

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ST. JUDE MEDICAL, CARDIOLOGY
DIVISION, INC., ST. JUDE MEDICAL
SYSTEMS AB, and ST. JUDE MEDICAL
S.C., INC.,

Plaintiffs,

v.

VOLCANO CORPORATION,

Defendant.

VOLCANO CORPORATION,

Counterclaimant,

v.

ST. JUDE MEDICAL, CARDIOLOGY
DIVISION, INC.; ST. JUDE MEDICAL
SYSTEMS AB; ST. JUDE MEDICAL S.C.,
INC.,

Counterclaim-Defendants.

Case No. 1:10-cv-00631-SLR

**ANSWER TO COMPLAINT AND
COUNTERCLAIMS**

JURY TRIAL DEMANDED

**DEFENDANT VOLCANO CORPORATION'S ANSWER TO COMPLAINT FOR
PATENT INFRINGEMENT AND COUNTERCLAIMS**

Defendant Volcano Corporation ("Volcano"), by and through its attorneys, hereby answers the Complaint for Patent Infringement of Plaintiffs St. Jude Medical, Cardiology Division, Inc., St. Jude Medical Systems AB, and St. Jude Medical S.C., Inc., (collectively "St. Jude"). Volcano denies each and every allegation in the Complaint that is not expressly admitted below. Volcano specifically responds as follows:

NATURE OF THE ACTION

1. Volcano admits that this action purports to be a civil action arising under the Patent Laws of the United States and that St. Jude alleges patent infringement. Volcano otherwise denies the allegations of paragraph 1 of the Complaint.

PARTIES

2. Volcano does not have sufficient information to admit or deny the allegations in paragraph 2 of the Complaint and therefore denies them.

3. Volcano does not have sufficient information to admit or deny the allegations in paragraph 3 of the Complaint and therefore denies them.

4. Volcano does not have sufficient information to admit or deny the allegations in paragraph 4 of the Complaint and therefore denies them.

5. Volcano admits the allegations of paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. Volcano admits that the Complaint alleges a civil action arising under the Patent Laws of the United States. Volcano admits the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Volcano admits the allegations of paragraph 7 of the Complaint.

8. Volcano admits that it does business in this judicial district. Volcano denies the remaining allegations of paragraph 8 of the Complaint.

9. Volcano admits the allegations of paragraph 9 of the Complaint.

10. Volcano denies the allegations of the first sentence of paragraph 10 of the Complaint. Volcano does not have sufficient information to admit or deny the allegations in

second sentence in paragraph 10 and therefore denies them. Volcano admits that FFR is used by physicians in making more informed decisions regarding proper patient treatment.

11. Volcano does not have sufficient information to admit or deny the allegations in paragraph 11 of the Complaint and therefore denies them.

12. Volcano does not have sufficient information to admit or deny the allegations in paragraph 12 of the Complaint and therefore denies them.

13. Volcano does not have sufficient information to admit or deny the allegations in paragraph 13 of the Complaint and therefore denies them.

14. Volcano denies that '624 patent was issued on August 17, 1991. Volcano admits the '624 patent is entitled "Male Connector With A Continuous Surface For A Guide Wire And Method Therefor" and that a copy of the '624 patent is attached to the Complaint. Volcano does not have sufficient information to admit or deny the remaining allegations in paragraph 14 of the Complaint and therefore denies them.

15. Volcano admits that the '980 patent is entitled "Male Connector With A Continuous Surface For A Guide Wire And Method Therefor," that the '980 patent issued on March 6, 2001 and that a copy of the '980 patent is attached to the Complaint. Volcano does not have sufficient information to admit or deny the remaining allegations in paragraph 15 of the Complaint and therefore denies them.

16. Volcano admits that the '598 patent is entitled "Pressure Sensor And Guide Wire Assembly For Biological Pressure Measurements," that the '598 patent issued on September 5, 2000 and that a copy of the '598 patent is attached to the Complaint. Volcano does not have sufficient information to admit or deny the remaining allegations in paragraph 16 of the Complaint and therefore denies them.

17. Volcano denies that '763 patent was issued on June 2, 2001. Volcano admits that the '763 patent is entitled "Pressure Sensor And Guide Wire Assembly For Biological Pressure Measurements" and that a copy of the '763 patent is attached to the Complaint. Volcano does not have sufficient information to admit or deny the remaining allegations in paragraph 17 of the Complaint and therefore denies them.

18. Volcano admits that the '083 patent is entitled "Device for Pressure Measurements," that the '083 patent issued on June 19, 2001 and that a copy of the '083 patent is attached to the Complaint. Volcano does not have sufficient information to admit or deny the remaining allegations in paragraph 18 of the Complaint and therefore denies them.

FIRST CLAIM FOR RELIEF

19. Volcano incorporates by reference its responses to paragraphs 1-18 as if repeated verbatim.

20. Volcano denies the allegations of paragraph 20 of the Complaint.

21. Volcano denies the allegations of paragraph 21 of the Complaint.

22. Volcano denies the allegations of paragraph 22 of the Complaint.

SECOND CLAIM FOR RELIEF

23. Volcano incorporates by reference its responses to paragraphs 1-22 as if repeated verbatim.

24. Volcano denies the allegations of paragraph 24 of the Complaint.

25. Volcano denies the allegations of paragraph 25 of the Complaint.

26. Volcano denies the allegations of paragraph 26 of the Complaint.

THIRD CLAIM FOR RELIEF

27. Volcano incorporates by reference its responses to paragraphs 1-26 as if repeated verbatim.

28. Volcano denies the allegations of paragraph 28 of the Complaint.

29. Volcano denies the allegations of paragraph 29 of the Complaint.

30. Volcano denies the allegations of paragraph 30 of the Complaint.

FOURTH CLAIM FOR RELIEF

31. Volcano incorporates by reference its responses to paragraphs 1-30 as if repeated verbatim.

32. Volcano denies the allegations of paragraph 32 of the Complaint.

33. Volcano denies the allegations of paragraph 33 of the Complaint.

34. Volcano denies the allegations of paragraph 34 of the Complaint.

FIFTH CLAIM FOR RELIEF

35. Volcano incorporates by reference its responses to paragraphs 1-34 as if repeated verbatim.

36. Volcano denies the allegations of paragraph 36 of the Complaint.

37. Volcano denies the allegations of paragraph 37 of the Complaint.

38. Volcano denies the allegations of paragraph 38 of the Complaint.

PRAYER FOR RELIEF

39. WHEREFORE, Volcano denies that Plaintiffs are entitled to the requested relief or any other relief.

AFFIRMATIVE DEFENSES

Volcano asserts the following affirmative defenses in response to Plaintiffs' Complaint. Volcano reserves the right to allege additional affirmative defenses as they become known throughout the course of discovery.

