

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

DR. GEORGE FREY, M.D.,
a Colorado citizen,

Plaintiff,

v.

SOFAMOR DANEK HOLDINGS, INC.,
a Delaware corporation, and,
MEDTRONIC SOFAMOR DANEK USA, INC.,
an Indiana corporation,

Defendants.

COMPLAINT AND JURY DEMAND

In accordance with Rule 13, 19, and 20 of the Federal Rules of Civil Procedure, Dr. George Frey, M.D., against Medtronic Sofamor Danek USA, Inc. and Sofamor Danek Holdings, Inc., alleges as follows:

NATURE OF ACTION

1. This claim arises, in part, out of breaches of contract and breaches of the covenant of good faith and fair dealing by Medtronic Sofamor Danek USA, Inc. and Sofamor Danek Holdings, Inc.

THE PARTIES

2. George Frey, M.D. ("Dr. Frey") is now and at all times relevant has been a citizen of the State of Colorado.

3. Medtronic Sofamor Danek USA, Inc. ("MSD"), is a corporation organized under the laws of the state of Indiana with its home office and principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132. MSD is a large multinational medical technology company engaged in the business of, among other things, researching, developing, and commercializing technology used in spinal fusion procedures. On information and belief, MSD is the world's largest spinal device manufacturer.

4. Sofamor Danek Holdings ("SDH") is a subsidiary corporation of MSD organized under the laws of Delaware with its principal offices located at 1800 Pyramid Place, Memphis, Tennessee 38132.

JURISDICTION AND VENUE

5. Jurisdiction of this Court arises under the laws of the United States, 28 U.S.C. §1332(a) (diversity), in that the amount in controversy concerns royalties in excess of twenty-five million dollars (\$25,000,000.00), exclusive of costs and interest, and the action is between citizens of different states.

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

7. Plaintiff is informed and believes and thereon alleges that MSD and SDH are directly advertising, importing, offering for sale, selling and shipping products utilizing Dr. Frey's spinal implant technology to and in this district and have a regular established business in

this district, and are thereby purposefully availing themselves of the privilege of conducting activities in this forum.

BACKGROUND

8. Plaintiff Dr. Frey is a noted spinal surgeon and inventor of cutting edge spinal fusion technologies and is the named inventor of several issued patents in the United States directed to spinal fixation and fusion, surgical implants, surgical instruments and surgical methods. His efforts and inventions have helped and continue to help make spinal surgery safer, more effective and less expensive.

9. This lawsuit arises out of SDH's and MSD's breach of two agreements with Dr. Frey concerning medical devices and instruments that Dr. Frey invented for spinal surgery.

10. Surgeons have typically performed interbody spinal fusion procedures via anterior (through the patient's abdomen) or posterior (directly accessing the patient's spine) methods. Each approach presents several difficulties for the surgeon and patient. For instance, many of the vertebrae are not readily accessible through the anterior approach. The posterior approach, while more direct, may require substantial incisions or access points as well as extensive retraction of the spinal cord.

11. A third approach, a posterior lateral approach, had been very uncommon prior to the year 2000 because the instruments and methods related to this approach made it difficult to keep the load on the spine evenly distributed. In an effort to overcome problems with this approach, Dr. Frey developed implants, instruments and methods particularly adapted for unilateral disc preparation and implant insertion from a posterior lateral approach. His inventions, while having numerous applications, have helped address the problems with the posterior approach to spinal surgery, thus making it safer and more beneficial to the patient.

The Boomerang Agreement with SDH

12. Effective January 1, 2000, Dr. Frey entered into a purchase agreement (the "Boomerang Agreement") with SDH and all its affiliated companies. One such affiliated company is MSD.

13. Pursuant to The Boomerang Agreement the parties agreed that:

- "Dr. Frey has developed an invention (hereinafter the "Invention" as described below) related to the Medical Device;"
- "SDH desires to acquire from Dr. Frey all his rights in and to the Invention in the United States of America and foreign countries with respect to the Medical Device; and"
- "Dr. Frey desires to assign to SDH the Invention and all his rights in and to the Invention with respect to the Medical Device in the United States of America and foreign countries."

