

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INNOVATIVE THERAPIES, INC.,

Plaintiff,

v.

KINETIC CONCEPTS, INC., KCI
LICENSING, INC. and KCI USA, INC.

Defendants.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Innovative Therapies, Inc. ("ITI") files the following Complaint for Declaratory Relief against Kinetic Concepts, Inc., KCI Licensing, Inc. and KCI USA, Inc. (collectively "the KCI defendants" or "KCI") and, in support thereof, alleges as set forth below:

THE PARTIES

1. Plaintiff ITI is a Delaware corporation having its principal place of business at 10948 Beaver Dam Road, Suite E, Hunt Valley, Maryland 21030.
2. On information and belief, Defendant Kinetic Concepts, Inc. ("KCI, Inc.") is a Texas corporation having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. According to its website, Kinetic Concepts, Inc. designs, manufactures, markets and services medical products aimed at improving clinical outcomes and reducing the cost of patient care.
3. On information and belief, Defendant KCI Licensing, Inc. ("KCI Licensing") is a Delaware corporation having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230, and is a wholly owned subsidiary of Kinetic Concepts, Inc.
4. On information and belief, Defendant KCI USA, Inc. ("KCI USA") is a Delaware corporation having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230, and is a wholly owned subsidiary of Kinetic Concepts, Inc.

JURISDICTION AND VENUE

5. ITI seeks declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338 because ITI's claims for declaratory relief arise under the patent laws of the United States, 35 U.S.C. §§ 101, *et seq.*

7. The KCI defendants are each subject to the personal jurisdiction of this Court because they each do and have done business in this judicial district, including regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from products and services to individuals and entities in this District, including without limitation Christiana Care Health System. In addition, KCI Licensing and KCI USA are both incorporated under the laws of the state of Delaware and have designated agents for service of process in Delaware.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c).

GENERAL ALLEGATIONS

9. Since 1995, KCI, Inc. and KCI USA have manufactured and sold a variety of negative pressure wound therapy devices under the registered trademark V.A.C.[®] On information and belief, aspects of these devices are covered by a portfolio of patents, including U.S. Patent Nos. 4,969,880 ("the '880 patent"), 5,636,643 ("the '643 patent"), 5,645,081 ("the '081 patent"), 7,198,046 ("the '046 patent") and 7,216,651 ("the '651 patent") ("the patents in suit," collectively).

10. The '880 patent, entitled "Wound Dressing and Treatment Method," issued on November 13, 1990 to David S. Zamierowski. On information and belief, the '880 patent is assigned to KCI Licensing, Inc. A true and accurate copy of the '880 patent is attached as Exhibit A.

11. The '643 patent, entitled "Wound Treatment Employing Reduced Pressure," issued on June 10, 1997 to Louis C. Argenta et al. On information and belief, KCI, Inc. is an

exclusive licensee of the '643 patent. Further, on information and belief, KCI holds the exclusive, worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '643 patent, which is owned by Wake Forest University Health Sciences ("Wake Forest"). A true and accurate copy of the '643 patent is attached as Exhibit B.

12. The '081 patent, entitled "Method of Treating Tissue Damage and Apparatus for Same," issued on July 8, 1997 to Louis C. Argenta et al. On information and belief, KCI, Inc. is an exclusive licensee of the '081 patent. Further, on information and belief, KCI holds the exclusive, worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '081 patent, which is owned by Wake Forest. A true and accurate copy of the '081 patent is attached as Exhibit C.

13. The '046 patent, entitled "Wound Treatment Employing Reduced Pressure," issued on April 3, 2007 to Louis C. Argenta et al. On information and belief, KCI, Inc. is an exclusive licensee of the '046 patent. Further, on information and belief, KCI holds the exclusive, worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '046 patent, which is owned by Wake Forest. A true and accurate copy of the '046 patent is attached as Exhibit D.

