

**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 themselves 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. 6,719,761 (the "'761 patent"). The '761 patent is entitled "System And Methods For Injecting

Flowable Materials Into Bones.” The ‘761 patent issued on April 13, 2004. A true and correct copy of the ‘761 patent is attached hereto as Exhibit A.

14. Orthophoenix is the owner by assignment of U.S. Patent No. 7,972,340 (the “‘340 patent”). The ‘340 patent is entitled “Systems and Methods For Injecting Flowable Materials Into Bones.” The ‘340 patent issued on July 5, 2011. A true and correct copy of the ‘340 patent is attached hereto as Exhibit B.

15. Orthophoenix is the owner by assignment of U.S. Patent No. 7,887,543 (the “‘543 patent”). The ‘543 patent is entitled “Systems And Methods For Injecting Flowable Materials Into Bones.” The ‘543 patent issued on February 15, 2011. A true and correct copy of the ‘543 patent is attached hereto as Exhibit C.

16. Orthophoenix is the owner by assignment of U.S. Patent No. 7,731,720 (the “‘720 patent”). The ‘720 patent is entitled “Systems And Methods For Injecting Flowable Materials Into Bones.” The ‘720 patent issued on June 8, 2010. A true and correct copy of the ‘720 patent is attached hereto as Exhibit D.

COUNT I
(Infringement of U.S. Patent No. 6,719,761)

17. Orthophoenix references and incorporates by reference paragraphs 1 through 16 of this Complaint.

18. Osseon has been and still is infringing at least Claim 25 of the ‘761 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 SN Steerable Needle.

19. By way of example only, with reference to Claim 25 of the ‘761 patent, the Osseoflex SN Steerable Needle manufactured, sold, offered for sale, or imported by

Osseon includes a cannula having an axis establishing a percutaneous path leading to inside a bone. The Osseoflex SN Steerable Needle includes a tube body having at least one substantially non-flexible section and at least one substantially flexible section, the tube body including an interior bore to carry a material flow and having a dispensing end having a side wall. The side wall of the dispensing ends contains an opening communicating with the bore to dispense the material flow. The Osseoflex SN Steerable Needle also contains a connector to releasably connect the tube body to an injecting tool wherein at least one of the connector and the tube body includes indicia to gauge orientation of the opening.

20. Defendant Does have been and still are infringing at least Claim 25 of the ‘761 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.

21. Osseon has also infringed indirectly and continues to infringe indirectly the ‘761 patent by active inducement under 35 U.S.C. § 271(b).

22. Upon information and belief, Osseon had knowledge of the ‘761 patent since at least as early as 2010. In 2010, Osseon cited the the ‘761 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.

23. 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 devices described by Claim 25. By using the infringing surgical instruments, including but not limited to the Osseoflex SN Steerable Needle, during procedures during which physicians use devices described by Claim 25 as instructed and trained by Osseon, physicians directly infringe at least Claim 25 of the '761 patent. By continuing to provide instruction and training on the use of the Osseoflex SN Steerable Needle to physicians despite its knowledge that the Osseoflex SN Steerable Needle infringes the '761 patent, Osseon has and continues to specifically intend to induce infringement of the '761 patent.

24. Since at least 2010, Osseon has been and still is willfully infringing the '761 patent. At least as early as 2010, Osseon had actual knowledge of the '761 patent. Despite having actual knowledge of the '761 patent, Osseon has continued to willfully, wantonly, and deliberately infringe the '761 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.

25. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '761 patent.

26. As a result of Defendants' infringement of the '761 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.

27. 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 '761 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT II
(Infringement of U.S. Patent No. 7,972,340)

28. Orthophoenix references and incorporates by reference paragraphs 1 through 27 of this Complaint.

29. Osseon has been and still is infringing at least Claim 1 of the '340 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 SN Steerable Needle.

30. Defendant Does have been and still are infringing at least Claim 1 of the '340 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.

31. Osseon has also infringed indirectly and continues to infringe indirectly the '340 patent by active inducement under 35 U.S.C. § 271(b).

32. At least after being served with the Complaint in this action, Osseon has had knowledge of the '340 patent.

33. 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 systems described by Claim 1. By using the infringing surgical instruments, including but not limited to the Osseoflex SN Steerable Needle, during procedures during which physicians use systems described by Claim 1 as instructed and trained by Osseon, physicians directly infringe at least Claim 1 of the '340 patent. By continuing to provide instruction and training on the use of the Osseoflex SN Steerable Needle to physicians despite its knowledge that the Osseoflex SN Steerable Needle infringes the '340 patent, Osseon has and continues to specifically intend to induce infringement of the '340 patent.

34. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '340 patent.

