UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Vascular Solutions, Inc.,

Plaintiff,

v.

Boston Scientific Corporation,

Defendant.

Civil File No. 0:13-cv-01172 (JRT-SER)

AMENDED COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Vascular Solutions, Inc. ("VSI"), for its Amended Complaint against Boston Scientific Corporation ("Boston Scientific"), states and alleges as follows:

1. This is a patent infringement action to stop Boston Scientific's infringement of VSI's United States Patent No. 8,048,032 ("'032 patent") (Ex. A), United States Patent No. 8,142,413 ("'413 patent") (Ex. B), and United States Patent No. 8,292,850 ("'850 patent") (Ex. C), all entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures" (collectively, the "patents-in-suit"). This is also an action for copyright infringement to stop Boston Scientific's infringement of VSI's copyright in its GuideLiner® Instructions for Use ("GuideLiner IFU"), as reflected in United States Copyright Registrations TX 7-679-165 (Ex. D) and TX 7-679-167 (Ex. E) (together, the "GuideLiner IFU Copyright Registrations").

PARTIES

2. Plaintiff VSI is a Minnesota corporation, with its principal place of business at 6464 Sycamore Court North, Maple Grove, Minnesota 55369. VSI is the owner by

assignment of the patents-in-suit and the owner of the GuideLiner IFU copyrights and the GuideLiner IFU Copyright Registrations.

3. Defendant Boston Scientific is a Delaware corporation, with its corporate headquarters at One Boston Scientific Place, Natick, Massachusetts 01760. Boston Scientific also maintains a place of business and manufacturing operations at Two Scimed Place, Maple Grove, Minnesota 55331, and in numerous other states and countries.

JURISDICTION AND VENUE

4. This action arises under the Patent Act, 35 U.S.C. § 1 *et seq*. and the Copyright Act, 17 U.S.C. § 101, *et seq*.

5. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. The Court has personal jurisdiction over Boston Scientific, because Boston Scientific maintains places of business within the State of Minnesota and this district; Boston Scientific regularly conducts business in the State of Minnesota and this district; and VSI's cause of action arises directly from Boston Scientific's infringing actions by manufacturing, marketing and selling the infringing Guidezilla™ product in the State of Minnesota and this district and by copying the GuideLiner IFU and distributing copies of the infringing Guidezilla IFU in the State of Minnesota and this district.

7. Venue is proper in the District of Minnesota pursuant to 28 U.S.C. §§ 1391(a) and 1400(a), (b).

BACKGROUND

Vascular Solutions, its GuideLiner Product, and the Patents-in-Suit

8. Formed in 1997, VSI is a medical device company focused on bringing new clinically unique solutions for vascular diseases to physicians worldwide. VSI has developed and markets over 75 different medical device products through its 91employee U.S. sales force and international distribution network covering 49 countries. VSI's annual revenue in 2012 was $98 million.

9. Starting in 2004, VSI's Chief Executive Officer, Howard Root, along with VSI employees Gregg Sutton, Jeffrey Welch, and Jason Garrity (together, the "Inventors"), conceived of a new idea and developed that idea into VSI's GuideLiner catheter. VSI's GuideLiner catheter is a medical device used in coronary catheterization medical procedures to provide stable access to the coronary arteries and thereby facilitate the placement of stents and other medical devices for the treatment of coronary artery disease. The GuideLiner catheter uses rapid exchange or "rail" technology to make the catheter easy to deliver and consistent with the lengths of other devices used in coronary catheterization procedures.

10. On May 3, 2006, the Inventors filed an application for a U.S. patent on their invention that would issue as the '032 patent.

11. The '032 patent issued on November 1, 2011. VSI is the assignee and sole owner of the '032 patent.

12. The Inventors filed two additional divisional U.S. patent applications relating to aspects of their invention that were issued as the '413 patent on March 27,

2012 and the ‘850 patent on October 23, 2012. VSI is the assignee and sole owner of the ‘413 and ‘850 patents.

