

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

ORTHOPHOENIX, LLC,
Plaintiff,

v.

ASCENDX SPINE, 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 Ascendx Spine, Inc. (“Ascendx”) is a Delaware corporation with a principal place of business at 7079 University Boulevard, Winter Park, Florida 32792. Ascendx has appointed National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904, 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 Ascendx. Does’ identities are not presently known to Orthophoenix; however, on information and belief, Defendant Ascendx 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 Ascendx because, among other reasons, Defendant Ascendx is a corporation organized and existing under the laws of the State of Delaware. Thus, Defendant Ascendx has purposefully availed itself of the benefits of the State of Delaware and the exercise of jurisdiction over Ascendx 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 approximately 500 patents and applications.

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

ASSERTED PATENTS

13. 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.

14. 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 B.

15. 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 C.

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

16. Orthophoenix references and incorporates by reference paragraphs 1 through 15 of this Complaint.

17. Ascendx has been and still is 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 including, but not limited to, the Acu-Cut Instrument.

18. By way of example only, with reference to Claim 1 of the ‘138 patent, the Acu-Cut Instrument manufactured, sold, offered for sale, or imported by Ascendx includes a cannula having an axis establishing a percutaneous path leading to inside a bone. The Acu-Cut Instrument 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.

19. Defendant Does 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 Acu-Cut Instrument Does purchased from Ascendx.

20. Ascendx has also infringed indirectly and continues to infringe indirectly the ‘138 patent by active inducement under 35 U.S.C. § 271(b).

21. Upon information and belief, Ascendx had knowledge of the ‘138 patent since at least as early as 2011. In 2011, Ascendx indicated that the Kyphon Kyphx Inflatable Bone Tamp was a “predicate device” to its Ascendx VCF Repair System, which includes the Acu-Cut Instrument, in its request to market the Ascendx VCF Repair System in the United States, which was prepared on July 1, 2011, and submitted to the United States Food and Drug Administration (“FDA”). By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a “predicate device,” Ascendx was representing to the FDA that the Ascendx VCF Repair 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 Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the VCF Repair System, Ascendx gained knowledge of the ‘138 patent at least as early as 2011.

22. On information and belief, Ascendx 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, Ascendx provides training and instruction materials to physicians on how to use the infringing surgical instruments, including the Acu-Cut Instrument, during the performance of surgical procedures during which physicians create cavities in cancellous bone. By using the infringing surgical instruments, including but not limited to the Acu-Cut Instrument, during procedures during which physicians create cavities in cancellous bone as instructed and trained by Ascendx, physicians directly infringe at least Claim 1 of the '138 patent. By continuing to provide instruction and training on the use of the Acu-Cut Instrument to physicians despite its knowledge that the Acu-Cut Instrument infringes the '138 patent, Ascendx has and continues to specifically intend to induce infringement of the '138 patent.

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

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

25. 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.

26. 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. 7,909,827)

27. Orthophoenix references and incorporates by reference paragraphs 1 through 26 of this Complaint.

28. Defendants Does 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 Acu-Cut Instrument Does purchased from Ascendx in the manner instructed and taught by Ascendx, and in the manner for which the Acu-Cut Instrument is approved for use by the FDA.

29. Ascendx has been and still is 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 Acu-Cut Instrument. By way of example only, Ascendx directly infringes the '9827 patent by using the Acu-Cut Instrument to perform the method described in Claim 1.

30. Ascendx has also infringed indirectly and continues to infringe indirectly the '9827 patent by active inducement under 35 U.S.C. § 271(b).

31. Upon information and belief, Ascendx had knowledge of the ‘9827 patent since at least as early as 2011. In 2011, Ascendx indicated that the Kyphon Kyphx Inflatable Bone Tamp was a “predicate device” to its Ascendx VCF Repair System, which includes the Acu-Cut Instrument, in its request to market the Ascendx VCF Repair System in the United States, which was prepared on July 1, 2011, and submitted to the FDA. By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a “predicate device,” Ascendx was representing to the FDA that the Ascendx VCF Repair 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 Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the VCF Repair System, Ascendx gained knowledge of the ‘9827 patent at least as early as 2011.

32. On information and belief, Ascendx 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, Ascendx provides training and instruction materials to physicians on how to use the infringing surgical instruments, including but not limited to the Acu-Cut Instrument, during the performance of surgical procedures during which physicians use surgical instruments to cut cancellous bone. By using the infringing surgical instruments, including the Acu-Cut Instrument, to cut cancellous bone as instructed and trained by Ascendx, 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 Acu-Cut Instrument, to perform procedures during which physicians cut cancellous bone in the manner described in Claim 1 of the '9827 patent, Ascendx has and continues to specifically intend to induce infringement of the '9827 patent.

