

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ORTHOPHOENIX, LLC,

Plaintiff

v.

OSSEON THERAPEUTICS, INC.;
JOHN AND/OR JANE DOES 1-100,

Defendants.

C.A. No. _____

JURY TRIAL DEMANDED

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 Osseon Therapeutics, Inc. (“Osseon”) is a California corporation with a principal place of business at 2330 Circadian Way, Santa Rosa, California 95407. Osseon has appointed H. John Stalcup, 2330 Circadian Way, Santa Rosa, California 95407, as its agent for service of process.

3. Defendants John and/or Jane Does 1-100 (“Does”) are orthopedic surgeons using the infringing products manufactured by Defendant Osseon. Does’ identities are not presently known to Orthophoenix; however, on information and belief, Defendant Osseon is in possession of documents and information from which Does’ identities can be readily ascertained.

JURISDICTION AND VENUE

4. 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).

5. This Court has personal jurisdiction over Defendant Osseon because, among other reasons, Defendant Osseon has established minimum contacts with the forum state of Delaware. Defendant Osseon, directly and/or through third-party intermediaries, makes, uses, imports, offers for sale, and/or sells products or performs infringing medical procedures within the state of Delaware. Thus, Defendant Osseon has purposefully availed itself of the benefits of the State of Delaware and the exercise of jurisdiction over Osseon would not offend traditional notions of fair play and substantial justice.

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

BACKGROUND

7. 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.

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

9. 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.

10. 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.

11. 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 over 500 patents and applications.

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

ASSERTED PATENTS

13. Orthophoenix is the owner by assignment of U.S. Patent No. 6,248,110 (the "'110 patent"). The '110 patent is entitled "Systems And Methods For Treating

Fractured Or Diseased Bone Using Expandable Bodies.” The ‘110 patent issued on June 19, 2001. A true and correct copy of the ‘110 patent is attached hereto as Exhibit A.

14. 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 issued on January 3, 2006. A true and correct copy of the ‘981 patent is attached hereto as Exhibit B.

15. 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 issued on May 16, 2006. A true and correct copy of the ‘954 patent is attached hereto as Exhibit C.

16. Orthophoenix is the owner by assignment of U.S. Patent No. 8,034,071 (the “‘071 patent”). The ‘071 patent is entitled “Systems And Methods For Forming A Cavity In Cancellous Bone.” The ‘071 patent issued on October 11, 2011. A true and correct copy of the ‘071 patent is attached hereto as Exhibit D.

17. Orthophoenix is the owner by assignment of U.S. Patent No. 5,972,015 (the “‘015 patent”). The ‘015 patent is entitled “Expandable, Asymetric Structures For Deployment In Interior Body Regions.” The ‘015 patent issued on October 26, 1999. A true and correct copy of the ‘015 patent is attached hereto as Exhibit E.

18. 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 F.

19. Orthophoenix is the owner by assignment of U.S. Patent No. 6,923,813 (the “‘813 patent”). The ‘813 patent is entitled “Devices For Creating Voids In Interior Body Regions And Related Methods.” The ‘813 patent issued on August 2, 2005. A true and correct copy of the ‘813 patent is attached hereto as Exhibit G.

COUNT I
(Infringement of U.S. Patent No. 6,248,110)

20. Orthophoenix references and incorporates by reference paragraphs 1 through 19 of this Complaint.

21. Defendants Does have been and still are infringing at least Claim 3 of the ‘110 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Osseoflex SN+ Steerable Needle and the Osseoflex SB Steerable Balloon Does purchased from Osseon in the manner instructed and taught by Osseon, and in the manner for which the Osseoflex SN+ Steerable Needle and the Osseoflex SB Steerable Balloon are approved for use by the FDA.

22. Osseon has been and still is infringing at least Claim 3 of the ‘110 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Osseoflex SN+ Steerable Needle and the Osseoflex SB Steerable Balloon. By way of example only, Osseon directly infringes the ‘110 patent by using the Osseoflex SN+ Steerable Needle and the Osseoflex SB Steerable Balloon to perform the method described in Claim 3.

23. Osseon has also infringed indirectly and continues to infringe indirectly the ‘110 patent by active inducement under 35 U.S.C. § 271(b).

