UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF NORTH CAROLINA

WAKE FOREST UNIVERSITY	§	
HEALTH SCIENCES, KINETIC	§	
CONCEPTS, INC., KCI	§	
LICENSING, INC., KCI USA, INC.,	§	
KCI MEDICAL RESOURCES,	§	
MEDICAL HOLDINGS LIMITED,	§	
and KCI MANUFACTURING,	§ C	CIVIL ACTION NO. 1:08-cv-32
	§	
Plaintiffs,	§	
	§	
VS.	§	
	§ J	URY TRIAL REQUESTED
INNOVATIVE THERAPIES, INC.	§	
	§	
Defendant.	§	

PLAINTIFFS' ORIGINAL COMPLAINT AND REQUEST FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

Plaintiffs Wake Forest University Health Sciences ("Wake Forest"), Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., KCI Medical Resources, Medical Holdings Limited, and KCI Manufacturing (collectively, "KCI," and collectively with Wake Forest, "Plaintiffs") file this Original Complaint seeking damages and preliminary and permanent injunctive relief against Innovative Therapies, Inc. ("Defendant"). In support, Plaintiffs allege as follows:

I. PARTIES

1. Plaintiff Wake Forest is a non-profit corporation organized under the laws of the State of North Carolina having its principal place of business at Medical Center Boulevard, Winston-Salem, North Carolina 27157-1023. Wake Forest is a wholly-controlled subsidiary of Wake Forest University.

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- 2. Plaintiff Kinetic Concepts, Inc. is a corporation organized under the laws of the State of Texas having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. Kinetic Concepts, Inc. is a global medical technology company with leadership positions in advanced wound care and therapeutic surfaces.
- 3. Plaintiff KCI USA, Inc. is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI USA, Inc. is a wholly owned subsidiary of Kinetic Concepts, Inc.
- 4. Plaintiff KCI Licensing, Inc. is a corporation organized under the laws of the State of Delaware having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI Licensing, Inc. is a wholly owned subsidiary of Kinetic Concepts, Inc.
- 5. Plaintiff KCI Medical Resources is a company governed by the laws of the Ireland having its principal place of business at Zephyr House, Mary Street, P.O. Box 709 GT, Grand Cayman, Cayman Islands.
- 6. Plaintiff Medical Holdings Limited is a company governed by the laws of Malta having its principal place of business at 171 Old Bakery Street, Valletta VLT 1455, Malta.
- 7. Plaintiff KCI Manufacturing is a company governed by the laws of Ireland having its principal place of business at 39/40 Upper Mount Street, Dublin 2 Ireland.
- 8. Defendant Innovative Therapies, Inc. ("ITI") is a Delaware corporation, which was formed in July of 2006, having its principal place of business at 10948 Beaver Dam Road, Suite E, Hunt Valley, Maryland 21030. ITI may be served with process by serving its registered agent, Corporation Service Company, at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

II. BACKGROUND

- 9. KCI is a leader in the development, manufacture, and distribution of specialty therapeutic medical devices.
- 10. Several of KCI's product lines feature products that provide wound care benefits for patients. KCI's wound care product lines include variations of the Vacuum Assisted Closure® System ("V.A.C. System").
- 11. The commercialization of the V.A.C. System dramatically revolutionized wound care by providing effective treatment for difficult-to-treat and chronic wounds.
- 12. The V.A.C. System incorporates certain novel features and characteristics invented by researchers working on behalf of Wake Forest in Winston-Salem, North Carolina. In recognition of the technological advances made by these researchers, the U.S. Patent and Trademark Office issued U.S. Patent Nos. 5,636,643 ("the '643 patent"); 5,645,081 ("the '081 patent"); and 7,216,651 ("the '651 patent"), all of which are assigned to Wake Forest (collectively, the "Wake Forest patents").
- 13. The '643 patent, entitled "Wound Treatment Employing Reduced Pressure," was duly and lawfully issued on June 10, 1997, and is extant and enforceable until its expiration date of June 10, 2014. Wake Forest is the true and record owner of the '643 patent. A true and correct copy of the '643 patent is attached hereto as **Exhibit A**.
- 14. The '081 patent, entitled "Method of Treating Tissue Damage and Apparatus for Same," was duly and lawfully issued on July 8, 1997, and is extant and enforceable until its expiration date of June 10, 2014. Wake Forest is the true and record owner of the '081 patent. A true and correct copy of the '081 patent is attached hereto as **Exhibit B**.