13. VSI obtained CE mark clearance from its European notified body and commenced international sales of the GuideLiner catheter in September 2009.

14. VSI obtained 510(k) regulatory clearance from the U.S. Food & Drug Administration and commenced U.S. sales of the GuideLiner catheter in November 2009.

15. The Instructions for Use (“IFU”) that VSI supplies with every unit of GuideLiner catheter shipped to a customer in the U.S. contains a listing of the numbers of the patents-in-suit and a description of the product and the deployment technique.

16. VSI is the owner of copyright in the GuideLiner IFUs and the sole owner of the GuideLiner IFU Copyright Registrations, effective May 15, 2013.

17. Since its introduction, the GuideLiner catheter has been described by physicians who use the product as “a game-changing device.” Physicians have stated that by using the GuideLiner catheter they have “been able to treat arteries previously deemed untreatable.” Other physicians have described the GuideLiner catheter as a device that “makes some impossible cases possible and difficult cases easier;” “an indispensable part of my tool kit;” and a device that “allows me to successfully complete previously unimaginable interventions.”

18. Before Boston Scientific introduced its infringing Guidezilla product, VSI’s patented GuideLiner catheter was the only available product that provided guide extension with rapid exchange, or “rail” technology, and therefore according to physicians using the product had “no competitor device.”

19. Since 2010, twenty-two articles have been published in peer-reviewed medical journals on the GuideLiner catheter; VSI has published twelve case reports on a variety of beneficial clinical uses of the GuideLiner catheter; and five medical symposia have been held on GuideLiner catheter at medical meetings in the United States and Europe.

20. The GuideLiner catheter has been a commercially successful product for VSI. From 2010 to current, the GuideLiner catheter has been VSI's fastest growing product, with sales growth of 48% in the first quarter of 2013 over the prior year, to an annual rate of approximately $20 million. GuideLiner catheter sales currently represent approximately 20% of VSI's total revenue.

Boston Scientific and its Infringing Guidezilla Product

21. Boston Scientific is the largest medical device company in the U.S. market for interventional cardiology devices, with a 40% share of the market according to 2010 market research estimates. Boston Scientific sells a variety of medical devices into this market through its interventional cardiology division, including drug-eluting stents and guide catheters. Boston Scientific's worldwide 2012 revenue was $7.2 billion.

22. Since VSI launched its GuideLiner catheter in 2009, interventional cardiologists have used VSI's GuideLiner catheter to deliver Boston Scientific's drug-eluting stents into coronary arteries, of which Boston Scientific's sales and marketing employees have been well aware.

23. On February 14, 2012, Boston Scientific filed a trademark application on "Guidezilla" for use as a medical guide catheter with the U.S. Patent & Trademark Office.

24. On October 2, 2012, VSI's CEO, Howard Root, met the president of Boston Scientific's Interventional Cardiology Division, Keven Ballinger, at an event sponsored by the trade organization LifeScience Alley in St. Louis Park, Minnesota. At the event, Root asked Ballinger if Boston Scientific was developing a new guide catheter called Godzilla or Guidezilla. In response, Ballinger stated that Boston Scientific hadn't developed a new guide catheter in over a decade.

25. On October 16, 2012, Root sent a letter to Ballinger informing him of the patents-in-suit. Ballinger did not respond.

26. Boston Scientific prepared its 510(k) application with the U.S. Food & Drug Administration ("FDA") for the Guidezilla catheter on December 6, 2012 and filed it on February 19, 2013. Boston Scientific's 510(k) filing identifies the GuideLiner catheter as the only predicate device for the Guidezilla catheter. The Guidezilla catheter "Intended Use / Indications for Use" included in the 510(k) application is the same as the Intended Use that VSI created and provides with its GuideLiner catheter.

27. As part of its filing with the FDA, Boston Scientific stated the following: "The GUIDEZILLA™ Guide Extension Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as the GuideLiner® V2 (K112082)."