First Affirmative Defense (Non-Infringement)

40. Volcano has not infringed and does not currently infringe, either directly or indirectly, any valid claim of United States Patent Nos. 5,938,624 (the "'624 patent"), 6,196,980 (the "'980 patent"), 6,112,598 (the "'598 patent"), 6,167,763 (the "'763 patent"), 6,248,083 (the "'083 patent"), (collectively, the "St. Jude patents-in-suit").

Second Affirmative Defense (Invalidity)

41. The claims of the asserted St. Jude patents in suit are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, Sections 101, 102, 103, and 112.

Third Affirmative Defense (Unenforceability)

42. The asserted '598 patent and '763 patent are unenforceable due to the inequitable conduct of those having a duty of disclosure under 37 C.F.R. § 1.56.

43. 37 C.F.R. § 1.56 provides:

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is

not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
 - (2) Each attorney or agent who prepares or prosecutes the application;
- and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

44. Individuals specifically identified by 37 C.F.R. § 1.56(c) as having a duty of candor and good faith in their dealings with the United States Patent and Trademark Office (“USPTO”) and having a duty to disclose to the USPTO all information known to that individual to be material to patentability, failed to disclose information material to the patentability of the claims of the ’598 patent and ’763 patent. As described in greater detail below, these individuals include at least, Mr. Glen Law, the attorney who prepared or prosecuted the applications for the ’598 patent and ’763 patent; two of the three named inventors of the ’598 patent and ’763 patent, Lars Tenerz and Leif Smith; and persons associated with the assignee of the ’598 patent and ’763 patent, Radi Medical Systems AB of Uppsala Sweden.

45. On information and belief, the information withheld from the USPTO by these individuals in violation of their duty to the USPTO was withheld with intent to deceive. On information and belief, the information withheld from the USPTO did in fact deceive the USPTO examiner, Primary Examiner William Oen, into concluding the claims of the ’598 patent and ’763 patent were novel and non-obvious over the prior art when, in fact, the claimed inventions were well known in the art and had previously been invented by scientists at Cardiometrics, Inc. Cardiometrics, Inc. is the predecessor-in-interest of Volcano Corporation and Volcano Corporation is the assignee of the inventions patented by Cardiometrics, Inc.

46. Patent application Serial No. 08/710,062, which ultimately issued as United States Patent No. 5,715,827 (the “’827 patent”) was filed with the USPTO on September 9, 1996. The

'827 patent claims a priority filing date of September 2, 1994 as a continuation of patent application serial number 08/300,455, now abandoned. The '827 patent issued on February 10, 1998. The '827 patent names Paul D. Corl, Robert Z. Obara and John F. Ortiz as inventors. The '827 patent was assigned to Cardiometrics, Inc. The '827 patent is entitled "Ultra Miniature Pressure Sensor and Guide Wire Using the Same and Method." The '827 patent was examined by Primary Examiner Robert L. Nasser. The '827 patent qualifies as prior art to the '598 patent and '763 patent under 35 U.S.C. § 102(e). The '827 patent qualifies as prior art to the '598 patent and '763 patent under 35 U.S.C. § 102(g)(2). The '827 patent anticipates or renders obvious the claims of the '598 patent and '763 patent.

47. International Publication No. WO 96/07351 (the "WO351 application") claims priority to patent application serial number 08/300,455. The WO351 application was published on March 14, 1996. The WO351 application has the same priority filing date as the '827 patent. The WO351 application names the same inventors as the '827 patent. The WO351 application names the same assignee as the '827 patent. The WO351 application has the same title as the '827 patent. The WO351 application contains the same 17 figures as the '827 patent. The WO351 application contains a written description that is nearly identical to the written description of the '827 patent. The WO351 application designates several "States" including the country of Sweden. Sweden is the country of residence of the named inventors of the '598 patent and '763 patent and the original assignee of these two patents.

48. On March 30, 2000, attorney Glenn Law, Reg. No. 34,371, submitted an Information Disclosure Statement (the "IDS") to the USPTO in the prosecution of Patent Application Serial No. 09/399,097 (the "'083 patent application"). Patent Application Serial No. 09/399,097 ultimately issued as the '083 patent on June 19, 2001.

49. The IDS filed by Mr. Law identified seven references. The IDS included a “Concise Explanation of Relevance of Each Document” also signed by Mr. Law. This document explained that the references “came to Applicants’ attention during a search of the corresponding International application.” The corresponding International application is PCT/SE 98/00541. PCT/SE 98/00541 is identified on the first page of the ’083 patent under the heading “Related U.S. Application Data”. Mr. Law provided pages one and two of the four page referenced International Search Report with the IDS. The two page portion of the International Search Report submitted by Mr. Law identifies the WO351 application. The two page portion of the International Search Report submitted by Mr. Law further identifies the WO351 application as being assigned to Cardiometrics, Inc. and having a publication date of March 14, 1996. The two page portion of the International Search Report withheld from the USPTO by Mr. Law identifies, at page 4, the ’827 patent as a United States patent in the WO351 application family. The International Search Report is dated August 14, 1998.

50. The named inventors of the PCT/SE 98/00541 and ’083 patent are Lars Tenerz and Leif Smith. The assignee of PCT/SE 98/00541 and the ’083 patent is Radi Medical Systems AB of Uppsala Sweden. Lars Tenerz, Leif Smith and individuals associated with Radi Medical Systems AB were placed on notice of and had knowledge of the WO351 application and the ’827 patent prior to the date of issuance of either the ’598 patent or the ’763 patent.

51. The WO351 application is identified in the International Search Report as a category X reference. A category X reference is defined in the International Search Report as a “document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.”

