IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORTHOPHOENIX, LLC, Plaintiff v. SOTEIRA, INC.; GLOBUS MEDICAL, INC.; JOHN AND/OR JANE DOES 1-200, Defendants.	C.A. No. 13-1006-LPS **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Orthophoenix, LLC ("Orthophoenix") alleges as follows:

PARTIES

1. Orthophoenix is a Delaware limited liability company with a principal place of business located at 2515 McKinney Avenue, Suite 1000-B, Dallas, Texas 75201.

2. Defendant Soteira, Inc. ("Soteira") is a Delaware corporation with a principal place of business at 14 Tech Circle, Natick, Massachusetts 01760. Soteira has appointed The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, as its agent for service of process.

3. Defendant Globus Medical, Inc. ("Globus") is a Delaware corporation with a principal place of business at 2560 General Armistead Avenue, Audubon, Pennsylvania 19403. Globus has appointed Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, as its agent for service of process.

4. Defendants John and/or Jane Does 1-200 ("Does") are orthopedic surgeons using the infringing products manufactured by Defendants. Does' identities are not presently known to Orthophoenix; however, on information and belief, Defendants are in possession of documents and information from which Does' identities can be readily ascertained.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendants Soteira and Globus because, among other reasons, Defendants Soteira and Globus are corporations organized and existing under the laws of the State of Delaware. Thus, Defendants Soteira and Globus have purposefully availed themselves of the benefits of the State of Delaware and the exercise of jurisdiction over Soteira and Globus would not offend traditional notions of fair play and substantial justice.

7. Venue is proper in this District under 28 U.S.C. §§ 1391 (b)-(c) and 1400(b) because Defendants are subject to personal jurisdiction in this District.

8. Joinder of Defendants is proper pursuant to 35 U.S.C. § 299 because Globus owns, or otherwise directs and controls, the businesses that distribute each of the accused products at issue. On information and belief, Globus purchased Soteira. In addition, after purchasing Soteira, Globus began manufacturing and distributing the accused Soteira products through Globus' division, Algea Therapies. Therefore, the

allegations against Soteira and Globus arise, at least in part, from sales of the same accused products.

BACKGROUND

9. In 1994 Dr. Mark Reiley, an orthopedic surgeon from Berkeley, California, Mr. Arie Scholten, an engineer and inventor of surgical products, and Dr. Karen Talmadge, a Harvard University biochemist, founded Kyphon Inc. ("Kyphon"). Kyphon quickly came to be recognized as the global leader in restoring spinal function through minimally invasive therapies via its innovative, and then disruptive, technology. Kyphon relentlessly pursued novel solutions and their translation into practice. Dr. Reiley performed the first balloon kyphoplasty in 1998; today, over 11,000 physicians throughout the world have been trained to perform balloon kyphoplasty.

10. Due to Kyphon's dedication to developing pioneering medical technologies, it was awarded over 500 U.S. Patents and Applications.

11. Kyphon became the industry leader and Dr. Karen Talmadge, then Executive Vice President, Co-Founder, and Chief Science Officer was given the Patient Quality of Life Award in November 2004 by the International Myeloma Foundation. This award recognized the impact of balloon kyphoplasty in helping myeloma patients with spinal fractures return to their daily lives. In the same year, Kyphon was named the top emerging medical device company in the industry by a group of 150 medical device CEOs.

12. The significant value of Kyphon and its patents is reflected in the $4.2 billion purchase price Medtronic, Inc. ("Medtronic") paid for Kyphon in 2007.

13. Medtronic is a world leader in medical device technologies and therapies. Medtronic specializes in developing and manufacturing medical device technologies and therapies to treat chronic disease worldwide. On April 26, 2013, Orthophoenix completed a transaction to acquire the Kyphon technology, which includes approximately 500 patents and applications.

14. On May 13, 2013, Orthophoenix, through its licensing agent, provided a letter via overnight delivery service to Soteira requesting that Soteira enter into discussions regarding the technology at issue in this case. Soteira never responded.

ASSERTED PATENTS

15. Orthophoenix is the owner by assignment of U.S. Patent No. 6,440,138 (the "'138 patent"). The '138 patent is entitled "Structures and Methods For Creating Cavities In Interior Body Regions." The '138 patent issued on August 27, 2002. A true and correct copy of the '138 patent is attached hereto as Exhibit A.

