

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

ORBUSNEICH MEDICAL CO. LTD., BVI,  
and ORBUSNEICH MEDICAL, INC.

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION

Defendant.

No. 1:09-CV-10962 (RGS)

JURY TRIAL DEMANDED

Leave to File Granted on August 31, 2011

**FOURTH AMENDED COMPLAINT**

Plaintiffs OrbusNeich Medical, Co. Ltd., BVI and OrbusNeich Medical, Inc., through its attorneys, Kelley Drye & Warren LLP, bring this action against defendant Boston Scientific Corporation (“BSC” or “Defendant”) and request a jury trial on all issues so triable. Orbus alleges as follows, upon personal knowledge with respect to its own acts, and upon information and belief, with respect to the circumstances and acts of others.

**PARTIES**

1. Plaintiff OrbusNeich Medical, Inc. (“Orbus Medical”) is a Delaware corporation with its principal place of business located at 5363 N.W. 35<sup>th</sup> Avenue, Ft. Lauderdale, Florida 33309. Orbus Medical is the owner of the patents at issue in this complaint, U.S. Patent No. 7,329,277, U.S. Patent No. 6,821,292, U.S. Patent No. 7,682,384, U.S. Patent No. 7,942,922 and U.S. Patent No 7,967,852 (collectively, the “Orbus Patents”).

2. Plaintiff OrbusNeich Medical Co. Ltd., BVI (“Orbus BVI”) is the beneficial owner of certain contract rights under the Confidential Disclosure Agreement (“CDA”) entered into between BSC and Orbus Medical Technologies, Inc., the predecessor-in-interest of Orbus Medical. Plaintiff Orbus Medical is a wholly-owned subsidiary of Orbus BVI. Plaintiffs Orbus

Medical and Orbus BVI are sometimes referred to collectively as “Orbus” or “Plaintiffs” for ease of reference.

3. Defendant BSC is a Delaware corporation, with its principal place of business located at One Boston Scientific Place, Natick, Massachusetts 01760.

### **JURISDICTION AND VENUE**

4. This is an action for infringement of the Orbus Patents, arising under the Patent Laws of the United States, 35 U.S.C. § 271, *et. seq.*; and for breach of written contract and breach of the implied covenant of good faith and fair dealing arising from BSC’s breach of the CDA as alleged herein. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this district under 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

6. This Court has personal jurisdiction over BSC because, *inter alia*, BSC has its headquarters and principal place of business and is authorized to and engages in continuous and systematic business activities in this judicial district.

### **FACTUAL BACKGROUND**

7. Orbus is an innovator in the field of luminal stent technology. Orbus has developed luminal stents that are commercially available in many countries throughout the world. Orbus is best known for a novel stent-based tissue engineering technology, which is used to treat coronary artery disease by promoting the body’s natural healing response and allowing the restoration of a diseased coronary vessel. Orbus has also invented a number of stent designs that have improved, *inter alia*, the mode of deployment and radial strength of Orbus’ stents. Orbus’ stent design innovations are critical to the success of its medical device business.

8. BSC is one of the largest manufacturers of intravascular stents in the world, and its annual sales of such stents in the United States amount to many billions of dollars.

9. Orbus is a comparatively small player in the worldwide luminal stent business. Nonetheless Orbus, due to the excellence of its product research and development, has introduced innovative luminal stents that are winning an ever growing share of the intravascular stent market. Because the product development and FDA approval process for stents is so lengthy and expensive, medical device manufacturers, like Orbus, strive to protect their stent technology and designs, *inter alia*, through obtaining patent protection.

***Orbus' Proprietary Stent Technology and Designs***

10. Coronary (heart) arteries are shaped like hollow tubes through which blood can flow freely. Coronary heart disease or atherosclerosis is the narrowing or blocking of the coronary arteries due to the buildup of tissue, fat and plaque on the interior artery walls, which restricts the flow of blood containing oxygen to the heart.