24. Upon information and belief, Osseon had knowledge of the ‘110 patent since at least as early as 2010. Osseon cited the ‘110 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No. 7,842,041. Alternatively, Osseon gained knowledge of the ‘110 patent at least as early as 2012. In 2012, Osseon indicated that the Kyphon Inflatable Bone Tamp was a “predicate device” to its Osseoflex SB Steerable Balloon in its request to market the Osseoflex SB Steerable Balloon in the United States, which was submitted to the FDA. By indicating that the Kyphon Inflatable Bone Tamp was a “predicate device,” Osseon was representing to the FDA that the Osseoflex SB Steerable Balloon is “substantially equivalent” to the Kyphon product. *See, e.g.,* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm>. On information and belief, the Kyphon Inflatable Bone Tamp was marked with the ‘110 patent. On information and belief, by analyzing the Kyphon Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Osseoflex SB Steerable Balloon, Osseon gained knowledge of the ‘110 patent at least as early as 2012.

25. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Osseoflex SN+ Steerable Needle and the Osseoflex SB

Steerable Balloon, to perform surgical procedures during which physicians use the surgical instruments to compact cancellous bone. By using the infringing surgical instruments, including the Osseoflex SN+ Steerable Needle and the Osseoflex SB Steerable Balloon, to compact cancellous bone as instructed and trained by Osseon, physicians directly infringe at least Claim 3 of the '110 patent. By continuing to provide instruction and training to physicians on how to use its surgical instruments, including the Osseoflex SN+ Steerable Needle and the Osseoflex SB Steerable Balloon, to perform procedures during which physicians compact cancellous bone in the manner described in Claim 3 of the '110 patent, Osseon has and continues to specifically intend to induce infringement of the '110 patent.

26. Since at least 2010, Osseon has been and still is willfully infringing the '110 patent. At least as early as 2010, Osseon had actual knowledge of the '110 patent. Despite having actual knowledge of the '110 patent, Osseon has continued to willfully, wantonly, and deliberately infringe the '110 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.

27. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '110 patent.

28. As a result of Defendants' infringement of the '110 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.

29. 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 '110 patent, Orthophoenix will be greatly and irreparably harmed.

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

30. Orthophoenix references and incorporates by reference paragraphs 1 through 29 of this Complaint.

31. Defendants Does 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 Osseoflex SB Steerable Balloon Does purchased from Osseon in the manner instructed and taught by Osseon, and in the manner for which the Osseoflex SB Steerable Balloon is approved for use by the FDA.

32. Osseon has been and still is infringing at least Claim 1 of the '981 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon. By way of example only, Osseon directly infringes the '981 patent by using the Osseoflex SB Steerable Balloon to perform the method described in Claim 1.

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

34. Upon information and belief, Osseon had knowledge of the ‘981 patent since at least as early as 2010. Osseon cited the ‘981 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No. 7,842,041. Alternatively, Osseon gained knowledge of the ‘981 patent at least as early as 2012. In 2012, Osseon indicated that the Kyphon Inflatable Bone Tamp was a “predicate device” to its Osseoflex SB Steerable Balloon in its request to market the Osseoflex SB Steerable Balloon in the United States, which was submitted to the FDA. By indicating that the Kyphon Inflatable Bone Tamp was a “predicate device,” Osseon was representing to the FDA that the Osseoflex SB Steerable Balloon 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 Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Osseoflex SB Steerable Balloon, Osseon gained knowledge of the ‘981 patent at least as early as 2012.

35. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, in surgical procedures during which physicians use the surgical instruments to compact cancellous bone and fill

the void created through such compacting with filling material. By using the infringing surgical instruments, including the Osseoflex SB Steerable Balloon, to compact cancellous bone then fill the void created through such compacting with filling material as instructed and trained by Osseon, 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 surgical instruments, including the Osseoflex SB Steerable Balloon, to perform procedures during which physicians compact cancellous bone then fill the void created through such compacting with filling material in the manner described in Claim 1 of the '981 patent, Osseon has and continues to specifically intend to induce infringement of the '981 patent.

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

37. Osseon has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, with the knowledge that the Osseoflex SB Steerable Balloon will be used by physicians to directly infringe at least Claim 1 of the '981 patent.

38. Osseon had knowledge of the '981 patent since at least 2010. Since at least 2010, Osseon has had knowledge that the surgical instruments, including the Osseoflex SB Steerable Balloon, are material components to practicing the surgical procedures claimed in the '981 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 '981 patent. For

example, despite having knowledge that the Osseoflex SB Steerable Balloon is used by physicians to perform surgical procedures infringing the ‘981 patent, Osseon continues to provide instruction and training to physicians on how to use the Osseoflex SB Steerable Balloon in a manner that directly infringes at least Claim 1 of the ‘981 patent. Osseon does not provide instructions or training on the use of the Osseoflex SB Steerable Balloon in a manner that does not infringe the ‘981 patent. Furthermore, upon information and belief, the FDA has only approved the Osseoflex SB Steerable Balloon for use in surgical procedures that infringe the ‘981 patent.