28. Boston Scientific describes its Guidezilla catheter in its Directions for Use as "a single lumen rapid exchange catheter" with "a stainless steel proximal shaft with a 25 cm single lumen distal guide segment . . . ." This description is the same as VSI's description of its GuideLiner catheter in its IFU as "a single lumen rapid exchange catheter" with "a stainless steel shaft with a 25cm single lumen . . . ."

29. Boston Scientific's Directions for Use for its Guidezilla catheter is a copy of the VSI IFU for its GuideLiner catheter, including the "Deployment Procedure" / "Delivery Procedure" section as shown below (language copied from GuideLiner Instructions into Guidezilla Directions is shown in bold):

GuideLiner	Guidezilla
Deploy **the Guide**Liner catheter **according to the following steps:**	Deliver **the Guide**zilla device **according to the following steps:**
1. Secure the previously inserted guidewire and backload the distal tip of the Guide Liner catheter **onto the guidewire and advance until the** catheter **is just proximal to the hemostasis valve.**	**1. Secure the previously inserted guidewire and backload the distal tip of the Guide**zilla device **onto the guidewire and advance until the** device **is just proximal to the hemostasis valve.**
2. Open the hemostasis valve and advance the Guide Liner catheter **through the hemostasis valve and into the guide catheter.**	**2. Open the hemostasis valve and advance the Guide**zilla device **through the hemostasis valve and into the guide catheter.**
3. Under fluoroscopy, advance the Guide Liner catheter **up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel.**	**3. Under fluoroscopy, advance the Guide**zilla device **up to a maximum of 15 cm beyond the distal tip of the guide catheter and into the desired location within the vessel.**
Warning: Never advance the Guide Liner catheter **into a vessel with an effective diameter less than 2.5mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting**	**Warning: Never advance the Guide**zilla device **into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting**

the Guide Liner **catheter, withdraw the Guide**Liner **catheter until the pressure returns to normal.**	**the Guide**zilla **catheter, withdraw the Guide**zilla catheter **until the pressure returns to normal.**
Warning: Due to the size and non-tapered tip of the Guide Liner, **extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.**	**Warning: Due to the size and non-tapered tip of the Guide**zilla device, **extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.***
4. Using fluoroscopy, confirm the desired position of the Guide Liner catheter **in the vessel.**	**4. Using fluoroscopy, confirm the desired position of the Guide**zilla device **in the vessel.**
5. If performing an interventional procedure, backload the interventional device over the in place **guidewire and advance the device through the guide catheter and Guide**Liner catheter **into the desired vascular space.**	**5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guide**zilla device **into the desired vascular space.** Note: Use caution when advancing the interventional device into the distal guide segment.
6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guide Liner catheter **to prevent back-bleeding.**	**6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guide**zilla device **to prevent back-bleeding.**
7. Perform the catheterization procedure. After completing the procedure, remove the Guide Liner catheter **prior to removing the guide catheter from the vessel.**	**7. Perform the catheterization procedure. After completing the procedure, remove the Guide**zilla device **prior to removing the guide catheter from the vessel.**

* The order of the two warnings is reversed in the Guidezilla document.

30. Boston Scientific has infringed the GuideLiner IFU Copyright Registrations, as described more fully below.

31. Boston Scientific received 510(k) clearance from the FDA for the Guidezilla catheter on March 19, 2013.

32. Sam Rasmussen was employed as a Senior Product Manager at VSI from June 2006 through November 2006, a time period during which VSI was actively developing its GuideLiner catheter. Rasmussen voluntarily left VSI's employ in November 2006 and is currently employed as a Senior Product Manager at Boston Scientific. Rasmussen is responsible for providing marketing leadership for the launch of the Guidezilla catheter at Boston Scientific.