14. The Boomerang Agreement contains several significant definitions, including definitions of the Invention, Intellectual Property Rights, Medical Device and Net Sales.

15. The Boomerang Agreement defines the Invention as "the Boomerang Cage for use in interbody fusion of vertebral bodies as described in Schedule A attached hereto." Schedule A contains hand-drawn diagrams of the Boomerang Cage Design and Boomerang Instruments.

16. Intellectual Property Rights are defined as "any patent and/or patent application, improvement, modification, enhancement, any and all know-how and technology, and any other intellectual property rights with respect to the Invention naming Dr. Frey as an inventor..."

17. Medical Device is defined as "any device, article, system, apparatus or product including the Invention..."

18. Net Sales shall mean "the invoice price charged by SDH to third parties for the Medical Device, less (i) any refunds, credits or allowances actually given to customers for returns of the Medical Device, (ii) any discounts actually given or credited, and (iii) any commissions actually paid or credited."

19. The Boomerang Agreement provided that SDH had the "right to prepare, file and prosecute patent applications for the Invention naming Dr. Frey as an inventor or co-inventor... on the Medical Device." In addition, SDH would be listed as the assignee on the patent application and would have sole ownership of any patent issued.

20. The Boomerang Agreement also provided that Dr. Frey would transfer his "interest in and to the Invention and Intellectual Property Rights relating to the Medical Device to SDH" and that "SDH shall pay to Dr. Frey for the Medical Device and the rights to the Invention related thereto an amount (the "Amount") equal to three and one half percent (3-1/2%) of the worldwide Net Sales of the Medical Device for a period of seven (7) years from the date of first sale."

21. Taking into account the significant value of Intellectual Property Rights covering the Invention, the Boomerang Agreement stated that "if the Medical Device is covered by valid claims of any patent within the Intellectual Property Rights directed to the Invention and conveyed to SDH," Dr. Frey would instead receive six percent (6%) of the worldwide Net Sales of any such Medical Device for the life of the patent.

Second Amendment to the Boomerang Agreement

22. SDH prepared and filed patent application PC401.7, Ser. No. 09/858,197. However, no patent had issued as of January 1, 2004. Both Dr. Frey and SDH agreed a patent should have been issued by this time, but failures to timely respond to the Patent Office and pursue the patent on the part of SDH's patent counsel caused the patent application to become administratively delayed for an indefinite period of time.

23. Due in part to these delays, Dr. Frey and SDH entered into the Second Amendment to Purchase Agreement (the "Second Amendment"). This amendment, effective January 1, 2004, increased the Amount to be paid to Dr. Frey. The amended provision of the Boomerang Agreement stated, in relevant part, that "as of January 1, 2004, and *as long as the Medical Device is covered by any of the claims* of United States PC401.7, Ser. No. 09/858,197 *or any other patent application within the Intellectual Property Rights directed to the Invention* and conveyed to SDH hereunder, the Amount shall be six percent (6%) of the worldwide Net Sales of any such Medical Device" (emphasis added).

The '193 Patent

24. On April 22, 2008, United States Patent No. 7,361,193 ("the '193 Patent") was issued, naming Dr. Frey as an inventor. The '193 Patent arose from the patent application numbered 10/721,642. Thus, it qualified as "any other patent application within the Intellectual Property Rights directed to the Invention and conveyed to SDH..." as specified in the Boomerang Agreement as well as the Second Amendment.

25. Dr. Frey's '193 Patent describes an invention that relates to methods and instruments for performing disc space separation and implant insertion from a unilateral

approach to the spine through a posterior lateral opening in the disc space. Instruments, procedures, and implants, among other things, are described in detail in the '193 Patent.

26. The '193 Patent describes a spinal implant that contains numerous distinguishing characteristics. For instance, Column 17, lines 14-37 describe and FIGS. 52 and 56 show a double convex or bioconvex shape designed to match the endplates of patients vertebral bodies. This customized shape, among other characteristics, is taught by Dr. Frey's patent.

27. Column 19, lines 9-13 of the '193 Patent recites "The double convexity of the upper and lower bearing members in combination with the boomerang shape provides an intimate fit in the disc space and a profile that matches the concavity of the endplates, providing implant stability and promoting fusion," which highlights the importance of the bioconvex design.