14. The '651 patent, entitled "Wound Treatment Employing Reduced Pressure," issued on May 15, 2007 to Louis C. Argenta et al. On information and belief, KCI, Inc. is an exclusive licensee of the '651 patent. Further, on information and belief, KCI holds the exclusive, worldwide right to make, have made, use, lease and sell products incorporating the inventions covered by the '651 patent, which is owned by Wake Forest. A true and accurate copy of the '651 patent is attached as Exhibit E.

15. ITI was founded in 2006 by various former officers and employees of KCI and by Dr. Paul Svedman, a plastic and reconstructive surgeon, prolific inventor, and professor of medicine. ITI is engaged in the research, development and production of innovative therapies in the field of patient wound care.

16. In 2007, ITI developed a new and improved negative pressure wound therapy device named the Svedman Wound Treatment System ("Svedman"). The Svedman provides superior wound care performance at a significantly reduced cost as compared to competitive products currently on the market, including KCI's V.A.C.[®] device. The superior performance of the Svedman is attributable to the fact that the device promotes wound healing by combining wound irrigation with vacuum assisted drainage. Because ITI can offer the Svedman at a substantial discount to the current market price for equivalent products, rentals of such devices to customers previously priced out of the market become feasible, thus enabling a greater number of patients with serious wounds to benefit from faster and more comfortable periods of healing.

17. ITI intends to begin offering the Svedman to certain potential customers on or about October 1, 2007.

18. Since at least 2001, the KCI defendants have consistently and aggressively sought to enforce their patent rights with respect to the V.A.C.[®] technology. In fact, KCI, Inc. has sued no fewer than ten different defendants in the past six years for alleged infringement of the patents in suit. *Kinetic Concepts, Inc. v. Med Center of La. At New Orleans, et al.*, No. 01-2950 (E.D. La. filed Sept. 25, 2001) (dismissed); *Kinetic Concepts, Inc. v. Botsford Gen Hosp., et al.*, No. 03-70135 (E.D. Mich. Filed Jan. 10 2003) (dismissed); *Kinetic Concepts, Inc., et al. v. Bluesky Med. Corp. et al.*, No. 03-832, 2007 WL 1113002 (W.D. Tex. Apr. 4, 2007); *Kinetic Concepts, Inc., et al. v. Bluesky Med. Corp., et al.*, No. 07-188 (E.D. Tex. filed May 14, 2007) (pending); *Kinetic Concepts, Inc., et al. v. Medela AG, et al.*, No. 07-187 (E.D. Tex. filed May 14 2007) (pending); *Medela, Inc. v. Kinetic Concepts, Inc. et al.*, No. 07-449 (W.D. Tex. filed May 22, 2007) (pending). Defendants in certain of these suits were not limited to competitors of the KCI defendants, but included the KCI defendants' customers such as hospitals, medical centers and individual doctors.

19. The KCI defendants' litigious history is consistent with the following statement in KCI, Inc.'s most recent 10-K Annual Report filed with the Securities and Exchange Commission: "***If we are unsuccessful in protecting and maintaining our intellectual property,***

particularly our rights under the Wake Forest patents, our competitive position would be harmed.” Kinetic Concepts, Inc., Annual Report (Form 10-K), at 22 (Feb. 23, 2007).

20. The KCI defendants are aware that ITI has received FDA approval for a negative pressure wound therapy device, and they have expressly warned ITI of the likelihood that they will sue ITI for patent infringement. Specifically, KCI, Inc.’s Senior Vice President of Manufacturing and Executive Committee Member Mike Burke asserted in a telephone conversation with an ITI officer on September 17, 2007 that the odds are “100%” that KCI will sue ITI if it launches a negative pressure, foam-based wound treatment device. Similarly, KCI, Inc. Director of Marketing Mike Girouard stated in a telephone conversation with ITI representatives on September 12, 2007 that “KCI will respond aggressively” to the ITI device and will “take legal action” if KCI believes that the ITI product infringes any KCI patents.

21. In light of ITI’s impending launch of its Svedman wound therapy system, an actual and substantial controversy now exists between ITI and the KCI defendants with respect to the ‘880, 643, ‘081, ‘046 and ‘651 patents.

22. The statements of the KCI defendants regarding the importance of protecting their patent rights generally and against ITI specifically demonstrate the immediacy of the current controversy.