11. "Lumen" is the technical term for the space in the interior of a tubular structure such as an artery or a vein. A stent is a small mesh or coil tube that is inserted in an artery or vein and acts as a scaffold that supports and holds it open. Luminal stents are used for a variety of medical purposes, including the treatment of coronary artery disease. One type of luminal stent is inserted using an angioplasty balloon catheter as a delivery system into coronary arteries at the target site. Once in place, the balloon is inflated and the stent is expanded or deployed to a determined size within the artery to hold it open and to maintain blood flow to the heart. The balloon is deflated and removed and the stent stays in place permanently.

12. Luminal stents are regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 396, *et seq.* Luminal stents are regulated as Class III medical devices, which are subject to the most stringent FDA controls.

13. Each stent design has its own unique geometric and mechanical properties. In order for luminal stents to be clinically acceptable, the stents must meet certain mechanical performance criteria. One such requirement is that a luminal stent must be at least partially flexible in its collapsed or crimped state, so that the stent may be threaded through the arterial system to the treatment site. Another desirable mechanical property sought in stent design is minimal recoil after deployment.

14. It is also important for a stent to have a geometrical structure that allows for controllable foreshortening (the difference between the crimped or mounted length and the actual length of a stent after deployment) when the stent is deployed and expanded. The stent structure must also provide stent scaffolding and radial strength after the stent has been expanded to support and mechanically augment the luminal wall strength of a diseased blood vessel. Without adequate vascular scaffolding, vessel repair may be inadequate.

15. “Crimpability” is also an important aspect of stent design. Stents are deployed with functional delivery devices such as balloon catheters. “Crimpability” refers to the ability of the stent to be crimped onto the delivery balloon catheter uniformly eliminating manufacturing rejects. Minimizing the outer diameter of the crimped stent enhances its ability to cross narrow and contorted blood vessels, as well as to navigate through diseased or compromised vascular anatomy.

16. “Conformability” is a geometric design feature that assures a stent, once deployed, mimics the natural curvature of the artery by conforming to the geometry of the blood vessel in which it has been inserted. This ability to re-scaffold the artery, while at the same time maintaining its natural centerline, are features of stent geometry that help to reduce the amount of trauma caused by the stent during placement.

17. In sum, recoil, controllable “foreshortening,” crimped flexibility, and conformability, as well as scaffold to vessel wall ratio, expanded flexibility, and radial strength of the stent upon deployment are all crucial features of stent design. The difficulty of designing stents meeting all of these mechanical and geometric requirements is greatly increased by the fact that the stent must be delivered in a radically constrained or collapsed configuration.

18. Stent design is, therefore, a very complex matter requiring skill, engineering prowess, and substantial experimentation after a particular design is first conceptualized. It is also costly to develop and commercialize stent technologies for the same reasons.

19. Because of the aforesaid difficulties, relatively few stent designs ever successfully make the leap from the drawing board to the marketplace.

20. Manufacturers of stents typically market and promote their stents to health care professionals based upon the design features of their particular stent platform. Such marketing is done because stent manufacturers know that the design features of their stents are important to the interventional cardiologists and radiologists who will decide whether or not to recommend a particular type of stent to their patients.

21. Manufacturers of stents, such as BSC and Orbus, almost invariably seek patent protection for the design of their stents, because of the substantial investment both in time and money that each such new stent represents.

22. It normally takes years for the FDA to approve a new stent design. The quicker a manufacturer can conceptualize and develop a new stent design and complete the research and clinical trials necessary to secure the approval of FDA to introduce that new stent into the U.S. marketplace, the sooner that manufacturer will recoup its costs and start earning a profit.

23. It is difficult to obtain FDA approval of stent designs. Accordingly, knowledge of the results of animal research and clinical trials conducted abroad concerning a particular stent design is quite valuable as the lessons learned from prior clinical research may significantly shorten the time and expense needed to obtain FDA approval for sale of a new or improved stent design in the United States.

***Orbus Provided its Highly Confidential and Proprietary Stent Design and Product Information to BSC in Strict Confidence for the Limited Purpose of Enabling BSC to Evaluate Possible Future Mutually Advantageous Business Arrangements Between BSC and Orbus***

24. Starting in early 2000, Orbus executives had several meetings at BSC's headquarters in Natick, Massachusetts with BSC's top management. The purpose of these meetings was to explore whether BSC would be interested in commercially exploiting Orbus' confidential and proprietary stent technology, including, without limitation, buying or licensing that stent technology or investing in such technology or other similar mutually beneficial business arrangement with Orbus.