52. Mr. Law was encouraged by 37 C.F.R. § 1.56(a)(1) to carefully examine the WO351 application because it was cited in the International Search Report. On information and belief, Mr. Law examined the WO351 application carefully in connection with the prosecution of the '083 patent. Mr. Law knew of Cardiometrics, the assignee of the WO351 application, at least as early as the filing date of the '083 patent application. Mr. Law knew of Cardiometrics' work in the field of guide wires having pressure sensors and related electronic circuitry, at least as early as the filing date of the '083 patent application, based on his description of one of Cardiometrics' patents in the disclosure of the '083 patent at column 1, lines 49-51. Mr. Law also knew of Cardiometrics' commercial guide wire products having pressure sensors based on his March 30, 2000 disclosure in the '083 patent of a document entitled "Cardiometrics WaveWire™ Pressure Guide Wire Apr. 6, 1998 Rev. C." Mr. Law also knew of Cardiometrics' commercial guide wires having flow sensors, at least as early as the filing date of the '598 patent application, based on his description of Cardiometrics' sensors in the disclosure of the '598 patent and '763 patent. Finally, Mr. Law knew that the '827 patent was an issued patent in the same patent family as the WO351 application based on its disclosure in the withheld pages of the International Search Report.

53. On March 31, 2000, just one day after submitting the IDS in the prosecution of the '083 patent application, Mr. Law submitted an "Amendment and Request for Reconsideration Under 37 C.F.R. § 1.111" in the prosecution of Application Serial No. 08/952,825 (the "'598 patent application"). Application Serial No. 08/952,825 issued as the '598 patent on September 5, 2000. The '598 Patent names Lars Tenerz, Leif Smith and Ola Hammarström as inventors. Prior to March 31, 2000, Mr. Law signed several other documents submitted to the USPTO during the prosecution the '598 patent application.

54. At no time during the prosecution of the '598 patent application did Mr. Law identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '598 patent application.

55. At no time during the prosecution of the '598 patent application did Lars Tenerz, Leif Smith or Ola Hammarström identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '598 patent application.

56. At no time during the prosecution of the '598 patent application did any representative of Radi Medical Systems AB identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '598 patent application.

57. The USPTO examiner responsible for the examination of the '598 patent application was Primary Examiner William Oen. The examiner responsible for the examination of the '083 patent application was Primary Examiner Max Hindenburg.

58. On April 12, 2000, less than two weeks after submitting the IDS in the prosecution of the '083 patent application, Mr. Law submitted an Information Disclosure Statement in the prosecution of Application Serial No. 09/547,733 (the "'763 patent application"). Application Serial No. 09/547,733 issued as the '763 patent on January 2, 2001. The '763 Patent names Lars Tenerz, Leif Smith and Ola Hammarström as inventors.

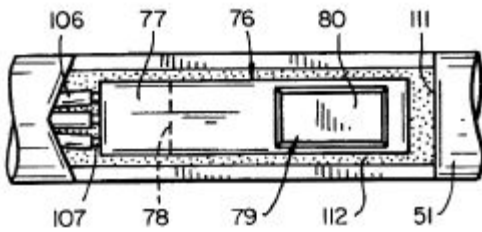
59. At no time during the prosecution of the '763 patent application did Mr. Law identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '763 patent application.

60. At no time during the prosecution of the '763 patent application did Lars Tenerz, Leif Smith or Ola Hammarström identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '763 patent application.

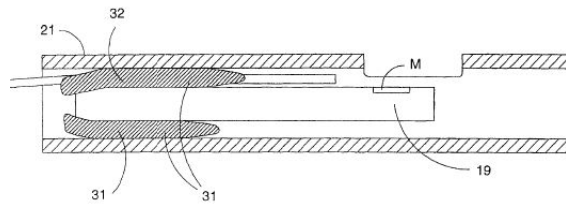
61. At no time during the prosecution of the '763 patent application did any representative of Radi Medical Systems AB identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '763 patent application.

62. The USPTO examiner responsible for the examination of the '763 patent application was Primary Examiner William Oen.

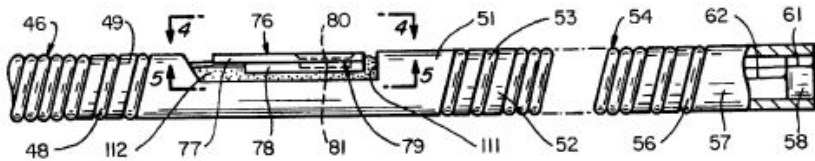
63. The teachings of the WO351 application and the '827 patent would have been highly material to the patentability of the claims of the '598 patent and the '763 patent. Relevant exemplary figures from the WO351 application/'827 patent and the '598/'763 patent are compared below:



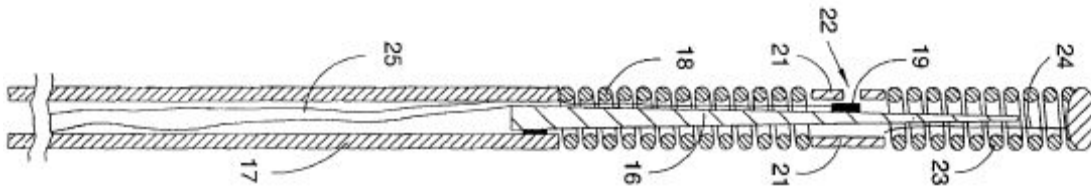
WO351 application/'827 patent, Fig. 4



'598/'763 patent, Fig. 3



WO351 application/'827 patent, Fig. 3



'598/'763 patent, Fig. 2

64. For example, claim 1 of the '598 patent recites, "A pressure sensor/guide wire assembly for biological pressure measurements in situ, comprising[.]" The WO351 application and the '827 patent teaches, by way of example, "This invention relates to an ultra miniature pressure sensor and guidewire and apparatus using the same and method, which is particularly suitable for making pressure measurements in coronary arteries of human beings." ('827 patent at column 1, lines 7-10).

65. Claim 1 of the '598 patent further recites, "(1) a guide wire (16, 17, 18, 21, 23) having a distal and a proximal end; and[.]" The WO351 application and the '827 patent teach, by way of example, "The guidewire 21 is shown in more detail in FIG. 2. . . [A] guidewire consists of a flexible elongate element 41 having a proximal and distal extremities 42 and 43." ('827 patent at column 3, lines 24-30).

