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.

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