16. Orthophoenix is the owner by assignment of U.S. Patent No. 6,863,672 (the "'672 patent"). The '672 patent is entitled "Structures And Methods For Creating Cavities In Interior Body Regions." The '672 patent issued on March 8, 2005. A true and correct copy of the '672 patent is attached hereto as Exhibit B.

17. Orthophoenix is the owner by assignment of U.S. Patent No. 7,909,827 (the "'9827 patent"). The '9827 patent is entitled "Systems And Methods For Creating Cavities In Interior Body Regions." The '9827 patent was issued on March 22, 2011. A true and correct copy of the '9827 patent is attached hereto as Exhibit C.

18. Orthophoenix is the owner by assignment of U.S. Patent No. 7,967,827 (the "'7827 patent"). The '7827 patent is entitled "Methods And Devices For Treating

Fractured And/Or Diseased Bone Using Expandable Structure That Remains Within The Bone." The '7827 patent was issued on June 28, 2011. A true and correct copy of the '7827 patent is attached hereto as Exhibit D.

19. Orthophoenix is the owner by assignment of U.S. Patent No. 6,981,981 (the "'981 patent"). The '981 patent is entitled "Inflatable Device For Use In Surgical Protocol Relating To Fixation Of Bone." The '981 patent was issued on January 3, 2006. A true and correct copy of the '981 patent is attached hereto as Exhibit E.

20. Orthophoenix is the owner by assignment of U.S. Patent No. 7,044,954 (the "'954 patent"). The '954 patent is entitled "Method For Treating A Vertebral Body." The '954 patent was issued on May 16, 2006. A true and correct copy of the '954 patent is attached hereto as Exhibit F.

COUNT I
(Infringement of U.S. Patent No. 6,440,138)

21. Orthophoenix references and incorporates by reference paragraphs 1 through 20 of this Complaint.

22. Soteira and Globus have been and still are infringing at least Claim 1 of the '138 patent, literally and under the doctrine of equivalents, by manufacturing, using, selling, offering to sell, or importing, without license or authority, surgical instruments used to create cavities within cancellous bone including, but not limited to, the Shield Kyphoplasty System.

23. By way of example only, with reference to Claim 1 of the '138 patent, the Shield Kyphoplasty System manufactured, sold, offered for sale, or imported by Soteira and Globus includes a cannula having an axis establishing a percutaneous path leading to inside a bone. The Shield Kyphoplasty System includes a shaft that carries a cavity-

forming structure adapted to be deployed inside bone by movement within and along the axis of the cannula. The cavity-forming structure comprises a surface which directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula.

24. Defendant Does 1-100 have been and still are infringing at least Claim 1 of the '138 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Shield Kyphoplasty System Does purchased from Soteira and/or Globus.

25. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '138 patent by active inducement under 35 U.S.C. § 271(b).

26. Upon information and belief, Soteira had knowledge of the '138 patent since at least as early as 2011. Soteira cited the '138 patent in the following U.S. Patents, both of which were issued in 2011: U.S. Patent No. 7,909,873 and U.S. Patent No. 7,959,634. Additionally, in 2011, Soteira indicated that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device" to its Shield Kyphoplasty System in its request to market the Shield Kyphoplasty System in the United States, which was filed on December 8, 2011, with the United States Food and Drug Administration ("FDA"). By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device," Soteira was representing to the FDA that the Shield Kyphoplasty System is "substantially equivalent" to the Kyphon product. *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm. Kyphon implemented a comprehensive marking policy. Further, on information and belief, by

analyzing the Kyphon Kyphx Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Shield Kyphoplasty System, Soteira gained knowledge of the '138 patent at least as early as 2011.

27. Upon information and belief, Globus had knowledge of the '138 patent as early as the date on which it acquired Soteira. Alternatively, at least after being served with the Amended Complaint in this action, Globus has had knowledge of the '138 patent.

28. On information and belief, Soteira and Globus have intended, and continue to intend, to induce patent infringement by third-party physicians and have had knowledge that the inducing acts would cause infringement or have been willfully blind to the possibility that their inducing acts would cause infringement. For example, Soteira and Globus provide training and instruction materials to physicians on how to use the infringing surgical instruments, including the Shield Kyphoplasty System, during the performance of surgical procedures during which physicians create a cavity in cancellous bone. By using the infringing surgical instruments, including but not limited to the Shield Kyphoplasty System, during procedures during which physicians create cavities in cancellous bone as instructed and trained by Soteira and/or Globus, physicians directly infringe at least Claim 1 of the '138 patent. By continuing to provide instruction and training on the use of the Shield Kyphoplasty System to physicians despite its knowledge that the Shield Kyphoplasty System infringes the '138 patent, Soteira and Globus have and continue to specifically intend to induce infringement of the '138 patent.