66. Claim 1 of the '598 patent further recites, "(2) a mounting structure (16, 36, 27, 28; 16, 33, 34a, 34b, 35; 36) for mounting a sensor element, said mounting structure being provided at the distal end of said guide wire[.]" The WO351 application and the '827 patent teaches, by way of example, "The pressure sensor assembly 76 is mounted within a cutout 111 provided in the transition housing 51 and secured therein by suitable means such as an epoxy 112 so that the outer surface of the pressure sensor assembly 76 is generally flush with the outer surface of the transition housing 51 (see FIG. 3) and so that the diaphragm 79 is exposed to ambient...." ('827 patent at column 6, lines 51-56).

67. Claim 1 of the '598 patent further recites, "(3) a sensor element (19) with a pressure sensitive device (M)[.]" The WO351 application and the '827 patent teaches, by way of example, "The pressure sensor assembly 76 consists of a diaphragm structure 77 supported by a base plate 78. . . . The diaphragm structure 77 is a die made from such a wafer. In accordance

with the present invention, the die has a suitable length, as for example, 1050 microns and for a 0.014” guidewire has a width of 250 microns and for a 0.018” guidewire has a width of between 250 and 350 microns. It can have a suitable thickness, as for example, 50 microns. A rectangular diaphragm 79 is formed in the diaphragm structure 77 of a suitable thickness, as for example, 2.5 microns and having dimensions such as a length of 350 microns.” (’827 patent at column 4, lines 33-46).

68. Claim 1 of the ’598 patent further recites, “4) said sensor element (19) being mounted at the distal end of said guide wire (16, 17, 18, 21, 23), on said mounting structure such that it does not contact any surrounding rigid structures of said guide wire (16, 17, 18, 21, 23).” The WO351 application and the ’827 patent teaches, by way of example, “In accordance with the present invention it is provided with a pressure measuring capability in the form of a pressure sensor assembly 76 which is mounted within the intermediate or transition housing 51.” (’827 patent at column 4, lines 29-32). (’827 patent at column 4, lines 33-46; Figs. 3-8).

69. For example, claim 1 of the ’763 patent recites, “A guide wire for biological pressure measurements comprising[.]” The WO351 application and the ’827 patent teach, by way of example, “This invention relates to an ultra miniature pressure sensor and guidewire and apparatus using the same and method, which is particularly suitable for making pressure measurements in coronary arteries of human beings.” (’827 patent at column 1, lines 7-10).

70. Claim 1 of the ’763 patent further recites, “a wire[.]” The WO351 application and the ’827 patent teaches, by way of example, “Typically such a guidewire includes a core wire (not shown) of the type disclosed in the above identified patents which extends from the proximal extremity to the distal extremity of the flexible elongate element 41 to provide the

desired torsional properties for guide wires (see U.S. Pat. No. 5,163,445, col. 18:40-51) to facilitate steering of the guide wire 21 in the vessel.” (’827 patent at column 3, lines 36-42).

71. Claim 1 of the ’763 patent further recites, “a mount[.]” The WO351 application and the ’827 patent teaches, by way of example, “The pressure sensor assembly 76 is mounted within a cutout 111 provided in the transition housing 51 and secured therein by suitable means such as an epoxy 112 so that the outer surface of the pressure sensor assembly 76 is generally flush with the outer surface of the transition housing 51 (see FIG. 3) and so that the diaphragm 79 is exposed to ambient....” (’827 patent at column 6, lines 51-56).

72. Claim 1 of the ’763 patent further recites, “a pressure transducer for biological pressure measurements mounted to the wire via the mount such that a pressure sensitive end of the pressure transducer does not contact any structure other than the mount.” The WO351 application and the ’827 patent teaches, by way of example, “In accordance with the present invention it is provided with a pressure measuring capability in the form of a pressure sensor assembly 76 which is mounted within the intermediate or transition housing 51.” (’827 patent at column 4, lines 29-32). (’827 patent at column 4, lines 33-46; Figs. 3-8).

73. The teachings of the WO351 application/’827 patent are not cumulative of the teachings of the art cited during the prosecution of the ’598 patent.

74. The teachings of the WO351 application/’827 patent are not cumulative of the teachings of the art cited during the prosecution of the ’763 patent.

75. In view of the level of materiality of the WO351 application/’827 patent to the patentability of the claims of the ’598 and ’763 patents, an intent to deceive can and should be inferred.

COUNTERCLAIMS

Volcano, for its counterclaims against Plaintiffs, alleges as follows:

Nature of the Action

1. This counterclaim seeks a declaratory judgment of non-infringement, invalidity and unenforceability as to each of the St. Jude patents-in-suit. This counterclaim also seeks judgment of infringement as to each of United States Patent Nos. 7,134,994, 6,976,965 and 5,178,159 (the “Volcano patents-in-suit”). Volcano seeks judgment under the patent laws of the United States, 35 U.S.C. § 101, et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

The Parties

2. Volcano Corporation is a Delaware corporation having its principal place of business at 3661 Valley Centre Drive, Suite 200, San Diego, California 92130.

3. Upon information and belief, St. Jude Medical, Cardiology Division, Inc., d/b/a St. Jude Medical Cardiovascular Division is a Delaware corporation having its principal place of business at 177 East County Road B, St. Paul, Minnesota 55117.

4. Upon information and belief, St. Jude Medical System AB, previously known as Radi Medical Systems AB, is a Swedish corporation, and has its principal place of business at Palmbladsgaten 10, SE-751 35, Uppsala, Sweden. In December 2008, St. Jude Medical, Inc., a Minnesota corporation, acquired Radi Medical Systems AB from Radi Medical AB, a Swedish corporation. In November 2009, Radi Medical Systems AB changed its name to St. Jude Medical Systems AB.

5. Upon information and belief, St. Jude Medical S.C., Inc. is a Minnesota corporation having its principal place of business at 807 Las Cimas Parkway, Suite 400, Austin, Texas 78746.

6. On information and belief, Radi Medical Systems AB and St. Jude Medical Systems AB manufacture and have manufactured guide wires including an electrical sensor known as the Radi PressureWire® 3, PressureWire® 5 and PressureWire® XT (the “Radi PressureWire products”). On information and belief, Radi Medical Systems AB and St. Jude Medical Systems AB manufacture and have manufactured guide wires including an electrical sensor known as the PressureWire® Aeris and PressureWire® Certus (the “PressureWire products”).

7. On information and belief, Radi Medical Systems AB and St. Jude Medical Systems AB manufacture and have manufactured a monitoring system known as the RadiAnalyzer® Xpress (the “RadiAnalyzer”). The Radi PressureWire products and the PressureWire products are used with the RadiAnalyzer.