33. Ascendx has also infringed indirectly and continues to infringe indirectly the '9827 patent by contributory infringement under 35 U.S.C. § 271(c).

34. Ascendx 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 Acu-Cut Instrument, with the knowledge that the Acu-Cut Instrument will be used by physicians to directly infringe at least Claim 1 of the '9827 patent.

35. Ascendx had knowledge of the '9827 patent since at least 2011. Since at least 2011, Ascendx has had knowledge that the surgical instruments, including the Acu-Cut Instrument, 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 Acu-Cut Instrument is used by physicians to perform surgical procedures infringing the '9827 patent, Ascendx continues to provide instruction and training to physicians on how to use the Acu-Cut Instrument in a manner that directly infringes at least Claim 1 of the '9827 patent. Ascendx does not provide instructions or training on the use of the Acu-Cut Instrument in a manner that does not infringe the

'9827 patent. Furthermore, upon information and belief, the FDA has only approved the Acu-Cut Instrument for use in surgical procedures that infringe the '9827 patent.

36. Since at least 2011, Ascendx has been and still is willfully infringing the '9827 patent. At least as early as 2011, Ascendx had actual knowledge of the '9827 patent. Despite having actual knowledge of the '9827 patent, Ascendx 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.

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

38. 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.

39. 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 '9827 patent, Orthophoenix will be greatly and irreparably harmed.

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

40. Orthophoenix references and incorporates by reference paragraphs 1 through 39 of this Complaint.

41. 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 Acu-Cut Instrument Does purchased from Ascendx in the manner instructed and taught by Ascendx, and in the manner for which the Acu-Cut Instrument is approved for use by the FDA.

42. Ascendx 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 Acu-Cut Instrument. By way of example only, Ascendx directly infringes the ‘672 patent by performing the method of treating a vertebral body described in Claim 19.

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

44. Upon information and belief, Ascendx had knowledge of the ‘672 patent since at least as early as 2011. In 2011, Ascendx indicated that the Kyphon Kyphx Inflatable Bone Tamp was a “predicate device” to its Ascendx VCF Repair System, which includes the Acu-Cut Instrument, in its request to market the Ascendx VCF Repair System in the United States, which was prepared on July 1, 2011, and submitted to the FDA. By indicating that the Kyphon Kyphx Inflatable Bone Tamp was a “predicate device,” Ascendx was representing to the FDA that the Ascendx VCF Repair 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 Bone Tamp product in sufficient detail to represent to the FDA that it is a predicate device to the VCR Repair System, Ascendx gained knowledge of the '672 patent at least as early as 2011.

45. On information and belief, Ascendx 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, Ascendx provides training and instruction materials to physicians on how to use the infringing surgical instruments, including the Acu-Cut Instrument, 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 Acu-Cut Instrument, to create cavities in cancellous bone as instructed and trained by Ascendx, 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 Acu-Cut Instrument to perform surgical procedures in the manner described in Claim 19 of the '672 patent, Ascendx has and continues to specifically intend to induce infringement of the '672 patent.

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

47. Ascendx 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 Acu-Cut Instrument, with the knowledge that the surgical instruments will be used by physicians to directly infringe at least Claim 19 of the '672 patent.

48. Ascendx had knowledge of the '672 patent since at least 2011. Since at least 2011, Ascendx has had knowledge that the surgical instruments, including the Acu-Cut Instrument, 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 Acu-Cut Instrument, are especially made and/or adapted for use in infringing the '672 patent. For example, despite having knowledge that the Acu-Cut Instrument is used by physicians to perform surgical procedures infringing the '672 patent, Ascendx continues to provide instruction and training to physicians on how to use the Acu-Cut Instrument in a manner that directly infringes at least Claim 19 of the '672 patent. Ascendx does not provide instructions or training on the use of the Acu-Cut Instrument in a manner that does not infringe the '672 patent. Furthermore, upon information and belief, the FDA has only approved the Acu-Cut Instrument for use in surgical procedures that infringe the '672 patent.

49. Since at least 2011, Ascendx has been and still is willfully infringing the '672 patent. At least as early as 2011, Ascendx had actual knowledge of the '672 patent. Despite having actual knowledge of the '672 patent, Ascendx 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.

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

51. 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.

52. 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.

PRAYER FOR RELIEF

Orthophoenix prays for the following relief:

1. A judgment that Defendants have infringed one or more claims of the '138, '9827, and/or '672 patents;
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 Defendants, from infringing the '138, '9827, and/or '672 patents;

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 Ascendx;
5. 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
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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