29. Since at least 2011, Soteira has been and still is willfully infringing the '138 patent. At least as early as 2011, Soteira had actual knowledge of the '138 patent.

Despite having actual knowledge of the '138 patent, Soteira has continued to willfully, wantonly, and deliberately infringe the '138 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

30. Since at least the date Globus acquired Soteira, Globus has been and still is willfully infringing the '138 patent. At least since the date Globus acquired Soteira, Globus had actual knowledge of the '138 patent. Despite having actual knowledge of the '138 patent, Globus has continued to willfully, wantonly, and deliberately infringe the '138 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

31. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '138 patent.

32. As a result of Defendants' infringement of the '138 patent, Orthophoenix has suffered monetary damages in an amount adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, and Orthophoenix will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

33. Unless a permanent injunction is issued enjoining Defendants and their agents, servants, employees, representatives, affiliates, and all others acting or in active

concert therewith from infringing the '138 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT II
(Infringement of U.S. Patent No. 6,863,672)

34. Orthophoenix references and incorporates by reference paragraphs 1 through 33 of this Complaint.

35. Defendants Does 1-100 have been and still are infringing at least Claim 11 of the '672 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Shield Kyphoplasty System Does purchased from Soteira and/or Globus in the manner instructed and taught by Soteira and/or Globus, and in the manner for which the Shield Kyphoplasty System is approved for use by the FDA.

36. Soteira and Globus have been and still are infringing at least Claim 11 of the '672 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Shield Kyphoplasty System. By way of example only, Soteira and Globus directly infringe the '672 patent by performing the method of treating a vertebral body described in Claim 11.

37. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '672 patent by active inducement under 35 U.S.C. § 271(b).

38. Upon information and belief, Soteira had knowledge of the '672 patent since at least as early as 2011. Soteira cited the '672 patent in the following U.S. Patents, both of which were issued in 2011: U.S. Patent No. 7,909,873 and U.S. Patent No. 7,959,634. Additionally, in 2011, Soteira indicated that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device" to its Shield Kyphoplasty System in its request to

market the Shield Kyphoplasty System in the United States, which was filed on December 8, 2011, with the United States Food and Drug Administration ("FDA"). By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device," Soteira was representing to the FDA that the Shield Kyphoplasty System is "substantially equivalent" to the Kyphon product. *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm. Kyphon implemented a comprehensive marking policy. Further, on information and belief, by analyzing the Kyphon Kyphx Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Shield Kyphoplasty System, Soteira gained knowledge of the '672 patent at least as early as 2011.

39. Upon information and belief, Globus had knowledge of the '672 patent as early as the date on which it acquired Soteira. Alternatively, at least after being served with the Amended Complaint in this action, Globus has had knowledge of the '672 patent.

40. On information and belief, Soteira and Globus have intended, and continue to intend, to induce patent infringement by third-party physicians and have had knowledge that the inducing acts would cause infringement or has been willfully blind to the possibility that their inducing acts would cause infringement. For example, Soteira and Globus provide training and instruction materials to physicians on how to use the infringing surgical instruments, including the Shield Kyphoplasty System, during the performance of surgical procedures during which physicians use the infringing surgical instruments to create cavities in the cancellous bone of a vertebral body. By using the

infringing surgical instruments, including the Shield Kyphoplasty System, to create cavities in cancellous bone as instructed and trained by Soteira and/or Globus, physicians directly infringe at least Claim 11 of the '672 patent. By continuing to provide instruction and training to physicians on how to use the Shield Kyphoplasty System to perform surgical procedures in the manner described in Claim 11 of the '672 patent, Soteira and Globus have and continue to specifically intend to induce infringement of the '672 patent.

41. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '672 patent by contributory infringement under 35 U.S.C. § 271(c).

42. Soteira and Globus have and continue to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Shield Kyphoplasty System, with the knowledge that the surgical instruments will be used by physicians to directly infringe at least Claim 11 of the '672 patent.