8. On information and belief, the Radi PressureWire products and the PressureWire products are distributed in the United States for Radi Medical Systems AB through its wholly owned subsidiary Radi Medical Systems, Inc.

9. On information and belief the RadiAnalyzer was distributed in the United States for Radi Medical Systems AB through its wholly owned subsidiary Radi Medical Systems, Inc.

10. On information and belief, after St. Jude Medical Inc.’s acquisition of Radi Medical Systems AB, the Radi PressureWire products and the PressureWire products continued to be manufactured in Sweden by St. Jude Medical Systems AB. On information and belief, the Radi PressureWire products and the PressureWire products are presently exclusively imported

into the United States by St. Jude Medical Cardiology Division, Inc., d/b/a St. Jude Medical Cardiovascular Division. On information and belief, the Radi PressureWire products and the PressureWire products are offered for sale and exclusively sold in the United States by St. Jude Medical S.C., Inc.

11. On information and belief, after St. Jude Medical Inc.'s acquisition of Radi Medical Systems AB, the RadiAnalyzer continued to be manufactured in Sweden by St. Jude Medical Systems AB. On information and belief, the RadiAnalyzer is presently exclusively imported into the United States by St. Jude Medical Cardiology Division, Inc., d/b/a St. Jude Medical Cardiovascular Division. On information and belief, the RadiAnalyzer is offered for sale and exclusively sold in the United States by St. Jude Medical S.C., Inc.

Jurisdiction and Venue

12. This Court has subject matter jurisdiction over Volcano Corporation's counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

13. St. Jude Medical Systems AB, St. Jude Medical, Cardiology Division, Inc. d/b/a St. Jude Medical Cardiovascular Division, St. Jude Medical S.C. and their predecessors in interest (the "St. Jude Defendants") have consented to personal jurisdiction by pursuing an action for patent infringement in this judicial district, as set forth in Plaintiffs' Complaint.

14. On information and belief, the St. Jude defendants are doing business in this judicial district and for this reason the Court also has personal jurisdiction over them.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Count I: Declaratory Judgment of Non-Infringement of the '624 Patent

16. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

17. Volcano has not infringed and does not currently infringe, either directly or indirectly, any valid claim of the '624 patent.

Count II: Declaratory Judgment of Invalidity of the '624 Patent

18. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

19. The claims of the '624 patent are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112.

Count III: Declaratory Judgment of Non-Infringement of the '980 Patent

20. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

21. Volcano has not infringed and does not currently infringe, either directly or indirectly, any valid claim of the '980 patent.

Count IV: Declaratory Judgment of Invalidity of the '980 Patent

22. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

23. The claims of the '980 patent are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112.

Count V: Declaratory Judgment of Non-Infringement of the '598 Patent

24. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

25. Volcano has not infringed and does not currently infringe, either directly or indirectly, any valid claim of the '598 patent.

Count VI: Declaratory Judgment of Invalidity of the '598 Patent

26. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

27. The claims of the '598 patent are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, Sections 101, 102, 103, and 112.

Count VII: Declaratory Judgment of Non-Infringement of the '763 Patent

28. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

29. Volcano has not infringed and does not currently infringe, either directly or indirectly, any valid claim of the '763 patent.

Count VIII: Declaratory Judgment of Invalidity of the '763 Patent

30. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

31. The claims of the '763 patent are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112

Count IX: Declaratory Judgment of Non-Infringement of the '083 Patent

32. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

33. Volcano has not infringed and does not currently infringe, either directly or indirectly, any valid claim of the '083 patent.

Count X: Declaratory Judgment of Invalidity of the '083 Patent

34. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

35. The claims of the '083 patent are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112.

Count XI: Declaratory Judgment of Unenforceability of the '598 and '763 Patents

36. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

37. The asserted '598 patent and '763 patent are unenforceable due to the inequitable conduct of those having a duty of disclosure under 37 C.F.R. § 1.56.

38. 37 C.F.R. § 1.56 provides:

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim

remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between

the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

39. Individuals specifically identified by 37 C.F.R. § 1.56(c) as having a duty of candor and good faith in their dealings with the United States Patent and Trademark Office (“USPTO”) and having a duty to disclose to the USPTO all information known to that individual to be material to patentability, failed to disclose information material to the patentability of the claims of the ’598 patent and ’763 patent. As described in greater detail below, these individuals include at least, Mr. Glen Law, the attorney who prepared or prosecuted the applications for the ’598 patent and ’763 patent; two of the three named inventors of the ’598 patent and ’763 patent, Lars Tenerz and Leif Smith; and persons associated with the assignee of the ’598 patent and ’763 patent, Radi Medical Systems AB of Uppsala Sweden.

40. On information and belief, the information withheld from the USPTO by these individuals in violation of their duty to the USPTO was withheld with intent to deceive. On information and belief, the information withheld from the USPTO did in fact deceive the USPTO examiner, Primary Examiner William Oen, into concluding the claims of the ’598 patent and ’763 patent were novel and non-obvious over the prior art when, in fact, the claimed inventions were well known in the art and had previously been invented by scientists at Cardiometrics, Inc. Cardiometrics, Inc. is the predecessor-in-interest of Volcano Corporation and Volcano Corporation is the assignee of the inventions patented by Cardiometrics, Inc.

41. Patent application Serial No. 08/710,062, which ultimately issued as United States Patent No. 5,715,827 (the “’827 patent”) was filed with the USPTO on September 9, 1996. The ’827 patent claims a priority filing date of September 2, 1994 as a continuation of patent application serial number 08/300,455, now abandoned. The ’827 patent issued on February 10, 1998. The ’827 patent names Paul D. Corl, Robert Z. Obara and John F. Ortiz as inventors. The

'827 patent was assigned to Cardiometrics, Inc. The '827 patent is entitled "Ultra Miniature Pressure Sensor and Guide Wire Using the Same and Method." The '827 patent was examined by Primary Examiner Robert L. Nasser. The '827 patent qualifies as prior art to the '598 patent and '763 patent under 35 U.S.C. § 102(e). The '827 patent qualifies as prior art to the '598 patent and '763 patent under 35 U.S.C. § 102(g)(2). The '827 patent anticipates or renders obvious the claims of the '598 patent and '763 patent.