39. Since at least 2010, Osseon has been and still is willfully infringing the ‘981 patent. At least as early as 2010, Osseon had actual knowledge of the ‘981 patent. Despite having actual knowledge of the ‘981 patent, Osseon 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.

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

41. 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.

42. Unless a permanent injunction is issued enjoining Defendants and its 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 III
(Infringement of U.S. Patent No. 7,044,954)

43. Orthophoenix references and incorporates by reference paragraphs 1 through 42 of this Complaint.

44. Defendants Does 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 Osseoflex SB Steerable Balloon Does purchased from Osseon in the manner instructed and taught by Osseon, and in the manner for which the Osseoflex SB Steerable Balloon is approved for use by the FDA.

45. Osseon has been and still is infringing at least Claim 1 of the '954 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon. By way of example only, Osseon directly infringes the '954 patent by using the Osseoflex SB Steerable Balloon to perform the method described in Claim 1.

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

47. Upon information and belief, Osseon had knowledge of the '954 patent since at least as early as 2010. Osseon cited the '954 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No.

7,842,041. Alternatively, Osseon gained knowledge of the '954 patent at least as early as 2012. In 2012, Osseon indicated that the Kyphon Inflatable Bone Tamp was a "predicate device" to its Osseoflex SB Steerable Balloon in its request to market the Osseoflex SB Steerable Balloon in the United States, which was submitted to the FDA. By indicating that the Kyphon Inflatable Bone Tamp was a "predicate device," Osseon was representing to the FDA that the Osseoflex SB Steerable Balloon 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 Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Osseoflex SB Steerable Balloon, Osseon gained knowledge of the '954 patent at least as early as 2012.

48. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, during the performance of surgical procedures during which physicians use surgical instruments to compact cancellous bone then fill the void created through such compacting with filling material. By using the infringing surgical instruments, including the Osseoflex SB Steerable Balloon, to compact cancellous bone then fill the void created through such compacting

with filling material as instructed and trained by Osseon, 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 surgical instruments, including the Osseoflex SB Steerable Balloon, to perform procedures during which physicians compact cancellous bone then fill the void created through such compacting with filling material in the manner described in Claim 1 of the '954 patent, Osseon has and continues to specifically intend to induce infringement of the '954 patent.

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

50. Osseon has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, with the knowledge that the Osseoflex SB Steerable Balloon will be used by physicians to directly infringe at least Claim 1 of the '954 patent.

51. Osseon had knowledge of the '954 patent since at least 2010. Since at least 2010, Osseon has had knowledge that the surgical instruments, including the Osseoflex SB Steerable Balloon, are material components to practicing the surgical procedures claimed in the '954 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 '954 patent. For example, despite having knowledge that the Osseoflex SB Steerable Balloon is used by physicians to perform surgical procedures infringing the '954 patent, Osseon continues to provide instruction and training to physicians on how to use the Osseoflex SB Steerable

Balloon in a manner that directly infringes at least Claim 1 of the ‘954 patent. Osseon does not provide instructions or training on the use of the Osseoflex SB Steerable Balloon in a manner that does not infringe the ‘954 patent. Furthermore, upon information and belief, the FDA has only approved the Osseoflex SB Steerable Balloon for use in surgical procedures that infringe the ‘954 patent.

52. Since at least 2010, Osseon has been and still is willfully infringing the ‘954 patent. At least as early as 2010, Osseon had actual knowledge of the ‘954 patent. Despite having actual knowledge of the ‘954 patent, Osseon 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.

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

54. 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.

55. Unless a permanent injunction is issued enjoining Defendants and its 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.

COUNT IV
(Infringement of U.S. Patent No. 8,034,071)

56. Orthophoenix references and incorporates by reference paragraphs 1 through 55 of this Complaint.

57. Defendants Does have been and still are infringing at least Claim 1 of the '071 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Osseoflex SB Steerable Balloon Does purchased from Osseon in the manner instructed and taught by Osseon, and in the manner for which the Osseoflex SB Steerable Balloon is approved for use by the FDA.

58. Osseon has been and still is infringing at least Claim 1 of the '071 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon. By way of example only, Osseon directly infringes the '071 patent by using the Osseoflex SB Steerable Balloon to perform the method described in Claim 1.