43. Soteira had knowledge of the '672 patent since at least 2011. Globus had knowledge of the '672 patent since at least the date on which it acquired Soteira, or alternatively, since being served with the Amended Complaint in this action. Soteira and Globus have had knowledge that the surgical instruments, including the Shield Kyphoplasty System, are material components to practicing the surgical procedures claimed in the '672 patent, that the surgical instruments are not staple articles or commodities of commerce suitable for substantial non-infringing use, and that the instruments, including the Shield Kyphoplasty System, are especially made and/or adapted for use in infringing the '672 patent. For example, despite having knowledge

that the Shield Kyphoplasty System is used by physicians to perform surgical procedures infringing the '672 patent, Soteira and Globus continue to provide instruction and training to physicians on how to use the Shield Kyphoplasty System in a manner that directly infringes at least Claim 11 of the '672 patent. Soteira and Globus do not provide instructions or training on the use of the Shield Kyphoplasty System in a manner that does not infringe the '672 patent. Furthermore, upon information and belief, the FDA has only approved the Shield Kyphoplasty System for use in surgical procedures that infringe the '672 patent.

44. Since at least 2011, Soteira has been and still is willfully infringing the '672 patent. At least as early as 2011, Soteira had actual knowledge of the '672 patent. Despite having actual knowledge of the '672 patent, Soteira has continued to willfully, wantonly, and deliberately infringe the '672 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

45. Since at least the date Globus acquired Soteira, Globus has been and still is willfully infringing the '672 patent. At least since the date Globus acquired Soteira, Globus had actual knowledge of the '672 patent. Despite having actual knowledge of the '672 patent, Globus has continued to willfully, wantonly, and deliberately infringe the '672 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

46. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '672 patent.

47. As a result of Defendants' infringement of the '672 patent, Orthophoenix has suffered monetary damages in an amount adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, and Orthophoenix will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

48. Unless a permanent injunction is issued enjoining Defendants and their agents, servants, employees, representatives, affiliates, and all others acting or in active concert therewith from infringing the '672 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT III
(Infringement of U.S. Patent No. 7,909,827)

49. Orthophoenix references and incorporates by reference paragraphs 1 through 48 of this Complaint.

50. Defendants Does 1-100 have been and still are infringing at least Claim 1 of the '9827 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Shield Kyphoplasty System Does purchased from Soteira and/or Globus in the manner instructed and taught by Soteira and/or Globus, and in the manner for which the Shield Kyphoplasty System is approved for use by the FDA.

51. Soteira and Globus have been and still are infringing at least Claim 1 of the '9827 patent, literally and under the doctrine of equivalents, by using surgical

instruments, including but not limited to the Shield Kyphoplasty System. By way of example only, Soteira and Globus directly infringe the '9827 patent by using the Shield Kyphoplasty System to perform the method described in Claim 1.

52. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '9827 patent by active inducement under 35 U.S.C. § 271(b).

53. Upon information and belief, Soteira had knowledge of the '9827 patent since at least as early as 2011. Soteira cited the '9827 patent in U.S. Patent No. 7,909,873, which was issued in 2011. Additionally, in 2011, Soteira indicated that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device" to its Shield Kyphoplasty System in its request to market the Shield Kyphoplasty System in the United States, which was filed on December 8, 2011, with the FDA. By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device," Soteira was representing to the FDA that the Shield Kyphoplasty System is "substantially equivalent" to the Kyphon product. *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm. Kyphon implemented a comprehensive marking policy. Further, on information and belief, by analyzing the Kyphon Kyphx Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Shield Kyphoplasty System, Soteira gained knowledge of the '9827 patent at least as early as 2011.

54. Upon information and belief, Globus had knowledge of the '9827 patent as early as the date on which it acquired Soteira. Alternatively, at least after being served

with the Amended Complaint in this action, Globus has had knowledge of the '9827 patent.

55. On information and belief, Soteira and Globus have intended, and continue to intend, to induce patent infringement by third-party physicians and have had knowledge that the inducing acts would cause infringement or have been willfully blind to the possibility that their inducing acts would cause infringement. For example, Soteira and/or Globus provide training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Shield Kyphoplasty System, during the performance of surgical procedures during which physicians use surgical instruments to cut cancellous bone. By using the infringing surgical instruments, including the Shield Kyphoplasty System, to cut cancellous bone as instructed and trained by Soteira and/or Globus, physicians directly infringe at least Claim 1 of the '9827 patent. By continuing to provide instruction and training to physicians on how to use its surgical instruments, including the Shield Kyphoplasty System, to perform procedures during which physicians cut cancellous bone in the manner described in Claim 1 of the '9827 patent, Soteira and Globus have and continue to specifically intend to induce infringement of the '9827 patent.

56. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '9827 patent by contributory infringement under 35 U.S.C. § 271(c).

57. Soteira and Globus have and continue to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Shield Kyphoplasty System, with the

knowledge that the Shield Kyphoplasty System will be used by physicians to directly infringe at least Claim 1 of the '9827 patent.

58. Soteira had knowledge of the '9827 patent since at least 2011. Globus had knowledge of the '9827 patent since at least the date on which it acquired Soteira, or alternatively, since being served with the Amended Complaint in this action. Soteira and Globus have had knowledge that the surgical instruments, including the Shield Kyphoplasty System, are material components to practicing the surgical procedures claimed in the '9827 patent, that the surgical instruments are not staple articles or commodities of commerce suitable for substantial non-infringing use, and that the instruments are especially made and/or adapted for use in infringing the '9827 patent. For example, despite having knowledge that the Shield Kyphoplasty System is used by physicians to perform surgical procedures infringing the '9827 patent, Soteira and Globus continue to provide instruction and training to physicians on how to use the Shield Kyphoplasty System in a manner that directly infringes at least Claim 1 of the '9827 patent. Soteira and Globus do not provide instructions or training on the use of the Shield Kyphoplasty System in a manner that does not infringe the '9827 patent. Furthermore, upon information and belief, the FDA has only approved the Shield Kyphoplasty System for use in surgical procedures that infringe the '9827 patent.

59. Since at least 2011, Soteira has been and still is willfully infringing the '9827 patent. At least as early as 2011, Soteira had actual knowledge of the '9827 patent. Despite having actual knowledge of the '9827 patent, Soteira has continued to willfully, wantonly, and deliberately infringe the '9827 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional

case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

60. Since at least the date Globus acquired Soteira, Globus has been and still is willfully infringing the '9827 patent. At least since the date Globus acquired Soteira, Globus had actual knowledge of the '9827 patent. Despite having actual knowledge of the '9827 patent, Globus has continued to willfully, wantonly, and deliberately infringe the '9827 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

61. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '9827 patent.

62. As a result of Defendants' infringement of the '9827 patent, Orthophoenix has suffered monetary damages in an amount adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, and Orthophoenix will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

63. Unless a permanent injunction is issued enjoining Defendants and their agents, servants, employees, representatives, affiliates, and all others acting or in active concert therewith from infringing the '9827 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT IV
(Infringement of U.S. Patent No. 7,967,827)

64. Orthophoenix references and incorporates by reference paragraphs 1 through 63 of this Complaint.

65. Defendants Does 1-100 have been and still are infringing at least Claim 1 of the '7827 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Shield Kyphoplasty System Does purchased from Soteira and/or Globus, in the manner instructed and taught by Soteira and/or Globus, and in the manner for which the Shield Kyphoplasty System is approved for use by the FDA.

66. Soteira and Globus have been and still are infringing at least Claim 1 of the '7827 patent, literally and under the doctrine of equivalents, by using medical devices, including but not limited to the Shield Kyphoplasty System. By way of example only, Soteira and Globus directly infringe the '7827 patent by performing the method of introducing an expandable structure into cancellous bone described in Claim 1.

67. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '7827 patent by active inducement under 35 U.S.C. § 271(b).

68. Upon information and belief, Soteira had knowledge of the '7827 patent since at least as early as 2011. In 2011, Soteira indicated that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device" to its Shield Kyphoplasty System in its request to market the Shield Kyphoplasty System in the United States, which was filed on December 8, 2011, with the FDA. By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device," Soteira was representing to the FDA that the Shield Kyphoplasty System is "substantially equivalent" to the Kyphon product. *See, e.g.*,

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm. Kyphon implemented a comprehensive marking policy. Further, on information and belief, by analyzing the Kyphon Kyphx Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Shield Kyphoplasty System, Soteira gained knowledge of the '7827 patent at least as early as 2011.

69. Upon information and belief, Globus had knowledge of the '7827 patent as early as the date on which it acquired Soteira. Alternatively, at least after being served with the Amended Complaint in this action, Globus has had knowledge of the '7827 patent.