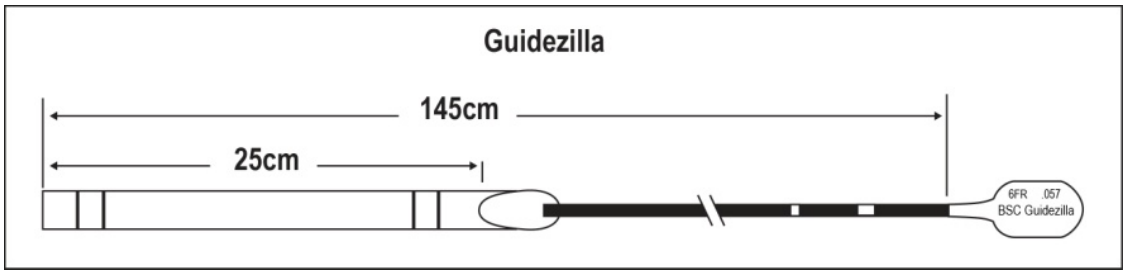
33. On March 21, 2013, Rasmussen contacted VSI's sales representative for the Minnesota territory, Matt Nigon, wanting to discuss the GuideLiner catheter. Rasmussen asked Nigon about the market size and pricing for the GuideLiner catheter.

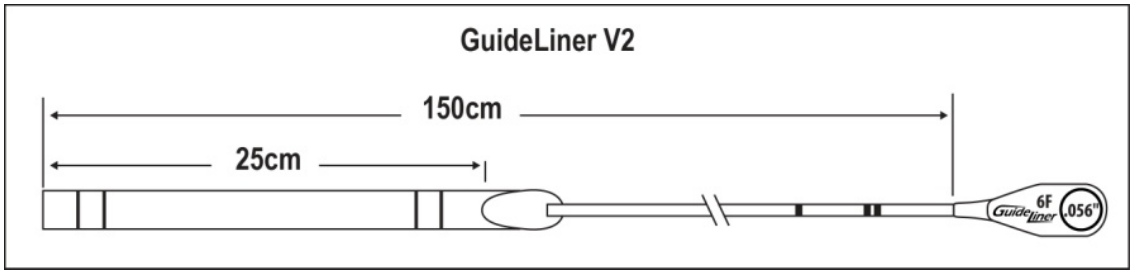
34. On April 12, 2013, Boston Scientific provided a Guidezilla catheter for clinical use at Barnes Jewish Hospital in St. Louis, Missouri, where it was used on a patient. Additional Guidezilla catheters have been provided by Boston Scientific since April 12, 2013 for clinical use in California, Illinois, New York and numerous other states across the U.S.

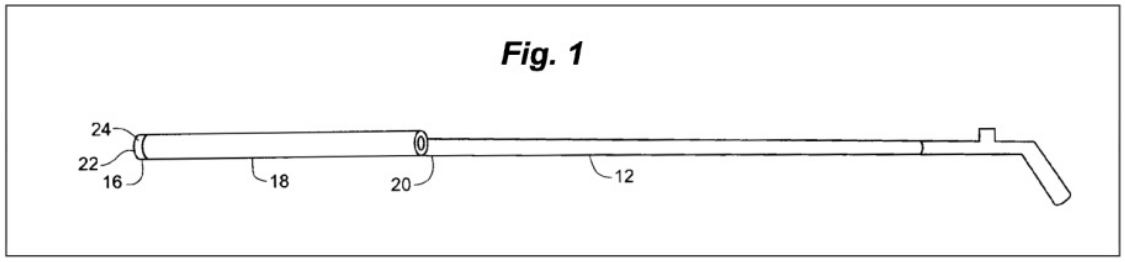
35. On April 25, 2013, Root sent another letter to Ballinger asking to purchase a sample of the Guidezilla for evaluation, to see any analysis performed by Boston Scientific with respect to the patents-in-suit, and to discuss the issue. On May 3, 2013, Root received a written reply stating only that Ballinger had forwarded Root's letter to his legal department for review. As of the time of this filing, no further response has been received from Ballinger or Boston Scientific.