35. As a result of Defendants' infringement of the '340 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.

36. 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 '340 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT III
(Infringement of U.S. Patent No. 7,887,543)

37. Orthophoenix references and incorporates by reference paragraphs 1 through 36 of this Complaint.

38. Defendants Does have been and still are infringing at least Claim 1 of the '543 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.

39. Osseon has been and still is infringing at least Claim 1 of the '543 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 '543 patent by using the Osseoflex SN Steerable Needle to perform the method described in Claim 1.

40. Osseon has also infringed indirectly and continues to infringe indirectly the '543 patent by active inducement under 35 U.S.C. § 271(b).

41. At least after being served with the Complaint in this action, Osseon has had knowledge of the '543 patent.

42. 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, during the performance of surgical procedures during which physicians use surgical instruments to modify the cancellous bone volume and introducing bone filling material into the cancellous bone. By using the infringing surgical instruments, including the Osseoflex SN Steerable Needle, to modify the cancellous bone volume and introducing bone filling material into the cancellous bone as instructed and trained by Osseon, physicians directly infringe at least Claim 1 of the '543 patent. By continuing to provide instruction and training to physicians on how to use its surgical instruments, including the Osseoflex SN Steerable Needle, to perform procedures during which physicians modify the cancellous bone volume and introducing bone filling material into the cancellous bone in the manner described in Claim 1 of the '543 patent, Osseon has and continues to specifically intend to induce infringement of the '543 patent.

43. Osseon has also infringed indirectly and continues to infringe indirectly the '543 patent by contributory infringement under 35 U.S.C. § 271(c).

44. 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 Osseoflex SN Steerable Needle will be used by physicians to directly infringe at least Claim 1 of the '543 patent.

45. Osseon had knowledge of the '543 patent since at least after being served with the Complaint in this action. 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 '543 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 '543 patent. For example, despite having knowledge that the Osseoflex SN Steerable Needle is used by physicians to perform surgical procedures infringing the '543 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 1 of the '543 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 '543 patent. Furthermore, upon information and belief, the FDA has only approved the Osseoflex SN Steerable Needle for use in surgical procedures that infringe the '543 patent.

46. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '543 patent.

47. As a result of Defendants' infringement of the '543 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 its agents, servants, employees, representatives, affiliates, and all others acting or in active

concert therewith from infringing the '543 patent, Orthophoenix will be greatly and irreparably harmed.

COUNT IV
(Infringement of U.S. Patent No. 7,731,720)

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

50. Defendants Does have been and still are infringing at least Claim 11 of the '720 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.

51. Osseon has been and still is infringing at least Claim 11 of the '720 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 '720 patent by using the Osseoflex SN Steerable Needle to perform the method described in Claim 11.

52. Osseon has also infringed indirectly and continues to infringe indirectly the '720 patent by active inducement under 35 U.S.C. § 271(b).

53. Upon information and belief, Osseon had knowledge of the '720 patent since at least as early as 2010. In 2010, Osseon cited the patent application leading to the '720 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 '720 patent issued as the '720 patent on June 8, 2010.

54. 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, during the performance of surgical procedures during which physicians use surgical instruments to modify the cancellous bone volume and introducing bone filling material into the cancellous bone. By using the infringing surgical instruments, including the Osseoflex SN Steerable Needle, to modify the cancellous bone volume and introducing bone filling material into the cancellous bone as instructed and trained by Osseon, physicians directly infringe at least Claim 11 of the '720 patent. By continuing to provide instruction and training to physicians on how to use its surgical instruments, including the Osseoflex SN Steerable Needle, to perform procedures during which physicians modify the cancellous bone volume and introducing bone filling material into the cancellous bone in the manner described in Claim 11 of the '720 patent, Osseon has and continues to specifically intend to induce infringement of the '720 patent.

55. Osseon has also infringed indirectly and continues to infringe indirectly the '720 patent by contributory infringement under 35 U.S.C. § 271(c).

56. 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 Osseoflex SN Steerable Needle will be used by physicians to directly infringe at least Claim 11 of the '720 patent.

57. Osseon had knowledge of the '720 patent 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 '720 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 '720 patent. For example, despite having knowledge that the Osseoflex SN Steerable Needle is used by physicians to perform surgical procedures infringing the '720 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 11 of the '720 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 '720 patent. Furthermore, upon information and belief, the FDA has only approved the Osseoflex SN Steerable Needle for use in surgical procedures that infringe the '720 patent.

58. To the extent applicable, the requirements of 35 U.S.C. § 287(a) have been met with respect to the '720 patent.

59. As a result of Defendants' infringement of the '720 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.

60. 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 '720 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 '761 patent, '340 patent, '543 patent, and/or '720 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 '761 patent, '340 patent, '543 patent, and/or '720 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.

June 4, 2013

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