unique and customized learning experience" at this facility, one that is "customized to the learning needs of the physician," "focus[es] on the safe and effective use of Boston Scientific products" in "a fully functional cath[eter] lab," and teaches Doctors how to perform "transseptal procedures" and "safe

septal crossing." *Id*. BSC knows that the Patented Method is the primary known and commonly utilized "transseptal procedure." BSC actively encourages Doctors to contact BSC sales representatives to set up trainings at this and its other educational facilities.

60. BSC trains its extensive network of sales representatives to market BSC Devices to Doctors. Upon information and belief, BSC's sales representatives are taught about the Patented Method and are trained to demonstrate and otherwise promote BSC Devices as effective tools for performing the Patented Method through, for example, distribution of printed publications or other marketing materials, and by providing invitations to BSC sponsored training programs. In a Securities and Exchange Commission filing, BSC stated that it develops highly knowledgeable and dedicated sales representatives to foster "collaborative relationships" with physicians. In addition to sales representatives who work directly with doctors, BSC also has a dedicated corporate sales organization in the U.S., focused principally on selling BSC Devices to major buying groups and integrated healthcare networks. These sales teams teach and promote the use of BSC Devices to perform the Patented Method.

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

61. While BSC's customers such as Doctors, hospitals, major buying groups, or integrated healthcare networks purchase BSC Devices, they generally seek reimbursement from the patients' insurers or Medicare for both the BSC Devices and for performing the Patented Method to treat AFib. The reimbursed medical service fee includes charges for the BSC Devices used in the procedure, many of which are one-time use catheters costing in excess of one thousand dollars ($1,000.00).

62. In addition to its other promotional activities, BSC has provided its customers with reimbursement support for BSC Devices used in performing the Patented Method, beginning as early as 2010. In particular, BSC has provided its customers a Medicare reimbursement guide for cardiac electrophysiology services, including for treatment of AFib. BSC's reimbursement billing guide, pertinent pages of which are attached hereto as Exhibit 8, provides Doctors with information on how to get reimbursed for performing the Patented Method under the Medicare

billing code for "[c]omprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia . . . with ***intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation***." *Id*. at 4 (emphasis added).

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

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

64. Promotion and marketing of medical devices for performing the Patented Method also is accomplished through literature and brochures provided to Doctors for their own education or for distribution to their patients. BSC routinely provides such materials to Doctors to promote the use of BSC Devices to perform the Patented Method. These materials serve the dual purpose of reinforcing to Doctors that BSC Devices can be used to perform the Patented Method, and to encourage patients to ask Doctors about the use of BSC Devices to perform the Patented Method.

65. For example, beginning no later than 2009, BSC published and widely distributed, through Doctors, a patient-focused handbook called "Understanding Atrial Fibrillation, a guide for patients," attached hereto as Exhibit 9, which teaches patients that the Patented Method is a treatment for AFib and tells the patient to ask their doctor for more information. *Id*.

BSC's Use of Press Kits to Promote BSC Devices to Perform the Patented Method

66. BSC has created and disseminated press kits which advertise the use of BSC Devices to perform the Patented Method. For example, in 2014, BSC published a media press kit, attached hereto as Exhibit 10, stating that "Catheter ablation is the first-line treatment for tachycardias," that the "European Society of Cardiology Guidelines recommend catheter ablation therapy as an alternative to medication for first-line treatment of rhythm control in certain patients with AF," and that "atrial fibrillation is the most common cardiac arrhythmia." *Id*. This press kit further extols BSC Devices, including BSC's mapping systems and ablation catheters, for treating atrial fibrillation, i.e., for performing the Patented Method. In addition to distributing this press

kit to media sources, BSC published the press kit on its corporate website.

67. BSC's marketing activities alleged herein were performed for the commercial purpose of selling BSC 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 BSC Device. The BSC Devices were FDA approved and on sale in the United States before BSC engaged in its infringing activities, alleged herein, by marketing and promoting the BSC Devices with knowledge and intent that Doctors would use the BSC Devices to perform the Patented Method.

68. On February 1, 2016, The Regents wrote to BSC and advised it of The Regents' concern that BSC Devices were being marketed and sold to Doctors for use in practicing the Patented Method. BSC did not change its marketing or promotional practices, but instead falsely asserted that BSC does not market, instruct, or encourage Doctors to use BSC Devices for performing pulmonary vein isolation.

COUNT I: INFRINGEMENT OF THE '283 PATENT

69. Plaintiff re-alleges here all of the allegations set forth in paragraphs 1-68 above.

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

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

72. 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.

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

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

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

76. A subset of BSC Devices sold by BSC, as set forth in paragraph 47, are material to performing the Patented Method, according to claim 1 of the ’283 Patent.

77. This subset of BSC Devices is not a staple article or commodity of commerce, suitable for substantial non-infringing uses. Moreover, by its actual knowledge and having been put on notice of the ’283 Patent, BSC knew that a subset of the BSC Devices are especially made or especially adapted for use in a manner that infringes the ’283 Patent. Accordingly, BSC’s sale of the subset of BSC Devices set forth in paragraph 47 contributes to infringement of the ’283 Patent by Doctors and/or their customers in violation of 35 U.S.C. § 271(c).

78. BSC has profited and will continue to profit from its infringement of the ’283 Patent.

79. BSC’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.

80. Further, BSC’s infringement of the ’283 Patent has been willful, deliberate, and with full knowledge that the use of BSC 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.

81. BSC'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

82. Plaintiff re-alleges here all of the allegations set forth in paragraphs 1-81 above.

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

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

85. 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.

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

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

88. Upon information and belief, both by manufacturing BSC Devices to be used in a manner that BSC knows infringes the '576 Patent, and by encouraging Doctors and/or customers to use the BSC Devices in a manner that BSC knows infringes the '576 Patent, BSC is inducing infringement of the '576 Patent by Doctors and/or customers in violation of 35 U.S.C. § 271(b). For example, BSC's marketing and promotion materials tout the use of BSC Devices to perform the Patented Method that falls within the scope of claim 12 of the '576 Patent.

89. At all relevant times, the BSC Devices were material to performing

circumferential PVI ablation according to the Patented Method. A subset of BSC Devices sold by BSC, as set forth in paragraph 47, are material to performing the Patented Method, according to claim 12 of the '576 Patent.

90. This subset of BSC Devices is not a staple article or commodity of commerce, suitable for substantial non-infringing uses. Moreover, by its actual knowledge and having been put on notice of the '576 Patent, BSC knew that a subset of the BSC Devices are especially made or especially adapted for use in a manner than infringes the '576 Patent. Accordingly, BSC's sale of the subset of BSC Devices set forth in paragraph 47 contributes to the infringement of the '576 Patent by Doctors and/or their customers in violation of 35 U.S.C. § 271(c).

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

92. BSC'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.

93. Further, BSC's infringement of the '576 Patent has been willful, deliberate, and with full knowledge that the use of BSC 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.

94. BSC'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 BSC has infringed the Asserted Patents;

B. Awarding The Regents damages, including enhanced damages, pursuant to 35 U.S.C. § 284, for BSC'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.

Respectfully submitted,

DATED: October 28, 2016

CROWELL & MORING LLP

By: */s/ Mark T. Jansen*

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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.

Respectfully submitted,

DATED: October 28, 2016

CROWELL & MORING LLP

By: */s/ Mark T. Jansen*

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