25. To facilitate these discussions and to enable BSC to obtain access to Orbus' confidential and proprietary technical information concerning Orbus' stents, including Orbus' coronary R stent platform and other stent related products (hereinafter: "Orbus Proprietary Stent Information"), Orbus and BSC negotiated and entered into the CDA, a true and correct copy of which is attached as Ex. A.

26. The negotiations leading up to the execution of the CDA were conducted between Orbus and BSC's Massachusetts-based management team, which included, among others, BSC's Vice President of Business Development and its Vice President and Assistant General Counsel. Orbus was ultimately induced to enter into the CDA based on the repeated assurances of confidentiality provided to Orbus by BSC's Massachusetts-based management team that were

then explicitly reiterated in the CDA itself. Because of this Massachusetts nexus, the CDA contained a choice of law clause which expressly provided that the CDA is “governed by the laws of the Commonwealth of Massachusetts, USA, without regard for the conflicts of law provisions.” (*See* Exhibit A, page 2).

27. BSC agreed in the CDA that BSC would use any Orbus Proprietary Stent Information disclosed to BSC “ ... solely for purposes of evaluating the mutual interests of the Parties in the Project” and that BSC would not distribute, disclose or use any Orbus Proprietary Stent Information except as expressly permitted by the CDA. (*See* Exhibit A, pages 1-2)

28. Orbus, relying upon the CDA and the presumed integrity of BSC’s management team, subsequently provided BSC with the Orbus Proprietary Stent Information, which included, *inter alia*, non-publicly disclosed stent samples, manufacturing techniques and other non-public information, experimental data, know-how, and show-how concerning certain coronary and peripheral stents exhibiting the designs seen in the later issued Orbus Patents, as well as providing information related in part to Orbus’ biliary/peripheral product portfolio.

29. After the CDA was signed, further work by Orbus led it to make a significant change in its coronary peripheral stent design to improve its mechanical properties. This change and the reasons for it were disclosed to BSC under the CDA. Orbus also provided BSC with samples of Orbus’ improved coronary peripheral and ePTFE covered SVG stents. Orbus’ labels identified the samples as proprietary pursuant to the CDA and specifically stated the sample stents were “for demonstration purposes only” and were “in no way to be evaluated [by BSC] for material composition, construction or design.”

30. The advantages of Orbus’ stent structures, the nature of the materials best suited for forming the most advantageous stent geometries, and the methods for making those stent

structures were all disclosed to BSC under the CDA as part of the Orbus Proprietary Stent Information. Orbus also disclosed to BSC the results of research, and clinical trials relating to certain of those stent designs that had been conducted in foreign countries.

31. The Orbus Proprietary Stent Information provided to BSC under the CDA was rightfully the exclusive property of Orbus and was identified and labeled by Orbus as proprietary prior to its disclosure to BSC. Orbus provided the Orbus Proprietary Stent Information to BSC pursuant to the CDA and in reliance upon the relationship of trust and confidence that existed between the parties. The Orbus Proprietary Stent Information was supposed to be used by BSC solely for the purpose of allowing the parties to explore their interests in pursuing a mutually advantageous business arrangement. The CDA provided that no license or right was granted to BSC to commercially exploit or use the Orbus Proprietary Stent Information for any other purpose than BSC's evaluation of this information in furtherance of such a contemplated possible future business arrangement between BSC and Orbus.

***BSC Breached the CDA By Secretly and Improperly Using Orbus' Proprietary Stent Information to Develop, Manufacture and Market and Sell BSC's Liberté™/Veriflex™/Atom™ Stent and its Element™/Ion™ Stent***

32. Members of BSC's stent team evaluated Orbus' stents at BSC's SciMed facility in Maple Grove, Minnesota for crimpability, radial strength, flexibility, construction, retention, and other properties. Orbus' stents were tested, cut up and, in some cases, destroyed. Some of the stents sample deployments and testing were photographed. BSC generated reports on certain of the test results. While Orbus received some test results from BSC, Orbus had no reason to suspect that BSC was misappropriating any of Orbus' Proprietary Stent Information in breach of the CDA.