59. Osseon has also infringed indirectly and continues to infringe indirectly the '071 patent by active inducement under 35 U.S.C. § 271(b).

60. Upon information and belief, Osseon had knowledge of the '071 patent since at least as early as 2010. In 2010, Osseon cited the patent application leading to the '071 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No. 7,842,041. The application leading to the '071 patent issued as the '071 patent on October 11, 2011. Alternatively, Osseon gained knowledge

of the '071 patent at least as early as 2012. In 2012, Osseon indicated that the Kyphon Inflatable Bone Tamp was a “predicate device” to its Osseoflex SB Steerable Balloon in its request to market the Osseoflex SB Steerable Balloon in the United States, which was submitted to the FDA. By indicating that the Kyphon Inflatable Bone Tamp was a “predicate device,” Osseon was representing to the FDA that the Osseoflex SB Steerable Balloon 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 Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Osseoflex SB Steerable Balloon, Osseon gained knowledge of the '071 patent at least as early as 2012.

61. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, during the performance of surgical procedures during which physicians use surgical instruments to compact cancellous bone. By using the infringing surgical instruments, including the Osseoflex SB Steerable Balloon, to compact cancellous bone as instructed and trained by Osseon, physicians directly infringe at least Claim 1 of the '071 patent. By continuing to provide instruction and training to physicians on how to use its surgical instruments, including the

Osseoflex SB Steerable Balloon, to perform procedures during which physicians compact cancellous bone in the manner described in Claim 1 of the '071 patent, Osseon has and continues to specifically intend to induce infringement of the '071 patent.

62. Osseon has also infringed indirectly and continues to infringe indirectly the '071 patent by contributory infringement under 35 U.S.C. § 271(c).

63. Osseon has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, with the knowledge that the Osseoflex SB Steerable Balloon will be used by physicians to directly infringe at least Claim 1 of the '071 patent.

64. Osseon had knowledge of the '071 patent since at least 2010. Since at least 2010, Osseon has had knowledge that the surgical instruments, including the Osseoflex SB Steerable Balloon, are material components to practicing the surgical procedures claimed in the '071 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 '071 patent. For example, despite having knowledge that the Osseoflex SB Steerable Balloon is used by physicians to perform surgical procedures infringing the '071 patent, Osseon continues to provide instruction and training to physicians on how to use the Osseoflex SB Steerable Balloon in a manner that directly infringes at least Claim 1 of the '071 patent. Osseon does not provide instructions or training on the use of the Osseoflex SB Steerable Balloon in a manner that does not infringe the '071 patent. Furthermore, upon information and

belief, the FDA has only approved the Osseoflex SB Steerable Balloon for use in surgical procedures that infringe the '071 patent.

65. Since at least 2010, Osseon has been and still is willfully infringing the '071 patent. At least as early as 2010, Osseon had actual knowledge of the '071 patent. Despite having actual knowledge of the '071 patent, Osseon has continued to willfully, wantonly, and deliberately infringe the '071 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.

66. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '071 patent.

67. As a result of Defendants' infringement of the '071 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.

68. Unless a permanent injunction is issued enjoining Defendants and its agents, servants, employees, representatives, affiliates, and all others acting or in active concert therewith from infringing the '071 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT V
(Infringement of U.S. Patent No. 5,972,015)

69. Orthophoenix references and incorporates by reference paragraphs 1 through 68 of this Complaint.

70. Osseon has been and still is infringing at least Claim 1 of the '015 patent, literally and under the doctrine of equivalents, by manufacturing, using, selling, offering to sell, or importing, without license or authority, surgical instruments including, but not limited to, the Osseoflex SB Steerable Balloon.

71. By way of example only, with reference to Claim 1 of the '015 patent, the Osseoflex SB Steerable Balloon manufactured, sold, offered for sale, or imported by Osseon includes a catheter tube having a distal end that extends along a first essentially linear axis, and a structure mounted about the distal end and comprising a body adapted to assume a collapsed geometry for deployment into bone and an expanded geometry for compacting cancellous bone to form a cavity. The expanded geometry is oriented about a second essentially linear axis not aligned with the first essentially linear axis.

72. Defendant Does have been and still are infringing at least Claim 1 of the '015 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Osseoflex SB Steerable Balloon Does purchased from Osseon.

73. Osseon has also infringed indirectly and continues to infringe indirectly the '015 patent by active inducement under 35 U.S.C. § 271(b).