70. On information and belief, Soteira and Globus have intended, and continue to intend, to induce patent infringement by third-party physicians and have had knowledge that the inducing acts would cause infringement or have been willfully blind to the possibility that its inducing acts would cause infringement. For example, Soteira and/or Globus provide training and instruction materials to physicians on how to use the infringing medical devices, including the Shield Kyphoplasty System, during the performance of medical procedures during which physicians introduce expandable structures into cancellous bone. By using the infringing medical devices, including the Shield Kyphoplasty System, to introduce expandable structures into cancellous bone as instructed and trained by Soteira and/or Globus, physicians directly infringe at least Claim 1 of the '7827 patent. By continuing to provide instruction and training to physicians on how to use its medical devices to perform procedures during which physicians introduce expandable structures into cancellous bone in the manner described

in Claim 1 of the '7827 patent, Soteira and Globus have and continue to specifically intend to induce infringement of the '7827 patent.

71. Soteira and Globus have also infringed indirectly and continue to infringe indirectly the '7827 patent by contributory infringement under 35 U.S.C. § 271(c).

72. Soteira and Globus have and continue to intentionally commit contributory infringement by selling, offering to sell, or importing the Shield Kyphoplasty System with the knowledge that medical devices, including but not limited to, the Shield Kyphoplasty System will be used by physicians to directly infringe at least Claim 1 of the '7827 patent.

73. Soteira had knowledge of the '7827 patent since at least 2011. Globus had knowledge of the '7827 patent since at least the date on which it acquired Soteira, or alternatively, since being served with the Amended Complaint in this action. Soteira and Globus have had knowledge that the medical devices, including the Shield Kyphoplasty System, are material components to practicing the surgical procedures claimed in the '7827 patent, that the medical devices are not a staple articles or commodities of commerce suitable for substantial non-infringing use, and that the medical devices, including the Shield Kyphoplasty System, are especially made and/or adapted for use in infringing the '7827 patent. For example, despite having knowledge that the Shield Kyphoplasty System is used by physicians to perform surgical procedures infringing the '7827 patent, Soteira and Globus continue to provide instruction and training to physicians on how to use the Shield Kyphoplasty System in a manner that directly infringes at least Claim 1 of the '7827 patent. Soteira and Globus do not provide instructions or training on the use of the Shield Kyphoplasty System in a manner that

does not infringe the '7827 patent. Furthermore, upon information and belief, the FDA has only approved the Shield Kyphoplasty System for use in surgical procedures that infringe the '7827 patent.

74. Since at least 2011, Soteira has been and still is willfully infringing the '7827 patent. At least as early as 2011, Soteira had actual knowledge of the '7827 patent. Despite having actual knowledge of the '7827 patent, Soteira has continued to willfully, wantonly, and deliberately infringe the '7827 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

75. Since at least the date Globus acquired Soteira, Globus has been and still is willfully infringing the '7827 patent. At least since the date Globus acquired Soteira, Globus had actual knowledge of the '7827 patent. Despite having actual knowledge of the '7827 patent, Globus has continued to willfully, wantonly, and deliberately infringe the '7827 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

76. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '7827 patent.

77. As a result of Defendants' infringement of the '7827 patent, Orthophoenix has suffered monetary damages in an amount adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, and

Orthophoenix will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

78. Unless a permanent injunction is issued enjoining Defendants and their agents, servants, employees, representatives, affiliates, and all others acting or in active concert therewith from infringing the '7827 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT V
(Infringement of U.S. Patent No. 6,981,981)

79. Orthophoenix references and incorporates by reference paragraphs 1 through 78 of this Complaint.

80. Defendants Does 101-200 have been and still are infringing at least Claim 1 of the '981 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Affirm VCF System Does purchased from Globus, in the manner instructed and taught by Globus, and in the manner for which the Affirm VCF System is approved for use by the FDA.

81. Globus has been and still is infringing at least Claim 1 of the '981 patent, literally and under the doctrine of equivalents, by using medical devices, including but not limited to the Affirm VCF System. By way of example only, Globus directly infringes the '981 patent by performing the method of introducing an expandable structure to create a void in cancellous bone as described in Claim 1.

82. Globus has also infringed indirectly and continues to infringe indirectly the '981 patent by active inducement under 35 U.S.C. § 271(b).