28. The '193 Patent includes claims that are directed to a spinal implant that is designed to restore and maintain spinal lordosis and claims that are directed to a double convex design. Claim 5 of the '193 Patent recites "said posterior wall has a height that is less than the height of said anterior wall." Claim 6 of the '193 Patent recites "The implant of claim 5, wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall."

29. Claim 12 of the '193 Patent recites "The implant of claim 11, wherein said anterior wall has a height that is greater than a height of said posterior wall."

30. Claim 15 of the '193 Patent recites "said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall and said anterior wall has a height greater than a height of said posterior wall."

Breach by SDH and MSD

31. MSD and SDH market and sell products that fall within the definition of Medical Device contained in the Boomerang Agreement. These products include, among others, Boomerang, Boomerang II and the Crescent Vertebral Body Spacer.

32. MSD and SDH pay Dr. Frey royalties based on the Net Sales of Boomerang, Boomerang II and Crescent Vertebral Body Spacer, among others, pursuant to the Boomerang Agreement.

33. Accordingly, MSD and SDH, by their course of conduct, concede that these products are Medical Devices under the Boomerang Agreement and that the Boomerang Agreement is not limited to the original Boomerang Implant.

34. Other products marketed and sold by MSD and SDH are also Medical Devices. These products include, but are not limited to, the Capstone Spinal System ("Capstone") which is also used in spinal fusion surgery.

35. As shown in the Capstone brochures, Capstone Implants embody a double convex or bioconvex shape designed to match the endplates of patients vertebral bodies that follows the teaching of the '193 Patent and is similar to the bioconvex design of Boomerang. In addition, Capstone is covered by claims of the Intellectual Property and is therefore by definition a Medical Device.

36. The bioconvex design is described in numerous patents that are related to the '193 patent and name Dr. Frey as the inventor, including, but not limited to, U.S. Patent Nos. 6,830,570 ("the '570 Patent"), 7,060,073 ("the '073 Patent"), 7,481,812 ("the '812 Patent"), 7,615,078 ("the '078 Patent") and 6,991,653 ("the '653 Patent"), as well as U.S. Patent Publication No. 2010/0004752 ("the '752 Application").

37. FIGS. 52 and 56 of the '570 Patent, FIGS. 54 and 58 of the '073 Patent, and FIGS. 54 and 58 of the '812 Patent are virtually identical to FIGS. 52 and 56 of the '193 Patent and, among others, show an implant with a bioconvex shape designed to match the endplates of patients vertebral bodies.

38. FIGS. 61 and 64 of the '073 Patent, FIGS. 61 and 64 of the '812 Patent, FIGS. 13, 14, 17-20 of the '078 Patent, FIGS. 13, 14, 17-20 of the '653 Patent, and FIGS. 13, 14, 17-20 of the '752 Application, among others also show an implant with a bioconvex shape designed to match the endplates of patients vertebral bodies.

39. Column 17, lines 9-32 of the '570 Patent, Column 19, lines 22-45 of the '073 Patent and Column 18, line 61 to Column 19, line 18 of the '812 Patent, are virtually identical to Column 17, lines 14-37 of the '193 Patent and describe an implant with a bioconvex shape designed to match the endplates of patients vertebral bodies.

40. Column 19, lines 4-8 of the '570 Patent, Column 21, lines 22-26 of the '073 Patent and Column 20, lines 59-64 of the '812 Patent are virtually identical to Column 19, lines 9-13 of the '193 Patent, and recite "[t]he double convexity of the upper and lower bearing members in combination with the boomerang shape provides an intimate fit in the disc space and a profile that matches the concavity of the endplates, providing implant stability and promoting fusion."

41. The '570 Patent also includes claims that are directed to a method for inserting an implant in a spinal disc space. For example, claim 1 of the '570 Patent recites "[a] method for inserting an implant in a spinal disc space, comprising: creating a posterior lateral opening into the disc space; providing an implant for insertion into the disc space; positioning a leading end of the implant at the opening; and alternately applying pushing and pivoting forces to the implant to position the implant through the opening and in the disc space along a non-linear insertion path."