33. The Orbus Proprietary Stent Information provided to BSC pursuant to the CDA was also reviewed and/or evaluated, in whole or in part, at BSC's Massachusetts' headquarters,



where the decision ultimately was made to disregard BSC's obligations under the CDA and misappropriate the Orbus Proprietary Stent Information for BSC's own business advantage. This decision of BSC and the resulting misappropriation of Orbus's Proprietary Stent Information to BSC's own use in violation of the CDA and other applicable law was approved and orchestrated by senior executives working at BSC's Massachusetts headquarters.

34. BSC was confronted with a dilemma in seeking patent protection for its new stent designs incorporating certain of the Orbus Proprietary Stent Information misappropriated by BSC in breach of the CDA. This patent protection was essential to maintain BSC's leading role in the market for intravascular stents, but U.S. patent applications are not confidential. One solution crafted by BSC was to bury the purloined Orbus Proprietary Stent Information in a family of patent applications involving other stents in a way calculated to conceal BSC's misuse of the Orbus Proprietary Stent Information, and its breach of the CDA, from Orbus.

35. Since being provided with the Orbus Proprietary Stent Information pursuant to the CDA, BSC has released several stents to the market, including Veriflex™, Taxus Express Atom™ (utilized in small coronary vessels), and Taxus Liberté™ (the uncoated (Veriflex™) and counterpart drug coated (Atom™ and Taxus Liberté™), platforms, hereinafter referred to collectively as the "Liberté™ Stent" or "Liberté™ Stent Brand" ), and Taxus Element™/Ion™ (collectively referred to as the "Ion™ Stent" or "Ion™ Stent Brand"). In addition, BSC has prosecuted a number of patent applications concerning stents and stent designs, including one listing Messrs. Gregorich and Girton as the inventors. One such BSC patent application entitled simply "Flexible and Expandable Stent" (the "Stent Patent Application") claimed priority from three (3) provisional patent applications. BSC caused a number of new drawings to be added to the Stent Patent Application that were not found in the three (3) provisional applications.

Included among the drawings added to the Stent Patent Application were several drawings that incorporated Orbus' Proprietary Stent Information provided to BSC pursuant to the CDA, including highly sensitive competitive information concerning helical elements, H connections, and so-called "spooky geometry." These new drawings clearly outlined a new stent geometry different from the prior embodiments shown in the provisional references. The new patterns and single geometry would enable this embodiment to possess quite different functional aspects including but not limited to flexibility of the stent in both a mounted and deployed state, uniform "stent to vessel" deployed geometry, foreshortening and clinical utility of the device. Furthermore, the authors erroneously attempted to claim the earliest provisional priority dates for the drawings, which would enable them to pre-date the CDA.

36. In April 2011, BSC announced in a press release that it had received United States Food and Drug Administration ("FDA") approval to market and sell its Ion Stent System in the United States. Upon information and belief, BSC has been commercializing, marketing and selling the Ion Stent system in Europe under the name Taxus Element since May 2010.

37. On April 25, 2011, BSC reported that it launched its Ion Stent system in the United States after receiving FDA approval (*Fierce Medical Devices Newsletter; Boston Scientific Press Release*). As is the case with BSC's Liberté™ Stent, the Ion™ Stent similarly includes cylindrical elements composed of a plurality of circumferential segments, which are traversed by helical segments, joined by connecting segments of a type taught by U.S. Patent Nos. 7,329,277 and 7,682,384 (*see* Counts I and III).

38. It has been reported that BSC began development of Ion™ in or about 2001. (*See*, Boston Scientific White Paper titled: "Boston Scientific Drug Eluting Stent Program: THE ELEMENT™ STENT SERIES" (September 2009)("Development of the breakthrough Platinum

Chromium (PtCr) alloy and the [Ion] stent series (or platform) is the result of over 8 years of research and development . . .”). This is the same time period that Orbus provided BSC with certain Orbus Proprietary Stent Information pursuant to the CDA.