36. Boston Scientific's Guidezilla catheter is a copy of VSI's GuideLiner catheter. Guidezilla's design, materials, and dimensions are materially the same as those

of GuideLiner and those described and claimed in the patents-in-suit. The drawings below show a comparison of Guidezilla and GuideLiner to Figure 1 of the patents-in-suit (orientation of the patent drawing has been reversed for comparison purposes):

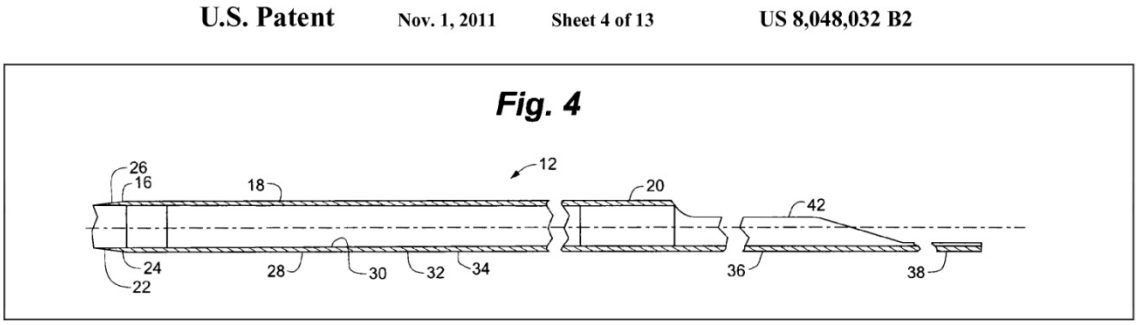






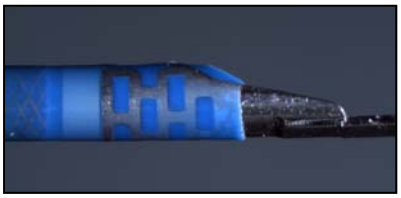
37. The rapid exchange, or "rail," technology used in the Guidezilla catheter is materially the same as VSI's GuideLiner and as described and claimed in VSI's patents-in-suit. The drawing and photographs below show a comparison of rapid exchange

transition of the Guidezilla and VSI's GuideLiner catheters and Figure 1 of VSI's patents-in-suit:



GuideLiner

Guidezilla



38. Boston Scientific's Guidezilla catheter infringes one or more claims of the patents-in-suit, as described more fully below.

COUNT ONE
Infringement of the '032 Patent

39. VSI restates and incorporates by reference the allegations in paragraphs 1-38.

40. VSI is the assignee and sole owner of the '032 patent.

41. Boston Scientific has infringed and continues to infringe one or more claims of the '032 patent, including at least claims 1-8, 11-17, and 19, by making, using, offering to sell, and selling (directly or through intermediaries), in this district and elsewhere in the United States, coaxial guide catheters for cardiac catheterization procedures, namely the Guidezilla catheter.

42. VSI did not give Boston Scientific authorization or license to make, use, offer to sell, or sell the Guidezilla catheter.

43. At least as early as October 2, 2012, and likely much earlier, Boston Scientific had knowledge of the ‘032 patent, and knew that its actions infringe the ‘032 patent. Boston Scientific did not develop the Guidezilla on its own, but instead copied VSI’s GuideLiner catheter. Boston Scientific has willfully infringed, and continues to willfully infringe, the ‘032 patent.

44. Boston Scientific’s willful infringement of the ‘032 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT TWO
Infringement of the ‘413 Patent

45. VSI restates and incorporates by reference the allegations in paragraphs 1-44.

46. VSI is the assignee and sole owner of the ‘413 patent.

47. Boston Scientific has infringed and continues to infringe one or more claims of the ‘413 patent, including at least claims 1, 2, 4, 5, and 7-13, by making, using, offering to sell, and selling (directly or through intermediaries), in this district and elsewhere in the United States, coaxial guide catheters for cardiac catheterization procedures, namely the Guidezilla catheter, and using such catheters for cardiac catheterization procedures.