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- 15. The '651 patent, entitled "Wound Treatment Employing Reduced Pressure," was duly and lawfully issued on May 15, 2007, and is extant and enforceable until its expiration date of November 14, 2011. Wake Forest is the true and record owner of the '651 patent. A true and correct copy of the '651 is attached hereto as **Exhibit C**.
- 16. Kinetic Concepts, Inc. is the exclusive licensee of the Wake Forest patents, by virtue of a written license agreement effective October 6, 1993 with Wake Forest. Pursuant to that license agreement, KCI has the exclusive worldwide right to make, have made, use, lease, and sell products incorporating the inventions covered by the Wake Forest patents.
- 17. At all times relevant to this complaint, KCI has complied with the marking requirement of 35 U.S.C. § 287.
- 18. ITI was founded by one or more former, high-level KCI employees, all of whom have extensive knowledge of both KCI's V.A.C. System and KCI's patent portfolio, including the Wake Forest patents. ITI claims it has developed a "new and improved" negative pressure wound therapy device ("the ITI System").

III. JURISDICTION AND VENUE

- 19. This is an action for patent infringement arising under the federal patent laws, 35 U.S.C. § 1 *et seq.* Therefore, this Court has jurisdiction of this suit under 28 U.S.C. §§ 1331, 1338(a), and 1367.
- 20. This Court has personal jurisdiction over the Defendant. Defendant has committed acts of infringement within the state of North Carolina and within this judicial district.
- 21. Venue is proper in this district under 28 U.S.C. § 1391(c) because Defendant is a corporation that is subject to personal jurisdiction in this district.

IV. CAUSES OF ACTION

COUNT 1: FEDERAL PATENT INFRINGEMENT

- 22. Paragraphs 1 through 21 are repeated and realleged as if fully set forth herein.
- 23. Defendant's ITI System, in whole or in part, incorporates the inventions of the Wake Forest patents exclusively licensed to KCI. The manufacture, sale, offer for sale, or use of the ITI System infringes the Wake Forest patents either literally or under the doctrine of equivalents.
- 24. Defendant is knowingly and directly infringing or inducing infringement of the Wake Forest patents within this District and elsewhere, without leave or license from Plaintiffs, all to Plaintiffs' substantial damage. Additionally, Defendant is contributorily infringing the Wake Forest patents within this District and elsewhere, without leave or license from Plaintiffs, all to Plaintiffs' substantial damage. Defendant will continue to do so unless enjoined by this Court.
- 25. Said direct or contributory infringement of the Wake Forest patents, or the active inducement of others to infringe the Wake Forest patents, is willful and is damaging Plaintiffs, and Plaintiffs will suffer additional and irreparable damage unless this Court enjoins Defendant from continuing to directly or contributorily infringe or induce others to infringe the Wake Forest patents.
- 26. Defendant's deliberate and willful infringement, contributory infringement, and inducement of others to infringe the Wake Forest patents makes this an exceptional case and justifies the assessment of increased damages pursuant to 35 U.S.C. §284 and the award of attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT 2: PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

- 27. Paragraphs 1 through 26 are repeated and realleged as if fully set forth herein.
- 28. Defendant's direct or contributory infringement of the Wake Forest patents, or its active inducement of others to infringe the Wake Forest patents, is causing immediate and irreparable injury to Plaintiffs, and Plaintiffs will suffer additional and irreparable damage unless and until this Court enjoins Defendant from its infringement of the Wake Forest patents.
- 29. If not enjoined by this Court, Defendant's infringement will deprive Plaintiffs of sales they otherwise would have made, will prevent KCI's exclusive enjoyment of its intellectual property rights and will damage Plaintiffs' established goodwill.
- 30. Plaintiffs therefore ask that the Court preliminarily and permanently enjoin Defendant's infringement, which has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law.

V. JURY DEMAND

Plaintiffs hereby request a trial by jury.

VI. PRAYER

For these reasons, Plaintiffs ask for judgment against Defendants for the following:

A. A preliminary and permanent injunction against Defendant, its officers, agents, servants, employees, successors, assigns, and attorneys, and all persons in active concert or participation with any of them, from any future acts of infringement (whether direct, contributory, or by inducement) of U.S. Patent Nos. 5,636,643; 5,645,081; and 7,216,651.

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- B. All damages Plaintiffs have sustained as a result of any infringement alleged herein, but not less than a reasonable royalty, together with interest and costs under 35 U.S.C. § 284.
- C. Increased damages under 35 U.S.C. § 284 for Defendant's willful infringement.
- D. That the Court declare this to be an exceptional case pursuant to 35 U.S.C. § 285 and award Plaintiffs their reasonable attorney fees.
- E. Plaintiffs' costs and expenses for prosecuting this action, as well as prejudgment and postjudgment interest.
- F. All other relief the Court deems appropriate.

This the 10th day of January, 2008.

/s/ William K. Davis

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