39. BSC used and is continuing to use certain of the Orbus Proprietary Stent Information rightfully belonging exclusively to Orbus in aid of, *inter alia*, development of BSC stents, including the Liberté™ Stent and the Ion™ Stent, as well as BSC’s prosecution of the above referenced patent applications, all in violation of BSC’s duties under the CDA including, without limitation, misusing Orbus’ technical information and drawings relating to stent structures, helical elements, special connectors, and so-called “spooky geometry.”

40. BSC willfully breached the CDA by: (a) producing and later refining BSC’s stent platform and other BSC stent technologies utilizing Orbus’ Proprietary Stent Information; and (b) its continuing efforts to utilize the Orbus Proprietary Stent Information to commercialize, obtain regulatory approvals, market, manufacture and sell BSC’s Liberté™ Stent and Ion™ Stent throughout the United States and the rest of the world.

41. BSC also breached its affirmative obligation under the CDA and the relationship of trust and confidence between the parties arising out of the CDA to affirmatively disclose to Orbus any use by BSC of any Orbus Proprietary Stent Information entrusted to BSC in a manner contrary to the CDA.

### **COUNT I**

#### **(Infringement of U.S. Patent No. 7,329,277)**

42. Orbus repeats and re-alleges paragraphs 1-41 as if fully set forth herein.

43. Orbus is the owner by assignment of all right, title, and interest in and to U.S. Patent No. 7,329,277 entitled “Stent Having Helical Elements.” (*See Exhibit B*).

44. The application for U.S. Patent No. 7,329,277 was filed in the United States Patent and Trademark Office on December 11, 2001. The application for U.S. Patent No. 7,329,277 is based on, and claims the benefit of, the priority filing date of an earlier provisional patent application filed December 11, 2000, as well as, through a stream of continuation applications, a foreign application filed on June 13, 1997. U.S. Patent No. 7,329,277 was lawfully issued on February 12, 2008.

45. The application for U.S. Patent No. 7,329,277 was filed in the name of the inventors Scott J. Addonizio, David L. Camp, Jr., Gary J. Becker and John D. Paziienza.

46. U.S. Patent No. 7,329,277 includes thirty-four (34) claims, which are all directed to expandable stents with H-shaped connecting segments with circumferential or helical segments.

47. BSC has made, used, sold, and offered to sell a line of stent products under the Liberté™ Stent brand. One or more of the stent products sold by BSC under the Liberté™ Stent brand infringe one or more claims of U.S. Patent No. 7,329,277, including claim 31 of the patent.

48. BSC has directly and indirectly infringed U.S. Patent No. 7,329,277 by making, using, selling, and/or offering for sale, and/or importing, Liberté™ Stents, contributed to the infringement of U.S. Patent No. 7,329,277 by others who use Liberté™ Stents, and induced others to infringe U.S. Patent No. 7,329,277 as a result of advocating the use of Liberté™ Stents and its manufacture by others.

49. Defendant BSC's infringement of U.S. Patent No. 7,329,277 has been willful and deliberate.

50. Defendant BSC's infringement of U.S. Patent No. 7,329,277 will continue unless enjoined by this Court.

51. As a direct and proximate result of defendant BSC's infringement of U.S. Patent No. 7,329,277, Orbus has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which Orbus is entitled to relief.

**COUNT II**

**(Infringement of U.S. Patent No. 6,821,292)**

52. Orbus repeats and re-alleges paragraphs 1-51 as if fully set forth herein.

53. The application for U.S. Patent No. 6,821,292, entitled "Crimpable Intraluminal Endoprosthesis Having Helical Elements," was filed in the United States Patent and Trademark Office on February 8, 2002. The application for U.S. Patent No. 6,821,292 is based on, and claims the benefit of, the priority filing date of an earlier provisional patent application filed February 9, 2001. U.S. Patent No. 6,821,292 was lawfully issued on November 23, 2004. (*See Exhibit C*).

54. The application for U.S. Patent No. 6,821,292 was filed in the name of the inventors John D. Paziienza, Peter G. Piferi and Gary J. Becker.

55. Orbus is the owner by assignment of all right, title, and interest in and to U. S. Patent No. 6,821,292.

56. U.S. Patent No. 6,821,292 includes thirty-three (33) claims. The patent in embodiments is directed to expandable prosthetic stents having helical segments and geometries that allow them to be readily crimped into a balloon delivery device.