48. Boston Scientific has induced and continues to induce infringement in this district and elsewhere in the United States of one or more claims of the ‘413 patent, including at least claims 1, 2, 4, 5, and 7-13, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its coaxial guide catheter for cardiac catheterization procedures, namely the Guidezilla catheter, in a manner which infringes the ‘413 patent.

49. At least as early as October 2, 2012, and likely much earlier, Boston Scientific had knowledge of the ‘413 patent. Boston Scientific did not develop the Guidezilla, or the instructions for using Guidezilla, on its own, but instead copied VSI’s GuideLiner and its IFU. Boston Scientific has specifically intended that its end users and/or customers use the Guidezilla catheter in a way that infringes the ‘413 patent by, at a minimum, providing instructions to its end users and/or customers on how to use the accused products, and Boston Scientific knew that its actions would induce, have induced, and will continue to induce infringement by end users and/or customers.

50. Boston Scientific has contributed to and continues to contribute to the infringement of one or more claims of the ‘413 patent, including at least claims 1, 2, 4, 5, and 7-13, by offering to sell and selling (directly or through intermediaries), to end users and/or customers, in this district or elsewhere in the United States, its coaxial guide catheter for cardiac catheterization procedures, namely the Guidezilla catheter, that constitutes a material or apparatus for use in practicing a patented process covered by the ‘413 patent, constituting a material part of the invention, and that end users and/or customers have used in a manner that infringes one or more claims of the ‘413 patent.

51. Boston Scientific has known since at least as early as October 2, 2012, and likely much earlier, that its Guidezilla catheters are specially made and/or adapted for use(s) that infringe one or more claims of the ‘413 patent and are, therefore, not staple articles or commodities of commerce suitable for substantial noninfringing use.

52. VSI did not give Boston Scientific authorization or license to engage in the activities described above.

53. Boston Scientific has willfully infringed, willfully induced infringement of, and willfully contributed to the infringement of one or more claims of the ‘413 patent, and continues to do so.

54. Boston Scientific’s willful infringement, willful inducement of infringement, and willful contributory infringement of the ‘413 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT THREE
Infringement of the ‘850 Patent

55. VSI restates and incorporates by reference the allegations in paragraphs 1-54.

56. VSI is the assignee and sole owner of the ‘850 patent.

57. Boston Scientific has infringed and continues to infringe one or more claims of the ‘850 patent, including at least claims 1-8, 12-18, and 20, by making, using, offering to sell, and selling (directly or through intermediaries), in this district and

elsewhere in the United States, coaxial guide catheters for cardiac catheterization procedures, namely the Guidezilla catheter, with standard guide catheters.

58. Boston Scientific has induced and continues to induce infringement in this district and elsewhere in the United States of one or more claims of the ‘850 patent, including at least claims 1-8, 12-18, and 20, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its coaxial guide catheter for cardiac catheterization procedures, namely the Guidezilla catheter, along with standard guide catheters, as a system which infringes the ‘850 patent.

59. At least as early as October 2, 2012, and likely much earlier, Boston Scientific had knowledge of the application that issued as the ‘850 patent, and knew that its Guidezilla product, when used with standard guide catheters, would infringe the ‘850 patent when issued. Boston Scientific did not develop the Guidezilla on its own, but instead copied VSI’s GuideLiner. Boston Scientific has specifically intended that its end users and/or customers use the Guidezilla catheter, along with standard guide catheters, as a system which infringes the ‘850 patent by, at a minimum, providing instructions to its end users and/or customers on how to use the accused products, and Boston Scientific knew that its actions would induce, have induced, and will continue to induce infringement by end users and/or customers.

60. Boston Scientific has contributed to and continues to contribute to the infringement of one or more claims of the ‘850 patent, including at least claims 1-8, 12-18, and 20, by offering to sell and selling (directly or through intermediaries), to end

users and/or customers, in this district or elsewhere in the United States, its coaxial guide catheter for cardiac catheterization procedures, namely the Guidezilla catheter, that constitutes a component of a machine, manufacture, combination or composition covered by the ‘850 patent, constituting a material part of the invention, and that end users and/or customers have used the Guidezilla catheter as part of a system that infringes one or more claims of the ‘850 patent.