42. Column 19, lines 45-51 of the '073 Patent and Column 19, lines 18-23 of the '812 Patent recite "[f]urthermore, the difference in heights between the upper and lower bearing members at the anterior and posterior walls can be provided so as to establish lordosis when implant 1000 is inserted in the disc space. Implant 1000 thus has application in restoring and maintaining spinal lordosis from a postero-lateral approach," which also demonstrates the significant advantage of the bioconvex design.

43. Column 12, line 61 to Column 13, line 12 of the '078 Patent and Column 13, lines 7-26 of the '653 Patent and Column describe an implant with a bioconvex shape designed to match the endplates of patients vertebral bodies.

44. Column 13, lines 6-8 of the '078 Patent and Column 13, lines 20-22 of the '653 Patent recite "[t]his double convex curvature substantially matches the double concave curvature of the adjacent vertebral endplates."

45. The '073 Patent includes claims that are directed to a spinal implant that is designed to restore and maintain spinal lordosis. Claim 8 of the '073 Patent recites "[t]he implant of claim 4, wherein said posterior wall has a height that is less than a height of said anterior wall." Claims 26, 42, 53, 63, 68 and 92 of the '073 Patent include similar recitations.

46. The '078 Patent includes claims that are directed to a method for assembling a vertebral replacement device. The method includes an implant that has at least one upper or lower end surface with a convex shape. Claim 7 of the '078 Patent recites "[t]he method of claim 1, wherein the first and second end surfaces of the first member each include a convex curvature."

47. Claim 21 of the '078 Patent recites "[t]he method of claim 16, wherein the first end surfaces of each of the first and second end members each include a convex curvature across

the respective one of the first and second end members in at least one direction transverse to a longitudinal axis of the vertebral replacement device and the upper and lower end surfaces of the connecting member each include a concave curvature across the connecting member in at least one direction transverse to the longitudinal axis of the vertebral replacement device to provide a concave to convex axially bearing relationship between the first end surface of the first end member and the upper end surface of the connecting member and the first end surface of the second end member and the lower end surface of the connecting member."

48. Claim 22 of the '078 Patent recites "[t]he method of claim 8, wherein the second end surface of the selected first member includes a convex curvature across the first end member in at least one direction transverse to a longitudinal axis of the vertebral replacement device and the at least one of the upper end surface and the lower end surface of the second member includes a concave curvature across the second member in at least one direction transverse to the longitudinal axis of the vertebral replacement device to provide a concave to convex axially bearing relationship between the second end surface of the first end member and the at least one of the upper end surface and the lower end surface of the second member."

49. The '653 Patent includes claims that are directed to a vertebral replacement device that includes at least one upper or lower end surface with a convex shape. Claim 11 of the '653 Patent recites "[t]he device of claim 1, wherein said one of said upper end surface and said lower end surface includes a first concave curvature and said second end surface includes a first convex curvature conforming to said first concave curvature." Claim 12 of the '653 Patent recites "[t]he device of claim 11, wherein said one of said upper end surface and said lower end surface includes a second concave curvature transverse to said first concave curvature and said second end surface includes a second convex curvature transverse to said first convex curvature to said

second concave curvature." Taken together, these claims define a device with a double convexity. Claims 15 and 16 recite similar language. Claims 42 and 45 recite similar language.

50. Claim 50 of the '653 Patent recites "[t]he device of claim 41, wherein said first end surface of said first member includes a convex curvature adapted to conform to the curvature of the adjacent vertebral endplate." Claim 51 recites "[t]he device of claim 50, wherein said first end surface and said second end surface of said first member include the same convex curvature." Claims 53 and 54 recite similar language.

51. Dr. Frey's Patent first conceived of and explained the bioconvex design. Accordingly, Capstone falls within the Intellectual Property Rights and is part of the Medical Device, entitling Dr. Frey to a payment based on Net Sales of Capstone in the amount of a six percent (6%) royalty rate of the worldwide Net Sales "of any such Medical Device."

52. In addition, all of these citations and recitations establish that the double convex or bioconvex design invented by Dr. Frey is an important feature. The Capstone Implants embody this double convex or bioconvex design.