42. International Publication No. WO 96/07351 (the "WO351 application") claims priority to patent application serial number 08/300,455. The WO351 application was published on March 14, 1996. The WO351 application has the same priority filing date as the '827 patent. The WO351 application names the same inventors as the '827 patent. The WO351 application names the same assignee as the '827 patent. The WO351 application has the same title as the '827 patent. The WO351 application contains the same 17 figures as the '827 patent. The WO351 application contains a written description that is nearly identical to the written description of the '827 patent. The WO351 application designates several "States" including the country of Sweden. Sweden is the country of residence of the named inventors of the '598 patent and '763 patent and the original assignee of these two patents.

43. On March 30, 2000, attorney Glenn Law, Reg. No. 34,371, submitted an Information Disclosure Statement (the "IDS") to the USPTO in the prosecution of Patent Application Serial No. 09/399,097 (the "'083 patent application"). Patent Application Serial No. 09/399,097 ultimately issued as the '083 patent on June 19, 2001.

44. IDS filed by Mr. Law identified seven references. The IDS included a "Concise Explanation of Relevance of Each Document" also signed by Mr. Law. This document explained that the references "came to Applicants' attention during a search of the corresponding

International application.” The corresponding International application is PCT/SE 98/00541. PCT/SE 98/00541 is identified on the first page of the ’083 patent under the heading “Related U.S. Application Data”. Mr. Law provided pages one and two of the four page referenced International Search Report with the IDS. The two page portion of the International Search Report submitted by Mr. Law identifies the WO351 application. The two page portion of the International Search Report submitted by Mr. Law further identifies the WO351 application as being assigned to Cardiometrics, Inc. and having a publication date of March 14, 1996. The two page portion of the International Search Report withheld from the USPTO by Mr. Law identifies, at page 4, the ’827 patent as a United States patent in the WO351 application family. The International Search Report is dated August 14, 1998.

45. The named inventors of the PCT/SE 98/00541 and ’083 patent are Lars Tenerz and Leif Smith. The assignee of PCT/SE 98/00541 and the ’083 patent is Radi Medical Systems AB of Uppsala Sweden. Lars Tenerz, Leif Smith and individuals associated with Radi Medical Systems AB were placed on notice of and had knowledge of the WO351 application and the ’827 patent prior to the date of issuance of either the ’598 patent or the ’763 patent.

46. The WO351 application is identified in the International Search Report as a category X reference. A category X reference is defined in the International Search Report as a “document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.”

47. Mr. Law was encouraged by 37 C.F.R. § 1.56(a)(1) to carefully examine the WO351 application because it was cited in the International Search Report. On information and belief, Mr. Law examined the WO351 application carefully in connection with the prosecution of the ’083 patent. Mr. Law knew of Cardiometrics, the assignee of the WO351 application, at least

as early as the filing date of the '083 patent application. Mr. Law knew of Cardiometrics' work in the field of guide wires having pressure sensors and related electronic circuitry, at least as early as the filing date of the '083 patent application, based on his description of one of Cardiometrics' patents in the disclosure of the '083 patent at column 1, lines 49-51. Mr. Law also knew of Cardiometrics' commercial guide wire products having pressure sensors based on his March 30, 2000 disclosure in the '083 patent of a document entitled "Cardiometrics WaveWire™ Pressure Guide Wire Apr. 6, 1998 Rev. C." Mr. Law also knew of Cardiometrics' commercial guide wires having flow sensors, at least as early as the filing date of the '598 patent application, based on his description of Cardiometrics' sensors in the disclosure of the '598 patent and '763 patent. Finally, Mr. Law knew that the '827 patent was an issued patent in the same patent family as the WO351 application.

48. On March 31, 2000, just one day after submitting the IDS in the prosecution of the '083 patent application, Mr. Law submitted an "Amendment and Request for Reconsideration Under 37 C.F.R. § 1.111" in the prosecution of Application Serial No. 08/952,825 (the "'598 patent application"). Application Serial No. 08/952,825 issued as the '598 patent on September 5, 2000. The '598 Patent names Lars Tenerz, Leif Smith and Ola Hammarström as inventors. Prior to March 31, 2000, Mr. Law signed several other documents submitted to the USPTO during the prosecution the '598 patent application.

49. At no time during the prosecution of the '598 patent application did Mr. Law identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '598 patent application.

50. At no time during the prosecution of the '598 patent application did Lars Tenerz, Leif Smith or Ola Hammarström identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '598 patent application.

51. At no time during the prosecution of the '598 patent application did any representative of Radi Medical Systems AB identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '598 patent application.

52. The USPTO examiner responsible for the examination of the '598 patent application was Primary Examiner William Oen. The examiner responsible for the examination of the '083 patent application was Primary Examiner Max Hindenburg.

53. On April 12, 2000, less than two weeks after submitting the IDS in the prosecution of the '083 patent application, Mr. Law submitted an Information Disclosure Statement in the prosecution of Application Serial No. 09/547,733 (the "'763 patent application"). Application Serial No. 09/547,733 issued as the '763 patent on January 2, 2001. The '763 Patent names Lars Tenerz, Leif Smith and Ola Hammarström as inventors.

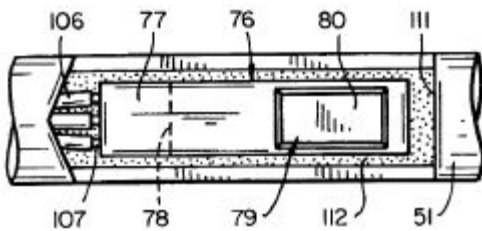
54. At no time during the prosecution of the '763 patent application did Mr. Law identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '763 patent application.

55. At no time during the prosecution of the '763 patent application did Lars Tenerz, Leif Smith or Ola Hammarström identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '763 patent application.

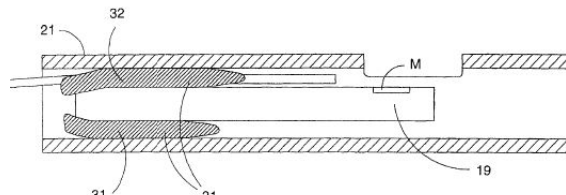
56. At no time during the prosecution of the '763 patent application did any representative of Radi Medical Systems AB identify the WO351 application or the '827 patent to the USPTO examiner responsible for the examination of the '763 patent application.