74. Upon information and belief, Osseon had knowledge of the '015 patent since at least as early as 2010. Osseon cited the '015 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No.

7,842,041. Alternatively, Osseon gained knowledge of the '015 patent at least as early as 2012. In 2012, Osseon indicated that the Kyphon Inflatable Bone Tamp was a “predicate device” to its Osseoflex SB Steerable Balloon in its request to market the Osseoflex SB Steerable Balloon in the United States, which was submitted to the FDA. By indicating that the Kyphon Inflatable Bone Tamp was a “predicate device,” Osseon was representing to the FDA that the Osseoflex SB Steerable Balloon is “substantially equivalent” to the Kyphon product. *See, e.g.,* <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm>. On information and belief, the Kyphon Inflatable Bone Tamp was marked with the '015 patent. On information and belief, by analyzing the Kyphon Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Osseoflex SB Steerable Balloon, Osseon gained knowledge of the '015 patent at least as early as 2012.

75. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including the Osseoflex SB Steerable Balloon, during the performance of surgical procedures during which physicians compact cancellous bone. By using the infringing surgical instruments, including but not limited to the Osseoflex SB Steerable Balloon, during procedures during which physicians compact cancellous bone as instructed and

trained by Osseon, physicians directly infringe at least Claim 1 of the '015 patent. By continuing to provide instruction and training on the use of the Osseoflex SB Steerable Balloon to physicians despite its knowledge that the Osseoflex SB Steerable Balloon infringes the '015 patent, Osseon has and continues to specifically intend to induce infringement of the '015 patent.

76. Since at least 2010, Osseon has been and still is willfully infringing the '015 patent. At least as early as 2010, Osseon had actual knowledge of the '015 patent. Despite having actual knowledge of the '015 patent, Osseon has continued to willfully, wantonly, and deliberately infringe the '015 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.

77. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '015 patent.

78. As a result of Defendants' infringement of the '015 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.

79. 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 '015 patent, Orthophoenix will be greatly and irreparably harmed.

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

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

81. Defendants Does have been and still are infringing at least Claim 19 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 Osseoflex SN Steerable Needle Does purchased from Osseon in the manner instructed and taught by Osseon, and in the manner for which the Osseoflex SN Steerable Needle is approved for use by the FDA.

82. Osseon has been and still is infringing at least Claim 19 of the '672 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Osseoflex SN Steerable Needle. By way of example only, Osseon directly infringes the '672 patent by performing the method of treating a vertebral body described in Claim 19.

83. Osseon has also infringed indirectly and continues to infringe indirectly the '672 patent by active inducement under 35 U.S.C. § 271(b).

84. Upon information and belief, Osseon had knowledge of the '672 patent since at least as early as 2010. Osseon cited the '672 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No. 7,842,041.

85. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including the Osseoflex SN Steerable Needle, 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 Osseoflex SN Steerable Needle, to create cavities in cancellous bone as instructed and trained by Osseon, physicians directly infringe at least Claim 19 of the '672 patent. By continuing to provide instruction and training to physicians on how to use the Osseoflex SN Steerable Needle to perform surgical procedures in the manner described in Claim 19 of the '672 patent, Osseon has and continues to specifically intend to induce infringement of the '672 patent.

86. Osseon has also infringed indirectly and continues to infringe indirectly the '672 patent by contributory infringement under 35 U.S.C. § 271(c).

87. Osseon has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Osseoflex SN Steerable Needle, with the knowledge that the surgical instruments will be used by physicians to directly infringe at least Claim 19 of the '672 patent.

88. Osseon had knowledge of the '672 patent since at least 2010. Since at least 2010, Osseon has had knowledge that the surgical instruments, including the

Osseoflex SN Steerable Needle, 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 Osseoflex SN Steerable Needle, are especially made and/or adapted for use in infringing the '672 patent. For example, despite having knowledge that the Osseoflex SN Steerable Needle is used by physicians to perform surgical procedures infringing the '672 patent, Osseon continues to provide instruction and training to physicians on how to use the Osseoflex SN Steerable Needle in a manner that directly infringes at least Claim 19 of the '672 patent. Osseon does not provide instructions or training on the use of the Osseoflex SN Steerable Needle in a manner that does not infringe the '672 patent. Furthermore, upon information and belief, the FDA has only approved the Osseoflex SN Steerable Needle for use in surgical procedures that infringe the '672 patent.

89. Since at least 2010, Osseon has been and still is willfully infringing the '672 patent. At least as early as 2010, Osseon had actual knowledge of the '672 patent. Despite having actual knowledge of the '672 patent, Osseon 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.