57. One or more of the products sold by BSC under the Liberté™ Stent brand infringe one or more claims of U.S. Patent No. 6,821,292, including claim 1.

58. Upon information and belief, defendant BSC has directly and indirectly infringed U.S. Patent No. 6,821,292 by making, using, selling, and/or offering for sale, and/or importing the Liberté™ Stents, contributed to the infringement of U.S. Patent No. 6,821,292 by others who

use the Liberté™ Stents, and induced others to infringe U.S. Patent No. 6,821,292 as a result of advocating their use of the Liberté™ Stents and its manufacture by others.

59. Upon information and belief, BSC's infringement of U.S. Patent No. 6,821,292 has been willful and deliberate.

60. Upon information and belief, BSC's infringement of U.S. Patent No. 6,821,292 will continue unless enjoined by this Court.

61. As a direct and proximate result of BSC's infringement of U.S. Patent No. 6,821,292, Orbus has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which Orbus is entitled to relief.

### **COUNT III**

#### **(Infringement of U.S. Patent No. 7,682,384)**

62. Orbus repeats and re-alleges paragraphs 1-61 as if fully set forth herein.

63. The application for U.S. Patent No. 7,682,384, entitled "Stent with Helical Elements," was filed in the United States Patent and Trademark Office on October 1, 2008. The application for U.S. Patent No. 7,682,384 is based on, and claims the benefit of, the priority filing date of an earlier provisional patent application filed December 11, 2000. U.S. Patent No. 7,682,384 was lawfully issued on March 23, 2010. (*See* Exhibit D).

64. The application for U.S. Patent No. 7,682,384 was filed in the name of the inventors Scott J. Addonizio, David L. Camp, Jr., Gary J. Becker and John D. Paziienza.

65. Orbus is the owner by assignment of all right, title, and interest in and to U. S. Patent No. 7,682,384.

66. U.S. Patent No. 7,682,384 includes thirteen (13) claims. The patent in embodiments is directed to expandable stents that are cylindrical in shape having a cylindrical axis, and comprised of a first and second set of helical elements.

67. One or more of the products sold by BSC under the Liberté™ Stent brand infringe one or more claims of U.S. Patent No. 7,682,384, including but not limited to claims 1, 2, 3, 6, 8, 9 and 13.

68. Upon information and belief, defendant BSC has directly and indirectly infringed U.S. Patent No. 7,682,384 by making, using, selling, and/or offering for sale, and/or importing, the Liberté™ Stents, contributed to the infringement of U.S. Patent No. 7,682,384 by others who use the Liberté™ Stents, and induced others to infringe U.S. Patent No. 7,682,384 as a result of advocating their use of the Liberté™ Stents and the manufacture of same by others.

69. Upon information and belief, BSC's infringement of U.S. Patent No. 7,682,384 has been willful and deliberate.

70. Upon information and belief, BSC's infringement of U.S. Patent No. 7,682,384 will continue unless enjoined by this Court.

71. As a direct and proximate result of BSC's infringement of U.S. Patent No. 7,682,384, Orbus has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which Orbus is entitled to relief.

#### **COUNT IV**

##### **(Infringement of U.S. Patent No. 7,942,922 )**

72. Orbus repeats and re-alleges paragraphs 1-71 as if fully set forth herein.

73. Orbus is the owner by assignment of all right, title, and interest in and to U.S. Patent No. 7,942,922 entitled "Stent Having Helical Elements." (*See* Exhibit E).

74. The application for U.S. Patent No. 7,942,922 was filed in the United States Patent and Trademark Office on September 9, 2010. The application for U.S. Patent No. 7,942,922 is based on, and claims the benefit of, the priority filing date of an earlier provisional patent application filed December 11, 2000, as well as, through a stream of continuation

applications, a foreign application filed on June 13, 1997. U.S. Patent No. 7,942,922 was lawfully issued on May 17, 2011.

75. The application for U.S. Patent No. 7,942,922 was filed in the name of the inventors Scott J. Addonizio, David L. Camp, Jr., Gary J. Becker and John D. Paziienza.