83. Upon information and belief, Globus had knowledge of the '981 patent since at least as early as 2011. In 2011, Globus indicated that the Kyphon Kyphx

Inflatable Bone Tamp was a "predicate device" to its Affirm VCF System in its request to market the Affirm VCF System in the United States, which was prepared on May 26, 2011, with the FDA. By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device," Globus was representing to the FDA that the Affirm VCF System is "substantially equivalent" to the Kyphon product. *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm. Kyphon implemented a comprehensive marking policy. Further, on information and belief, by analyzing the Kyphon Kyphx Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Affirm VCF System, Globus gained knowledge of the '981 patent at least as early as 2011.

84. On information and belief, Globus has intended, and continues to intend, to induce patent infringement by third-party physicians and has had knowledge that the inducing acts would cause infringement or has been willfully blind to the possibility that its inducing acts would cause infringement. For example, Globus provides training and instruction materials to physicians on how to use the infringing medical devices, including the Affirm VCF System, during the performance of medical procedures during which physicians introduce expandable structures into cancellous bone. By using the infringing medical devices, including the Affirm VCF System, to introduce expandable structures into cancellous bone as instructed and trained by Globus, physicians directly infringe at least Claim 1 of the '981 patent. By continuing to provide instruction and training to physicians on how to use its medical devices to perform procedures during which physicians introduce expandable structures into cancellous bone in the manner

described in Claim 1 of the '981 patent, Globus has and continues to specifically intend to induce infringement of the '981 patent.

85. Globus has also infringed indirectly and continues to infringe indirectly the '981 patent by contributory infringement under 35 U.S.C. § 271(c).

86. Globus has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the Affirm VCF System with the knowledge that medical devices, including but not limited to, the Affirm VCF System will be used by physicians to directly infringe at least Claim 1 of the '981 patent.

87. Globus had knowledge of the '981 patent since at least 2011. Since at least 2011, Globus has had knowledge that the medical devices, including the Affirm VCF System, are material components to practicing the surgical procedures claimed in the '981 patent, that the medical devices are not a staple articles or commodities of commerce suitable for substantial non-infringing use, and that the medical devices, including the Affirm VCF System, are especially made and/or adapted for use in infringing the '981 patent. For example, despite having knowledge that the Affirm VCF System is used by physicians to perform surgical procedures infringing the '981 patent, Globus continues to provide instruction and training to physicians on how to use the Affirm VCF System in a manner that directly infringes at least Claim 1 of the '981 patent. Globus does not provide instructions or training on the use of the Affirm VCF System in a manner that does not infringe the '981 patent. Furthermore, upon information and belief, the FDA has only approved the Affirm VCF System for use in surgical procedures that infringe the '981 patent.

88. Since at least 2011, Globus has been and still is willfully infringing the '981 patent. At least as early as 2011, Globus had actual knowledge of the '981 patent. Despite having actual knowledge of the '981 patent, Globus has continued to willfully, wantonly, and deliberately infringe the '981 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

89. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '981 patent.

90. As a result of Defendants' infringement of the '981 patent, Orthophoenix has suffered monetary damages in an amount adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, and Orthophoenix will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

91. Unless a permanent injunction is issued enjoining Defendants and their agents, servants, employees, representatives, affiliates, and all others acting or in active concert therewith from infringing the '981 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT VI
(Infringement of U.S. Patent No. 7,044,954)

92. Orthophoenix references and incorporates by reference paragraphs 1 through 91 of this Complaint.

93. Defendants Does 101-200 have been and still are infringing at least Claim 1 of the '954 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Affirm VCF System Does purchased from Algea Therapies, which is a division of Defendant Globus, in the manner instructed and taught by Globus, and in the manner for which the Affirm VCF System is approved for use by the FDA.

94. Globus has been and still is infringing at least Claim 1 of the '954 patent, literally and under the doctrine of equivalents, by using medical devices, including but not limited to the Affirm VCF System. By way of example only, Globus directly infringes the '954 patent by performing the method of introducing an expandable structure to create a void in cancellous bone as described in Claim 1.

95. Globus has also infringed indirectly and continues to infringe indirectly the '954 patent by active inducement under 35 U.S.C. § 271(b).

96. Upon information and belief, Globus had knowledge of the '954 patent since at least as early as 2011. In 2011, Globus indicated that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device" to its Affirm VCF System in its request to market the Affirm VCF System in the United States, which was prepared on May 26, 2011, with the FDA. By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a "predicate device," Globus was representing to the FDA that the Affirm VCF System is "substantially equivalent" to the Kyphon product. *See, e.g.*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm. Kyphon implemented a comprehensive marking policy. Further, on information and belief, by

analyzing the Kyphon Kyphx Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Affirm VCF System, Globus gained knowledge of the '954 patent at least as early as 2011.