COUNT I

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ‘081 PATENT

23. Each of paragraphs 1-22 is incorporated herein by reference.

24. ITI has not infringed and does not infringe any valid claim of the ‘081 patent.

25. There is an actual and substantial controversy between the adverse interests of ITI and the Defendants as to whether the use, making, sale, or offering for sale of the Svedman infringes the claims of the ‘081 patent.

26. The KCI defendants’ policy of aggressively pursuing allegations of infringement of the ‘081 patent against ITI, and the threatening statements by KCI, Inc.’s Senior Vice President of Manufacturing and Director of Marketing to ITI, demonstrate sufficient immediacy

of the controversy to warrant issuance of a declaratory judgment.

27. ITI is entitled to a judicial declaration and order that ITI has not infringed and does not infringe, directly, by inducement or by contribution, any valid claim of the '081 patent.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF THE '081 PATENT

28. Each of paragraphs 1-27 is incorporated herein by reference.

29. The '081 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United State Code, including, but not limited to, 35 U.S.C. 101, 102, 103 and 112.

30. An actual, substantial and immediate controversy exists between ITI and Defendants as to whether the claims of the '081 patent are valid.

31. ITI is entitled to a judicial declaration and order that the '081 patent is invalid.

COUNT III
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '643 PATENT

32. Each of paragraphs 1-22 is incorporated herein by reference.

33. ITI has not infringed and does not infringe any valid claim of the '643 patent.

34. There is an actual and substantial controversy between the adverse interests of ITI and the Defendants as to whether the use, making, sale, or offering for sale of the Svedman infringes the claims of the '643 patent.

35. The KCI defendants' policy of aggressively pursuing allegations of infringement of the '643 patent against ITI, and the threatening statements by KCI, Inc.'s Senior Vice President of Manufacturing and Director of Marketing to ITI, demonstrate sufficient immediacy of the controversy to warrant issuance of a declaratory judgment.

36. ITI is entitled to a judicial declaration and order that ITI has not infringed and does not infringe, directly, by inducement or by contribution, any valid claim of the '643 patent.

COUNT IV
DECLARATORY JUDGMENT OF INVALIDITY OF THE '643 PATENT

37. Each of paragraphs 1-22 and 32-36 is incorporated herein by reference.

38. The '643 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United State Code, including, but not limited to, 35 U.S.C. 101, 102, 103 and 112.

39. An actual, substantial and immediate controversy exists between ITI and Defendants as to whether the claims of the '643 patent are valid.

40. ITI is entitled to a judicial declaration and order that the '643 patent is invalid.

COUNT V

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '046 PATENT

41. Each of paragraphs 1-22 is incorporated herein by reference.

42. ITI has not infringed and does not infringe any valid claim of the '046 patent.

43. There is an actual and substantial controversy between the adverse interests of ITI and the Defendants as to whether the use, making, sale, or offering for sale of the Svedman infringes the claims of the '046 patent.

44. The KCI defendants' policy of aggressively pursuing allegations of infringement of the '046 patent against ITI, and the threatening statements by KCI, Inc.'s Senior Vice President of Manufacturing and Director of Marketing to ITI, demonstrate sufficient immediacy of the controversy to warrant issuance of a declaratory judgment.

45. ITI is entitled to a judicial declaration and order that ITI has not and does not infringe, directly, by inducement or by contribution, any valid claim of the '046 patent.

COUNT VI

DECLARATORY JUDGMENT OF INVALIDITY OF THE '046 PATENT

46. Each of paragraphs 1-22 and 41-45 is incorporated herein by reference.

47. The '046 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United State Code, including, but not limited to, 35 U.S.C. 101, 102, 103 and 112.

48. An actual, substantial and immediate controversy exists between ITI and Defendants as to whether the claims of the '046 patent are valid.

49. ITI is entitled to a judicial declaration and order that the '046 patent is invalid.

COUNT VII

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '651 PATENT

50. Each of paragraphs 1-22 is incorporated herein by reference.

51. ITI has not infringed and does not infringe any valid claim of the '651 patent.

52. There is an actual and substantial controversy between the adverse interests of ITI and the Defendants as to whether the use, making, sale, or offering for sale of the Svedman infringes the claims of the '651 patent.