76. U.S. Patent No. 7,942,922 includes twenty (20) claims, all of which are directed to expandable stents compromised of a plurality of helical segments.

77. BSC has made, used, sold, and offered to sell a line of stent products under the Ion™ Stent brand. One or more of the stent products sold by BSC under the Ion™ Stent brand infringe one or more claims of U.S. Patent No. 7,942,922.

78. BSC has directly and indirectly infringed U.S. Patent No. 7,942,922 by making, using, selling, and/or offering for sale, and/or importing, Ion™ Stents, contributed to the infringement of U.S. Patent No. 7,942,922 by others who use Ion™ Stents, and induced others to infringe U.S. Patent No. 7,942,922 as a result of advocating the use of Ion Stents™ and its manufacture by others.

79. BSC's infringement of U.S. Patent No. 7,942,922 has been willful and deliberate.

80. BSC's infringement of U.S. Patent No. 7,942,922 will continue unless enjoined by this Court.

81. As a direct and proximate result of BSC's infringement of U.S. Patent No. 7,942,922, Orbus has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which Orbus is entitled to relief.

#### **COUNT V**

#### **(Infringement of U.S. Patent No. 7,967,852)**

82. Orbus repeats and re-alleges paragraphs 1-81 as if fully set forth herein.



83. Orbus is the owner by assignment of all right, title, and interest in and to U.S. Patent No. 7,967,852 entitled “Stent Having Helical Elements.” (*See* Exhibit F).

84. The application for U.S. Patent No. 7,967,852 was filed in the United States Patent and Trademark Office on September 9, 2010. The application for U.S. Patent No. 7,967,852 is based on, and claims the benefit of, the priority filing date of an earlier provisional patent application filed December 11, 2000, as well as, through a stream of continuation applications, a foreign application filed on June 13, 1997. U.S. Patent No. 7,967,852 was lawfully issued on June 28, 2011.

85. The application for U.S. Patent No. 7,967,852 was filed in the name of the inventors Scott J. Addonizio, David L. Camp, Jr., Gary J. Becker and John D. Paziienza.

86. U.S. Patent No. 7,967,852 includes twenty (20) claims, all of which are directed to expandable stents compromised of a plurality of helical segments.

87. BSC has made, used, sold, and offered to sell a line of stent products under the Ion™ Stent brand. One or more of the stent products sold by BSC under the Ion™ Stent brand infringe one or more claims of U.S. Patent No. 7,967,852.

88. BSC has directly and indirectly infringed U.S. Patent No. 7,967,852 by making, using, selling, and/or offering for sale, and/or importing, Ion™ Stents, contributed to the infringement of U.S. Patent No. 7,967,852 by others who use Ion™ Stents, and induced others to infringe U.S. Patent No. 7,967,852 as a result of advocating the use of Ion™ Stents and its manufacture by others.

89. BSC’s infringement of U.S. Patent No. 7,967,852 has been willful and deliberate.

90. BSC’s infringement of U.S. Patent No. 7,967,852 will continue unless enjoined by this Court.

91. As a direct and proximate result of BSC's infringement of U.S. Patent No. 7,967,852, Orbus has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which Orbus is entitled to relief.

**COUNT VI**

**(Breach of Contract)**

92. Orbus repeats and realleges paragraphs 1-91 as if fully set forth herein.

93. By virtue of the all the foregoing, BSC has willfully breached the CDA by, *inter alia*, misappropriating the Orbus Proprietary Stent Information provided to BSC in confidence, and for a limited purpose, for BSC's own selfish advantage and pecuniary gain.

94. Orbus has been damaged in an amount to be proven at trial and seeks all damages and injunctive relief it may be entitled to under the CDA and applicable law.

**COUNT VII**

**(Breach of Implied Covenant of Good Faith and Fair Dealing)**

95. Orbus repeats and realleges paragraphs 1-94 as if fully set forth herein.

96. The CDA contains an implied covenant of good faith and fair dealing under applicable Massachusetts law.

97. BSC's willful breach of the CDA violates this implied covenant of good faith and fair dealing.

98. Orbus has been damaged in an amount to be proven at trial and seeks all damages and injunctive relief it may be entitled to under applicable law.