53. Nonetheless, MSD and SDH refuse to pay to Dr. Frey royalties for products including, but not limited to, Capstone, that are Medical Devices. Although Dr. Frey has asked MSD and SDH to pay royalties to which he is entitled under the Boomerang Agreement, MSD and SDH continue to intentionally and willfully declined to perform their obligations under the Boomerang Agreement.

54. Thus, MSD and SDH have intentionally breached the express terms of the Boomerang Agreement by continuing to market and sell Medical Devices without paying the required royalties to Dr. Frey.

55. In addition, on information and belief, MSD and SDH have benefitted from Dr. Frey's inventions under the Boomerang Agreement by not enforcing Dr. Frey's patents. This benefit has included both monetary and non-monetary compensation.

The Pyramesh Agreement with SDH

56. Effective January 1, 2000, Dr. Frey entered into a purchase agreement (the "Pyramesh Agreement") with SDH and all its affiliated companies. One such affiliated company is MSD.

57. Pursuant to The Pyramesh Agreement the parties agreed that:

- "Dr. Frey has developed an invention (hereinafter the "Invention" as described below) related to the Medical Device;"
- "Dr. Frey desires to assign to SDH the Invention and all his rights in and to the Invention with respect to the Medical Device in the United States of America and all foreign countries; and"
- "SDH desires to acquire from Dr. Frey all his rights in and to the Invention in the United States of America and foreign countries with respect to the Medical Device."

58. The Pyramesh Agreement contains several significant definitions, including definitions of the Invention, Intellectual Property Rights, Medical Device and Net Sales.

59. The Pyramesh Agreement defines the Invention as "an instrument set used for insertion of SDH's Pyramesh titanium mesh products via a transforaminal lumbar interbody fusion (TLIF) or a posterior lumbar interbody fusion (PLIF) procedure, as described and shown in Schedule A, attached hereto." Schedule A lists various types of chisels, scrapers, reamers, and forceps among other instruments.

60. Intellectual Property Rights are defined as "any patent and/or patent application, improvement, modification, enhancement, any and all know-how and technology, and any other intellectual property rights with respect to the Invention, as described and set forth in Schedule B, attached hereto. Company shall update Schedule B from time to time and at least yearly."

61. Medical Device is defined as "any device, article, system, apparatus or product, which is implanted via use of the Invention. Such Medical Devices shall be listed in accordance with SDH catalog numbers and descriptions as set forth in Schedule C attached to this Agreement and as agreed upon in writing between the parties."

62. Net Sales "shall mean the invoice price charged by SDH to third parties for the Medical Device, less (i) any refunds, credits or allowances actually given to customers for returns of the Medical Device, (ii) any discounts actually given or credited, and (iii) any commissions actually paid or credited."

63. The Pyramesh Agreement also provides that on the effective date of the Pyramesh Agreement, Dr. Frey "irrevocably transfers, assigns, and conveys to SDH all his entire right, title, and interest in and to the Invention and Intellectual Property Rights..."

64. In exchange for this transfer, Section 4B of the Pyramesh Agreement stated "SDH shall pay to Dr. Frey for the rights to the Invention and Intellectual Property Rights a running royalty of two percent (2%) of the incremental U.S. Net Sales of the Medical Device(s) over the Benchmark Net Sales of Medical Device(s) of Three Million Six Hundred Thousand Dollars (\$3,600,000) per year. The benchmark Net Sales will be determined quarterly (hereinafter Quarterly Benchmark Net Sales (\$900,000)), and the running royalty is to be paid to Dr. Frey on a quarterly basis and within forty five (45) days following the end of the applicable calendar

quarter... The Medical Device(s) upon which Net Sales shall be determined are listed in Schedule C, attached hereto."

65. Paragraph 6 of the Pyramesh Agreement states that "[i]n the event that SDH breaches the Agreement, Dr. Frey is entitled to... the return to Dr. Frey of all of his rights in and to the Invention."

Amendment to Purchase Agreement with SDH

66. Effective June 1, 2002 (the "Effective Date"), the royalty rate of the Pyramesh Agreement was amended (the "Amendment").

67. The Amendment stated in part that "Schedule C to the Purchase Agreement is hereby amended to include the Amendment Medical Devices (hereinafter defined). From and after the Effective Date, the Amendment Medical Devices shall be deemed to be included in Schedule C to the Purchase Agreement for all purposes and the term "Medical Devices," when used in the Purchase Agreement or in this Amendment, shall include the Amendment Medical Devices and Other Medical Devices (hereinafter defined) for all purposes."