97. On information and belief, Globus has intended, and continues to intend, to induce patent infringement by third-party physicians and has had knowledge that the inducing acts would cause infringement or has been willfully blind to the possibility that its inducing acts would cause infringement. For example, Globus provides training and instruction materials to physicians on how to use the infringing medical devices, including the Affirm VCF System, during the performance of medical procedures during which physicians introduce expandable structures into cancellous bone. By using the infringing medical devices, including the Affirm VCF System, to introduce expandable structures into cancellous bone as instructed and trained by Globus, physicians directly infringe at least Claim 1 of the '954 patent. By continuing to provide instruction and training to physicians on how to use its medical devices to perform procedures during which physicians introduce expandable structures into cancellous bone in the manner described in Claim 1 of the '954 patent, Globus has and continues to specifically intend to induce infringement of the '954 patent.

98. Globus has also infringed indirectly and continues to infringe indirectly the '954 patent by contributory infringement under 35 U.S.C. § 271(c).

99. Globus has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the Affirm VCF System with the knowledge that medical devices, including but not limited to, the Affirm VCF System will be used by physicians to directly infringe at least Claim 1 of the '954 patent.

100. Globus had knowledge of the '954 patent since at least 2011. Since at least 2011, Globus has had knowledge that the medical devices, including the Affirm VCF System, are material components to practicing the surgical procedures claimed in the '954 patent, that the medical devices are not a staple articles or commodities of commerce suitable for substantial non-infringing use, and that the medical devices, including the Affirm VCF System, are especially made and/or adapted for use in infringing the '954 patent. For example, despite having knowledge that the Affirm VCF System is used by physicians to perform surgical procedures infringing the '954 patent, Globus continues to provide instruction and training to physicians on how to use the Affirm VCF System in a manner that directly infringes at least Claim 1 of the '954 patent. Globus does not provide instructions or training on the use of the Affirm VCF System in a manner that does not infringe the '954 patent. Furthermore, upon information and belief, the FDA has only approved the Affirm VCF System for use in surgical procedures that infringe the '954 patent.

101. Since at least 2011, Globus has been and still is willfully infringing the '954 patent. At least as early as 2011, Globus had actual knowledge of the '954 patent. Despite having actual knowledge of the '954 patent, Globus has continued to willfully, wantonly, and deliberately infringe the '954 patent. Accordingly, Orthophoenix seeks enhanced damages pursuant to 35 U.S.C. § 284 and a finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, entitling Orthophoenix to its attorneys' fees and expenses.

102. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '954 patent.

103. As a result of Defendants' infringement of the '954 patent, Orthophoenix has suffered monetary damages in an amount adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty for the use made of the invention by Defendants, together with interest and costs as fixed by the Court, and Orthophoenix will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

104. Unless a permanent injunction is issued enjoining Defendants and their agents, servants, employees, representatives, affiliates, and all others acting or in active concert therewith from infringing the '954 patent, Orthophoenix will be greatly and irreparably harmed.

PRAYER FOR RELIEF

Orthophoenix prays for the following relief:

1. A judgment that Soteira, Globus, and Does 1-100 have infringed one or more claims of the '138, '672, '9827, and/or '7827 patents;

2. A judgment that Globus and Does 101-200 have infringed one or more claims of the '981 and/or '954 patents;

3. A permanent injunction enjoining Soteira, Globus, and Does 1-100 and their officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert or participation with Defendants, from infringing the '138, '672, '9827, and/or '7827 patents;

4. A permanent injunction enjoining Globus and Does 101-200 and their officers, directors, agents, servants, affiliates, employees, divisions, branches,

subsidiaries, parents, and all others acting in active concert or participation with Defendants, from infringing the '981 and/or '954 patents;

5. An award of damages resulting from Defendant's acts of infringement in accordance with 35 U.S.C. § 284;

6. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Orthophoenix its reasonable attorneys' fees against Soteira and Globus;

7. A judgment and order requiring Defendants to provide accountings and to pay supplemental damages to Orthophoenix, including, without limitation, prejudgment and post-judgment interest; and

8. Any and all other relief to which Orthophoenix may show itself to be entitled.

JURY TRIAL DEMANDED

Orthophoenix hereby demands a trial by jury of all issues so triable.

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