**PRAYER FOR RELIEF**

WHEREFORE, Orbus requests entry of judgment in its favor and against defendant BSC as follows:

- (a) Enter judgment that defendant BSC has directly infringed Orbus's U.S. Patent No. 7,329,277;
- (b) Enter judgment that defendant BSC has directly infringed Orbus's U.S. Patent No. 6,821,292;
- (c) Enter judgment that defendant BSC has directly infringed Orbus's U.S. Patent No. 7,682,384;
- (d) Enter judgment that defendant BSC has directly infringed Orbus's U.S. Patent No. 7,942,922;
- (e) Enter judgment that defendant BSC has directly infringed Orbus' U.S. Patent No. 7,967,852
- (f) Enter judgment that defendant BSC has induced infringement of Orbus's U.S. Patent Nos. 7,329,277
- (g) Enter judgment that defendant BSC has induced infringement of Orbus's U.S. Patent No. 6,821,292;
- (h) Enter judgment that defendant BSC has induced infringement of Orbus's U.S. Patent No. 7,682,384;
- (i) Enter judgment that defendant BSC has induced infringement of Orbus's U.S. Patent No. 7,942,922;
- (j) Enter judgment that defendant BSC has induced infringement of Orbus' U.S. Patent No. 7,967,852;
- (k) Enter judgment that defendant BSC has contributed to infringement of Orbus's U.S. Patent No. 7,329,277;
- (l) Enter judgment that defendant BSC has contributed to infringement of Orbus's U.S. Patent No. 6,821,292;
- (m) Enter judgment that defendant BSC has contributed to infringement of Orbus's U.S. Patent No. 7,682,384;
- (n) Enter judgment that defendant BSC has contributed to infringement of Orbus's U.S. Patent No. 7,942,922;
- (o) Enter judgment that defendant BSC has contributed to infringement of Orbus' U.S. Patent No. 7,967,852;
- (p) Enter a permanent injunction, pursuant to 25 U.S.C. § 283, restraining and enjoining defendant BSC and its respective officers, agents, servants, employees, attorneys, customers, and those in concert or participation with

them from any further sales or use of infringing products and services and any other infringement of Orbus' s Patents, whether direct or indirect;

- (q) Enter judgment ordering defendant BSC to compensate Orbus for infringement of Orbus's U.S. Patent No. 7,329,277 pursuant to 35 U.S.C. § 284;
- (r) Enter judgment ordering defendant BSC to compensate Orbus for infringement of Orbus's U.S. Patent No. 6,821,292 pursuant to 35 U.S.C. § 284;
- (s) Enter judgment ordering defendant BSC to compensate Orbus for infringement of Orbus's U.S. Patent No. 7,682,384 pursuant to 35 U.S.C. § 284;
- (t) Enter judgment ordering defendant BSC to compensate Orbus for infringement of Orbus's U.S. Patent No. 7,942,922 pursuant to 35 U.S.C. § 284;
- (u) Enter judgment ordering defendant BSC to compensate Orbus for infringement of Orbus' U.S. Patent No. 7,967,852 pursuant to 35 U.S.C. § 284;
- (v) Enter a judgment ordering defendant BSC to pay Orbus damages in the amount proven at trial owing to BSC's breach of the CDA and Covenant of Good Faith and Fair Dealing.
- (w) Enter a judgment against defendant BSC for an award of pre-judgment and postjudgment interest and costs to Orbus pursuant to 35 U.S.C. § 284, and applicable Massachusetts law;
- (x) Grant such other relief as the Court may deem just, proper, and equitable.

**Demand for Jury Trial**

Orbus hereby demands a trial by jury on all issues so triable.

Date: August 31, 2011

THE PLAINTIFFS

/s/ Arthur J Guray

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- and -

/s/ Steven J Moore

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*Attorneys for Plaintiffs OrbusNeich Medical Co.  
Ltd., BVI and OrbusNeich Medical, Inc.*

**CERTIFICATE OF SERVICE**

I, Arthur J. Guray, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on August 31, 2011.

/s/ Arthur J. Guray