68. The royalty rate was amended, stating "the royalty rate for Amendment Medical Devices shall be one percent (1%). The royalty rate for Other Medical Devices shall remain two percent (2%), as provided in the Purchase Agreement. With the exception of the difference in royalty rates for Amendment Medical Devices and Other Medical Devices, all other terms and provisions of Section 4B shall be applicable to both Amendment Medical Devices and Other Medical Devices..."

69. Amendment Medical Devices were defined as "the medical devices listed in Schedule C-1 attached to this Amendment." Schedule C-1 lists Mirage Mesh instruments not previously identified in the original Pyramesh Agreement.

70. Other Medical Devices were defined as "all medical devices specifically listed in Schedule C to the Purchase Agreement and shall not include Amendment Medical Devices."

Breach by SDH and MSD

71. The instruments of the Invention are contained in many instrument sets sold and marketed by MSD and SDH including the Pyrametrix and Pyrametrix Advance instrument sets.

72. MSD and SDH have marketed and sold the Pyrametrix Advance instruments, and its derivatives, as the preferred disc space preparation instrument set for use in teaching the procedure of posterior access interbody fusions with many devices, including, but not limited to Capstone, during its sponsored surgeon training programs.

73. MSD and SDH sales representatives also commonly request the Pyrametrix Advance Instrument set when preparing for a surgeon customer who will perform surgery in which the Capstone Implant is implanted via use of the Pyrametrix Advance Instrument set to prepare the disc space for the implant.

74. Thus, Capstone is frequently implanted through the use of the Pyrametrix Advance Instrument set to prepare the disc space. Accordingly, Capstone falls within the definition of Medical Device and Dr. Frey is entitled to royalties pursuant to the Pyramesh Agreement in that the Medical Device is defined as a "product [Capstone], which is implanted via use of the Invention [the Pyrametrix Advance Instrument set]."

75. Nonetheless, MSD and SDH have refused to pay royalties to Dr. Frey on Capstone. In addition, MSD and SDH have also failed to pay royalties on the sale of Pyrametrix instruments.

76. SDH's and MSD's refusal to carry out its obligations under the Pyramesh Agreement is a breach of its express terms.

77. Accordingly, in addition to damages, Section 6 of the Pyramesh Agreement states, in the event that SDH breaches the Agreement, Dr. Frey is entitled to the return of "all of his rights in and to the Invention."

FIRST CLAIM FOR RELIEF
(Breach of Written Contract - Boomerang Agreement and Amendment)

78. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 77.

79. The terms of the Boomerang Agreement contain the definition of Medical Device and the terms by which Dr. Frey is entitled to receive royalties for Net Sales of the Medical Device.

80. MSD and SDH market and sell products, including the Capstone Implant among others, that are Medical Devices as defined in the Boomerang Agreement.

81. According to the terms of the Boomerang Agreement, MSD and SDH are obligated to pay Dr. Frey a six percent (6%) royalty rate because the implants being used are Medical Devices developed by Dr. Frey according to the Agreement.

82. MSD and SDH have breached the Boomerang Agreement in failing to pay Dr. Frey amounts to which he is entitled.

83. MSD and SDH have also intentionally failed to pay to Dr. Frey royalties to which he is entitled.

84. In addition, on information and belief, MSD and SDH have failed to enforce the patents according to paragraph 8 of the Boomerang Agreement.

85. Dr. Frey has duly performed all of the conditions of the Purchase Agreement, other than those conditions, if any, which have been waived by MSD and SDH or excused by its breaches of the Purchase Agreement.

86. As a direct and proximate result of MSD's and SDH's breaches of the Boomerang Agreement, Dr. Frey has sustained damages in an amount to be proven at trial but in no event less than twenty-five million dollars (\$25,000,000.00). Dr. Frey is also entitled to recover punitive damages because MSD and SDH have intentionally and willfully undertaken actions with a conscious disregard of the rights of Dr. Frey under the Boomerang Agreement, including the intentional withholding of royalty payments.