61. At least as early as October 2, 2012, and likely much earlier, Boston Scientific knew that its Guidezilla catheters are specially made and/or adapted for use(s) as part of a system that would infringe one or more claims of the ‘850 patent when issued and are, therefore, not staple articles or commodities of commerce suitable for substantial noninfringing use.

62. VSI did not give Boston Scientific authorization or license to engage in the activities described above.

63. Boston Scientific has willfully infringed, willfully induced infringement, and willfully contributed to infringement of one or more claims of the ‘850 patent and continues to do so.

64. Boston Scientific’s willful infringement, willful inducement of infringement, and willful contributory infringement of the ‘850 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT FOUR
Copyright Infringement

65. VSI restates and incorporates by reference the allegations in paragraphs 1-64.

66. VSI is the sole owner of copyright in the GuideLiner IFUs.

67. VSI provided notice of its copyright on the first and every subsequent published copy of the GuideLiner IFUs.

68. VSI deposited the GuideLiner IFUs with the United States Copyright Office on May 15, 2013, and is the sole owner of the GuideLiner IFU Copyright Registrations.

69. Boston Scientific has infringed VSI's copyright in the GuideLiner IFUs as provided in 17 U.S.C. §501 by, among other things, copying and distributing copies of the GuideLiner IFUs as the Guidezilla Directions for Use in this district and elsewhere in the United States and in the world.

70. VSI did not authorize Boston Scientific to copy or distribute copies of the GuideLiner IFUs.

71. Boston Scientific knew or should have known of VSI's copyright in the GuideLiner IFUs, and proceeded to copy and distribute copies of the GuideLiner IFUs as the Guidezilla Directions for Use. Boston Scientific's violation of VSI's copyright has been and continues to be willful.

72. Boston Scientific's willful copyright infringement has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

JURY DEMAND

VSI requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

WHEREFORE, Vascular Solutions, Inc. prays for Judgment:

(a) In favor of VSI and against Boston Scientific on all of VSI's claims;

(b) Finding that Boston Scientific has willfully infringed one or more claims of the patents-in-suit, has willfully induced others to infringe one or more claims of the patents-in-suit, and has willfully contributed to infringement of one or more claims of the patent-in-suit;

(c) Preliminarily and permanently enjoining Boston Scientific, its agents, servants, employees, officers, directors, successors, licensees, assigns, and all others in active concert or participation with Boston Scientific, from making, using, offering to sell, or selling its Guidezilla catheters in the United States, or from otherwise infringing, inducing infringement, and contributing to the infringement of claims of the patents-in-suit;

(d) Awarding VSI damages adequate to compensate VSI for Boston Scientific's acts of patent infringement, together with pre-judgment and post-judgment interest;

(e) Declaring this to be an exceptional case and awarding VSI enhanced damages and reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285;

(f) Finding that Boston Scientific has willfully infringed VSI's copyright in the GuideLiner IFUs;

(g) Permanently enjoining Boston Scientific, its agents, servants, employees, officers, directors, successors, licensees, assigns, and all others in active concert or participation with Boston Scientific, from distributing further copies of the Guidezilla Directions for Use, or from otherwise infringing VSI's copyright in the GuideLiner IFUs;

(h) Ordering Boston Scientific to deliver up for destruction all copies of the Guidezilla Directions for Use in its or its agents' possession;

(i) Awarding VSI damages adequate to compensate VSI for Boston Scientific's acts of copyright infringement, as well as any unlawful profits earned by Boston Scientific, together with pre-judgment and post-judgment interest;

(j) Awarding VSI reasonable attorneys' fees and costs pursuant to 17 U.S.C. § 505;

(k) Awarding VSI its taxable costs and expenses, with interest; and

(l) Granting such other and further relief as this Court may deem just and equitable.

DORSEY & WHITNEY LLP

Dated: May 28, 2013

By s/ Heather D. Redmond

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