57. The USPTO examiner responsible for the examination of the '763 patent application was Primary Examiner William Oen.

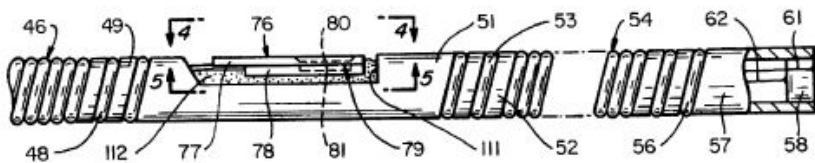
58. The teachings of the WO351 application and the '827 patent would have been highly material to the patentability of the claims of the '598 patent and the '763 patent. Relevant exemplary figures from the WO351 application/'827 patent and the '598/'763 patent are compared below:



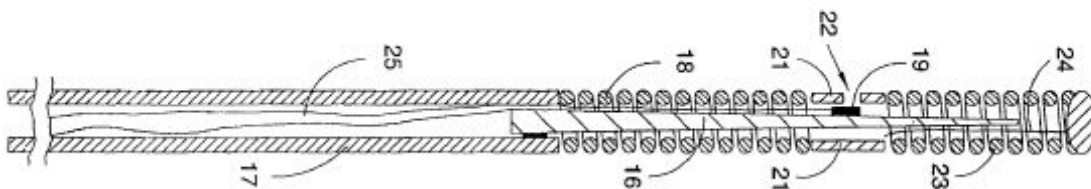
WO351 application/'827 patent, Fig. 4



'598/'763 patent, Fig. 3



WO351 application/'827 patent, Fig. 3



'598/'763 patent, Fig. 2

59. For example, claim 1 of the '598 patent recites, “A pressure sensor/guide wire assembly for biological pressure measurements in situ, comprising[.]” The WO351 application and the '827 patent teaches, by way of example, “This invention relates to an ultra miniature

pressure sensor and guidewire and apparatus using the same and method, which is particularly suitable for making pressure measurements in coronary arteries of human beings.” (’827 patent at column 1, lines 7-10).

60. Claim 1 further recites, “(1) a guide wire (16, 17, 18, 21, 23) having a distal and a proximal end; and[.]” The WO351 application and the ’827 patent teaches, by way of example, “The guidewire 21 is shown in more detail in FIG. 2. . . [A] guidewire consists of a flexible elongate element 41 having a proximal and distal extremities 42 and 43.” (’827 patent at column 3, lines 24-30).

61. Claim 1 further recites, “(2) a mounting structure (16, 36, 27, 28; 16, 33, 34a, 34b, 35; 36) for mounting a sensor element, said mounting structure being provided at the distal end of said guide wire[.]” The WO351 application and the ’827 patent teaches, by way of example, “The pressure sensor assembly 76 is mounted within a cutout 111 provided in the transition housing 51 and secured therein by suitable means such as an epoxy 112 so that the outer surface of the pressure sensor assembly 76 is generally flush with the outer surface of the transition housing 51 (see FIG. 3) and so that the diaphragm 79 is exposed to ambient....” (’827 patent at column 6, lines 51-56).

62. Claim 1 further recites, “(3) a sensor element (19) with a pressure sensitive device (M)[.]” The WO351 application and the ’827 patent teaches, by way of example, “The pressure sensor assembly 76 consists of a diaphragm structure 77 supported by a base plate 78. . . . The diaphragm structure 77 is a die made from such a wafer. In accordance with the present invention, the die has a suitable length, as for example, 1050 microns and for a 0.014” guidewire has a width of 250 microns and for a 0.018” guidewire has a width of between 250 and 350 microns. It can have a suitable thickness, as for example, 50 microns. A rectangular diaphragm

79 is formed in the diaphragm structure 77 of a suitable thickness, as for example, 2.5 microns and having dimensions such as a length of 350 microns.” (’827 patent at column 4, lines 33-46).

63. Claim 1 further recites, “4) said sensor element (19) being mounted at the distal end of said guide wire (16, 17, 18, 21, 23), on said mounting structure such that it does not contact any surrounding rigid structures of said guide wire (16, 17, 18, 21, 23).” The WO351 application and the ’827 patent teaches, by way of example, “In accordance with the present invention it is provided with a pressure measuring capability in the form of a pressure sensor assembly 76 which is mounted within the intermediate or transition housing 51.” (’827 patent at column 4, lines 29-32). (’827 patent at column 4, lines 33-46; Figs. 3-8).

64. For example, claim 1 of the ’763 patent recites, “A guide wire for biological pressure measurements comprising[.]” The WO351 application and the ’827 patent teaches, by way of example, “This invention relates to an ultra miniature pressure sensor and guidewire and apparatus using the same and method, which is particularly suitable for making pressure measurements in coronary arteries of human beings.” (’827 patent at column 1, lines 7-10).

65. Claim 1 further recites, “a wire[.]” The WO351 application and the ’827 patent teaches, by way of example, “Typically such a guidewire includes a core wire (not shown) of the type disclosed in the above identified patents which extends from the proximal extremity to the distal extremity of the flexible elongate element 41 to provide the desired torsional properties for guide wires (see U.S. Pat. No. 5,163,445, col. 18:40-51) to facilitate steering of the guide wire 21 in the vessel.” (’827 patent at column 3, lines 36-42).

66. Claim 1 further recites, “a mount[.]” The WO351 application and the ’827 patent teaches, by way of example, “The pressure sensor assembly 76 is mounted within a cutout 111 provided in the transition housing 51 and secured therein by suitable means such as an epoxy 112

so that the outer surface of the pressure sensor assembly 76 is generally flush with the outer surface of the transition housing 51 (see FIG. 3) and so that the diaphragm 79 is exposed to ambient....” (’827 patent at column 6, lines 51-56).

67. Claim 1 further recites, “a pressure transducer for biological pressure measurements mounted to the wire via the mount such that a pressure sensitive end of the pressure transducer does not contact any structure other than the mount.” The WO351 application and the ’827 patent teaches, by way of example, “In accordance with the present invention it is provided with a pressure measuring capability in the form of a pressure sensor assembly 76 which is mounted within the intermediate or transition housing 51.” (’827 patent at column 4, lines 29-32). (’827 patent at column 4, lines 33-46; Figs. 3-8).

68. The teachings of the WO351 application/’827 patent are not cumulative of the teachings of the art cited during the prosecution of the ’598 patent.