SECOND CLAIM FOR RELIEF
**(Breach of the Covenant of Good Faith and Fair Dealing –
Boomerang Agreement and Amendment)**

87. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 86.

88. SDH and MSD have breached the covenant of good faith and fair dealing which precludes a party to a contract from engaging in conduct that will deprive the other part of the benefits of their agreement.

89. SDH and MSD market and sell Medical Devices as defined in the Boomerang Agreement, including, but not limited to, the Capstone System.

90. MSD and SDH have intentionally failed to pay to Dr. Frey the royalties to which he is entitled under the Boomerang Agreement.

91. In addition, on information and belief, MSD and SDH have failed to enforce the patents according to paragraph 8 of the Boomerang Agreement.

92. Dr. Frey has duly performed all of the conditions of the Purchase Agreement, other than those conditions, if any, which have been waived by MSD and SDH or excused by its breaches of the Purchase Agreement.

93. As a direct and proximate result of MSD's and SDH's breaches of the Boomerang Agreement, Dr. Frey has sustained damages in an amount to be proven at trial but in no event less than twenty-five million dollars (\$25,000,000.00). Dr. Frey is also entitled to recover punitive damages because MSD and SDH have intentionally and willfully undertaken actions with a conscious disregard of the rights of Dr. Frey under the Boomerang Agreement, including the intentional withholding of royalty payments.

THIRD CLAIM FOR RELIEF
(Breach of Contract - Pyramesh Agreement and Amendment)

94. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 93.

95. MSD and SDH market and sell various instruments contained in the instrument set developed by Dr. Frey generating income for itself in excess of Benchmark Net Sales defined in the Pyramesh Agreement.

96. Pursuant to the Pyramesh Agreement, MSD and SDH are obligated and Dr. Frey is entitled to royalty rates as outlined in the Pyramesh Agreement.

97. MSD and SDH have refused to pay royalties to Dr. Frey.

98. By failing to pay royalties, MSD and SDH have breached their agreement with Dr. Frey.

99. Dr. Frey has duly performed all of the conditions of the Pyramesh Agreement, other than those conditions, if any, which have been waived by MSD and SDH or excused by its breaches of the Purchase Agreement.

100. As a direct and proximate result of MSD's and SDH's breaches of the Pyramesh Agreement, Dr. Frey has sustained damages in an amount to be proven at trial.

FOURTH CLAIM FOR RELIEF
**(Breach of the Covenant of Good Faith and Fair Dealing –
Pyramesh Agreement and Amendment)**

101. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 100.

102. SDH and MSD have breach the covenant of good faith and fair dealing which precludes a party to a contract from engaging in conduct that will deprive the other part of the benefits of their agreement.

103. By the facts set forth above, SDH and MSD breach the covenant of good faith and fair dealing through, among other things, profiting from Dr. Frey's inventions and continuing to use instruments developed by Dr. Frey in numerous applications without paying to Dr. Frey the royalties to which he is entitled as required by the terms of the Pyramesh Agreement.

104. As a direct and proximate result of MSD's and SDH's breaches of the Purchase Agreement, Dr. Frey has sustained damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Dr. Frey prays for judgment in its favor and against SDH and MSD as follows:

A. On the First Claim for Relief, that Dr. Frey be awarded damages against SDH and MSD according to proof, plus accrued interest thereon and punitive damages; and

B. On the Second Claim for Relief, that Dr. Frey be awarded damages against SDH and MSD according to proof, plus accrued interest thereon and punitive damages; and

C. On the Third Claim for Relief:

1. That Dr. Frey be awarded damages against SDH and MSD according to proof, plus accrued interest thereon; and

2. That Dr. Frey be awarded the return of all his rights in and to the Invention as he is entitled under the Pyramesh Agreement.

D. On the Fourth Claim for Relief, that Dr. Frey be awarded damages against SDH and MSD according to proof, plus accrued interest thereon.

E. On all Claims for Relief:

1. That Plaintiff be awarded his costs of suit;

2. That Plaintiff be awarded his attorneys' fees;

3. That Plaintiff be awarded prejudgment interest; and

4. That the Court grant such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff Dr. Frey requests a jury trial on all issues so triable.

DATED: March 25, 2011

Respectfully submitted,

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