53. The KCI defendants' policy of aggressively pursuing allegations of infringement of the '651 patent against ITI, and the threatening statements by KCI, Inc.'s Senior Vice President of Manufacturing and Director of Marketing to ITI, demonstrate sufficient immediacy of the controversy to warrant issuance of a declaratory judgment.

54. ITI is entitled to a judicial declaration and order that ITI has not and does not infringe, directly, by inducement or by contribution, any valid claim of the '651 patent.

COUNT VIII

DECLARATORY JUDGMENT OF INVALIDITY OF THE '651 PATENT

55. Each of paragraphs 1-22 and 50-54 is incorporated herein by reference.

56. The '651 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United State Code, including, but not limited to, 35 U.S.C. 101, 102, 103 and 112.

57. An actual, substantial and immediate controversy exists between ITI and Defendants as to whether the claims of the '651 patent are valid.

58. ITI is entitled to a judicial declaration and order that the '651 patent is invalid.

COUNT IX

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '880 PATENT

59. Each of paragraphs 1-22 is incorporated herein by reference.

60. ITI has not infringed and does not infringe any valid claim of the '880 patent.

61. There is an actual and substantial controversy between the adverse interests of ITI and the Defendants as to whether the use, making, sale, or offering for sale of the Svedman

infringes the claims of the '880 patent.

62. The KCI defendants' policy of aggressively pursuing allegations of infringement of the '880 patent against ITI, and the threatening statements by KCI, Inc.'s Senior Vice President of Manufacturing and Director of Marketing to ITI, demonstrate sufficient immediacy of the controversy to warrant issuance of a declaratory judgment.

63. ITI is entitled to a judicial declaration and order that ITI has not and does not infringe, directly, by inducement or by contribution, any valid claim of the '880 patent.

COUNT X
DECLARATORY JUDGMENT OF INVALIDITY OF THE '880 PATENT

64. Each of paragraphs 1-22 and 59-63 is incorporated herein by reference.

65. The '880 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United State Code, including, but not limited to, 35 U.S.C. 101, 102, 103 and 112.

66. An actual, substantial and immediate controversy exists between ITI and Defendants as to whether the claims of the '880 patent are valid.

67. ITI is entitled to a judicial declaration and order that the '880 patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Innovative Therapies, Inc. respectfully requests that the Court enter judgment in its favor and against the Defendants as follows:

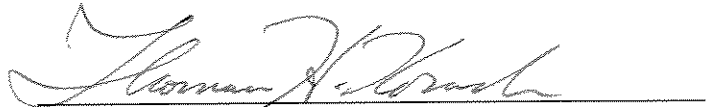
1. The Court enter judgment that the '081 patent is invalid and not infringed by ITI;
2. The Court enter judgment that the '643 patent is invalid and not infringed by ITI;
3. The Court enter judgment that the '046 patent is invalid and not infringed by ITI;
4. The Court enter judgment that the '651 patent is invalid and not infringed by ITI;
5. The Court enter judgment that the '880 patent is invalid and not infringed by ITI;
6. The Court find this case to be an exceptional case pursuant to 35 U.S.C. § 285 and award ITI its attorneys' fees and costs in this action; and

7. The Court enter an order for such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff Innovative Therapies, Inc. hereby respectfully requests trial by jury of all issues triable of right by a jury.

Dated: September 25, 2007



Thomas H. Kovach (DE Bar #3964)
PEPPER HAMILTON LLP
Hercules Plaza, Suite 5100
1313 Market Street
P.O. Box 1709
Wilmington, DE 19899-1709
Telephone: (302) 777-6500

Of Counsel:

Jonathan G. Graves
Erik B. Milch
Scott Cole
COOLEY GODWARD KRONISH LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, Virginia 20190-5656
Telephone: (703) 456-8000
Facsimile: (703) 456-8100

Attorneys for Plaintiff Innovative Therapies, Inc.