69. The teachings of the WO351 application/’827 patent are not cumulative of the teachings of the art cited during the prosecution of the ’763 patent.

70. In view of the level of materiality of the WO351 application/’827 patent to the patentability of the claims of the ’598 and ’763 patents, an intent to deceive can and should be inferred.

Count XII: Infringement of United States Patent No. 6,976,965

71. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

72. On December 20, 2005, the USPTO issued U.S. Patent No. 6,976,965 (the “’965 patent”). The ’965 patent is entitled “Ultra Miniature Pressure Sensor” A true and correct copy

of the '965 patent is attached to this answer and counterclaim as Exhibit A. Volcano Corporation is the owner by assignment of the entire right, title and interest in and to the '965 patent.

73. The St. Jude Defendants have made, used, offered to sell, sold and/or imported into the United States guide wires, including the Radi PressureWire products, that infringe, induce infringement, and/or contribute to the infringement of the claims of the '965 patent in violation of Volcano's statutory rights.

74. Infringement by the St. Jude Defendants has injured Volcano Corporation and Volcano Corporation is entitled to recover damages adequate to compensate for such infringement, including the recovery of lost profits and in no event less than a reasonable royalty for the St. Jude Defendants' use of the invention claimed by the '965 patent.

75. The St. Jude Defendants' infringement of the '965 patent has irreparably injured Volcano Corporation and will continue to injure Volcano Corporation unless and until the Court enters an injunction prohibiting these entities and those acting on their behalf from committing further acts of infringement by enjoining the further use, offer for sale, sale, and importation into the United States of the Radi PressureWire products.

Count XIII: Infringement of United States Patent No. 7,134,994

76. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

77. On November 14, 2006, the USPTO issued U.S. Patent No. 7,134,994 (the "'994 patent"). The '994 patent is entitled "Multipurpose Host System for Invasive Cardiovascular Diagnostic Measurement Acquisition and Display." A true and correct copy of the '994 patent is attached to this answer and counterclaim as Exhibit B. Volcano Corporation is the owner by assignment of the entire right, title and interest in and to the '994 patent.

78. The St. Jude Defendants have made, used, offered to sell, sold and/or imported into the United States diagnostic measurement acquisition and display devices, including the RadiAnalyzer product, that infringe, induce infringement, and/or contribute to the infringement of the claims of the '994 patent in violation of Volcano's statutory rights.

79. Infringement by the St. Jude Defendants has injured Volcano Corporation and Volcano Corporation is entitled to recover damages adequate to compensate for such infringement, including the recovery of lost profits and in no event less than a reasonable royalty for the St. Jude Defendants' use of the invention claimed by the '994 patent.

80. The infringement of the '994 patent by the St. Jude defendants has irreparably injured Volcano Corporation and will continue to injure Volcano Corporation unless and until the Court enters an injunction prohibiting these entities and those acting on their behalf from committing further acts of infringement by enjoining the further use, offer for sale, sale, and importation into the United States of the RadiAnalyzer.

Count XIV: Infringement of United States Patent No. 5,178,159

81. Volcano Corporation realleges Paragraphs 1-15 of its Counterclaims as if repeated verbatim in this Paragraph.

82. On January 12, 1993, the USPTO issued U.S. Patent No. 5,178,159 (the "'159 patent"). The '159 patent is entitled "Torqueable guide wire assembly with electrical functions, male and female connectors rotatable with respect to one another" A true and correct copy of the '159 patent is attached to this answer and counterclaim as Exhibit C. Volcano Corporation is the owner by assignment of the entire right, title and interest in and to the '159 patent.

83. The St. Jude Defendants have made, used, offered to sell, sold and/or imported into the United States guide wires, including the Radi PressureWire products and the

PressureWire products, that infringe, induce infringement, and/or contribute to the infringement of the claims of the '159 patent in violation of Volcano's statutory rights.

84. Infringement by the St. Jude Defendants has injured Volcano Corporation and Volcano Corporation is entitled to recover damages adequate to compensate for such infringement, including the recovery of lost profits and in no event less than a reasonable royalty for the St. Jude Defendants' use of the invention claimed by the '159 patent.

85. The St. Jude Defendants' infringement of the '159 patent has irreparably injured Volcano Corporation and will continue to injure Volcano Corporation unless and until the Court enters an injunction prohibiting these entities and those acting on their behalf from committing further acts of infringement by enjoining the further use, offer for sale, sale, and importation into the United States of the Radi PressureWire products and the PressureWire products.

PRAYER FOR RELIEF

WHEREFORE, Volcano Corporation respectfully requests that the Court enter judgment in Volcano Corporation's favor and against Plaintiffs and provide Volcano Corporation the following relief:

(1) A declaration that Volcano Corporation has not infringed and is not infringing, either directly, indirectly, or otherwise, any valid claim of:

- a. The '624 patent;
- b. The '980 patent;
- c. The '598 patent;
- d. The '763 patent;
- e. The '083 patent.

(2) A declaration that the asserted claims of the following patents-in-suit are invalid:

- a. The '624 patent;
 - b. The '980 patent;
 - c. The '598 patent;
 - d. The '763 patent;
 - e. The '083 patent.
- (3) A declaration that the '598 and '763 patents are unenforceable due to inequitable conduct.
- (4) A permanent injunction preventing Plaintiffs, including their officers, agents, employees, and all persons acting in concert or participation with them, from charging that any of the claims of the St. Jude patents-in-suit is infringed by Volcano Corporation or its customers.
- (5) A judgment that the St. Jude Defendants have infringed the '965 patent, '994 patent and '159 patent.
- (6) A permanent injunction prohibiting the St. Jude Defendants, including their officers, agents, employees, and all persons acting in concert or participation with them who receive actual notice of the Court's Order, from committing further acts of infringement;
- (7) An award of damages to Volcano Corporation, and an increase in damages under 28 U.S.C. § 284, together with prejudgment interest from the date the infringement began and post-judgment interest;
- (8) An accounting for any infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales;
- (9) A finding that this case is "exceptional within the meaning of 28 U.S.C. § 285, and an award to plaintiffs of their reasonable attorney fees and expenses;
- (10) An award of costs to Volcano Corporation; and

(11) An award of any further relief that the Court deems just and proper.

JURY DEMAND

Volcano demands a trial by jury on all issues appropriately triable by a jury.

Dated: September 20, 2010

FISH & RICHARDSON P.C.

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