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

91. 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.

92. 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 VII
(Infringement of U.S. Patent No. 6,923,813)

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

94. Defendants Does have been and still are infringing at least Claim 14 of the '813 patent, literally and under the doctrine of equivalents, by using, without license or authority, surgical instruments including, but not limited to, the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon Does purchased from Osseon in the manner instructed and taught by Osseon, and in the manner for which the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon are approved for use by the FDA.

95. Osseon has been and still is infringing at least Claim 14 of the '813 patent, literally and under the doctrine of equivalents, by using surgical instruments, including but not limited to the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable

Balloon. By way of example only, Osseon directly infringes the ‘813 patent by using the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon to perform the method described in Claim 14.

96. Osseon has also infringed indirectly and continues to infringe indirectly the ‘813 patent by active inducement under 35 U.S.C. § 271(b).

97. Upon information and belief, Osseon had knowledge of the ‘813 patent since at least as early as 2010. Osseon cited the ‘813 patent in the following U.S. Patents, both of which were issued in 2010: U.S. Patent No. 7,811,291 and U.S. Patent No. 7,842,041. Alternatively, Osseon gained knowledge of the ‘813 patent at least as early as 2012. In 2012, Osseon indicated that the Kyphon Inflatable Bone Tamp was a “predicate device” to its Osseoflex SB Steerable Balloon in its request to market the Osseoflex SB Steerable Balloon in the United States, which was submitted to the FDA. By indicating that the Kyphon Inflatable Bone Tamp was a “predicate device,” Osseon was representing to the FDA that the Osseoflex SB Steerable Balloon 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 Inflatable Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the Osseoflex SB Steerable Balloon, Osseon gained knowledge of the ‘813 patent at least as early as 2012.

98. On information and belief, Osseon 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, Osseon provides training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon, during the performance of surgical procedures during which physicians use surgical instruments to compact cancellous bone. By using the infringing surgical instruments, including the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon, to compact cancellous bone as instructed and trained by Osseon, physicians directly infringe at least Claim 14 of the '813 patent. By continuing to provide instruction and training to physicians on how to use its surgical instruments, including the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon, to perform procedures during which physicians compact cancellous bone in the manner described in Claim 14 of the '813 patent, Osseon has and continues to specifically intend to induce infringement of the '813 patent.

99. Osseon has also infringed indirectly and continues to infringe indirectly the '813 patent by contributory infringement under 35 U.S.C. § 271(c).

100. Osseon has and continues to intentionally commit contributory infringement by selling, offering to sell, or importing the infringing surgical instruments, including but not limited to the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon, with the knowledge that the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon will be used by physicians to directly infringe at least Claim 14 of the '813 patent.

101. Osseon had knowledge of the ‘813 patent since at least 2010. Since at least 2010, Osseon has had knowledge that the surgical instruments, including the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon, are material components to practicing the surgical procedures claimed in the ‘813 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 ‘813 patent. For example, despite having knowledge that the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon are used by physicians to perform surgical procedures infringing the ‘813 patent, Osseon continues to provide instruction and training to physicians on how to use the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon in a manner that directly infringes at least Claim 14 of the ‘813 patent. Osseon does not provide instructions or training on the use of the Osseoflex SN Steerable Needle and the Osseoflex SB Steerable Balloon in a manner that does not infringe the ‘813 patent.

102. Since at least 2010, Osseon has been and still is willfully infringing the ‘813 patent. At least as early as 2010, Osseon had actual knowledge of the ‘813 patent. Despite having actual knowledge of the ‘813 patent, Osseon has continued to willfully, wantonly, and deliberately infringe the ‘813 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.

103. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the ‘813 patent.

104. As a result of Defendants' infringement of the '813 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.

105. 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 '813 patent, Orthophoenix will be greatly and irreparably harmed.

PRAYER FOR RELIEF

Orthophoenix prays for the following relief:

1. A judgment that Defendants have infringed one or more claims of the '110 patent, '981 patent, '954 patent, '071 patent, '015 patent, '672 patent, and/or '813 patent;
2. A permanent injunction enjoining Defendants and their officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert or participation with Defendant, from infringing the '110 patent, '981 patent, '954 patent, '071 patent, '015 patent, '672 patent, and/or '813 patent;
3. An award of damages resulting from Defendant's acts of infringement in accordance with 35 U.S.C. § 284;
4. 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 Osseon.

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

6. 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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