

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

**KCI LICENSING, INC., KCI  
MEDICAL RESOURCES UNLIMITED  
COMPANY, MEDICAL HOLDINGS  
LIMITED, KCI MANUFACTURING,  
INC., KCI IMPORTS, INC., AND KCI  
USA, INC.**

**Plaintiffs,**

**v.**

**SMITH & NEPHEW, INC.,  
SMITH & NEPHEW HOLDINGS, INC.,  
and SMITH & NEPHEW PLC**

**Defendants.**

**Civil Action No.**

**JURY TRIAL DEMANDED**

**COMPLAINT**

Plaintiffs KCI Licensing, Inc. (“KCI Licensing”), KCI Medical Resources Unlimited Company (“KCI Medical Resources”), Medical Holdings Limited (“Medical Holdings”), KCI Manufacturing, Inc. (“KCI Manufacturing”), KCI Import, Inc. (“KCI Import”), and KCI USA, Inc. (“KCI USA”) (collectively “KCI”) for their Complaint against Defendants Smith & Nephew, Inc. (“SNI”), Smith & Nephew Holdings, Inc. (“SNHI”), and Smith & Nephew PLC (“SNPLC”) (collectively “S&N”), hereby allege as follows:

**PARTIES**

1. Plaintiff KCI Licensing is a Delaware corporation with its principal place of business at 12930 West Interstate 10, San Antonio, TX 78249.

2. Plaintiff KCI Medical Resources is a company governed by the laws of Ireland having its principal place of business at Willow House, Cricket Square, P.O. Box 709, Grand Cayman KY1-1107, Cayman Islands.

3. Plaintiff Medical Holdings is a company governed by the laws of Malta having its principal place of business at 171 Old Bakery Street, Valletta VLT 1455, Malta.

4. Plaintiff KCI Manufacturing Unlimited Company is a company governed by the laws of Ireland with its principal place of business at Unit B IDA Business & Technology Park, Dublin Road, Athlone, Co. Westmeath, Ireland.

5. Plaintiff KCI Import, Inc. is a Delaware corporation with its principal place of business at 12930 West Interstate 10, San Antonio, TX 78249.

6. Plaintiff KCI USA, Inc. is a corporation organized under the laws of the State of Delaware having its principal place of business at 12930 West Interstate 10, San Antonio, Texas 78230.

7. On information and belief, Defendant SNI is a Delaware corporation with its principal place of business at 1450 Brooks Road, Memphis, Tennessee 38116. Defendant SNI is a subsidiary of Defendant SNHI.

8. On information and belief, Defendant SNHI is a Delaware corporation with its principal place of business at 1201 North Orange Street, Suite 788, Wilmington, Delaware 19801. Defendant SNHI is a subsidiary of Defendant SNPLC.

9. On information and belief, Defendant SNPLC is a public limited company under the laws of the United Kingdom, having its principal place of business at 15 Adam Street, London, WC2N 6LA, England, United Kingdom.

### **NATURE OF THE ACTION**

10. This is a civil action for infringement of United States Patent Nos. 7,004,915 (“the ’915 Patent”), 8,758,315 (“the ’315 Patent”), 7,108,683 (“the ’683 Patent”), and 8,795,244 (“the ’244 Patent”) (collectively, “the Patents-In-Suit”) under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

### **JURISDICTION AND VENUE**

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, including 35 U.S.C. § 271 et seq.

12. This Court has personal jurisdiction over SNI because, among other things, SNI is a Delaware corporation and has a designated agent for service of process in Delaware. On information and belief, SNI engages in substantial and ongoing business in this 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 but not limited to sales of infringing products to, for example and without limitation, First State Surgery Center, located at 1000 Twin C Ln # 200, Newark, Delaware 19713. This Court also has personal jurisdiction over SNI because, among other things, SNI has committed, aided, abetted, contributed to, and/or participated in the commission of patent infringement in this District and elsewhere that led to foreseeable harm and injury to KCI.

13. This Court has personal jurisdiction over SNHI because, among other things, SNHI is a Delaware corporation and has a designated agent for service of process in Delaware. On information and belief, SNHI engages in substantial and ongoing business in this 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 but not limited to sales of infringing products to, for example and without limitation, First State Surgery Center, located at 1000 Twin C Ln # 200, Newark, Delaware 19713. This Court also has personal jurisdiction over SNHI because, among other things, SNHI has committed, aided, abetted, contributed to, and/or participated in the commission of patent infringement in this District and elsewhere that led to foreseeable harm and injury to KCI.

14. This Court has personal jurisdiction over SNPLC because, on information and belief, as the corporate parent of SNI and SNHI, it directs and is involved in the collective activities of SNI and SNHI, including engaging in substantial and ongoing business in this 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.

15. This Court has personal jurisdiction over SNPLC because, on information and belief, SNPLC is in the business of manufacturing, marketing, using, selling, and/or offering for sale in the United States, and/or importing into the United States NPWT products directly, or through its wholly-owned subsidiaries, including SNI and SNHI. For example, SNPLC directly or through its wholly owned subsidiaries, offers for sale and sells NPWT and/or other wound care products throughout the United States and in this District, including but not limited to sales of infringing products to, for example and without limitation, First State Surgery Center, located at 1000 Twin C Ln # 200, Newark, Delaware 19713. This Court also has personal jurisdiction over SNPLC because, among other things, SNPLC has committed, aided, abetted, contributed to, and/or participated in the commission of patent infringement in this judicial district and

elsewhere that led to foreseeable harm and injury to KCI. SNPLC derives substantial revenue from the direct and/or indirect sale of its products in this District.

16. This Court has personal jurisdiction over Defendants because, among other things, Defendants have established minimum contacts within the forum such that the exercise of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice. Defendants have placed products that practice the claimed inventions of one or more of the Patents-In-Suit into the stream of commerce with the reasonable expectation and/or knowledge that purchasers and users of such products were located within this District. Defendants have sold, advertised, marketed, and/or distributed products in this District that practice the claimed inventions of one or more of the Patent-In-Suit.

17. Venue is proper in this district pursuant to at least 28 U.S.C. §§ 1391(c) and 1400(b).

#### **BACKGROUND OF THE TECHNOLOGY AND THE PATENTS-IN-SUIT**

18. KCI is a world leader in the development, manufacture and distribution of specialty therapeutic medical devices, including negative pressure wound therapy (“NPWT”) devices.

19. NPWT is a therapeutic technique that applies sub-atmospheric pressure to a wound site using a sealed wound dressing and a vacuum pump device. The application of sub-atmospheric pressure draws fluid out of the wound, thereby increasing blood flow to the affected area and promoting healing of the wound.

20. NPWT is commonly used to treat chronic wounds, such as difficult-to-treat wounds suffered by diabetes patients.

21. In 1995, the U.S. Food and Drug Administration (“FDA”) cleared KCI to market its first NPWT device: the Vacuum Assisted Closure® System, also known as the “V.A.C.® System” (hereinafter, “V.A.C. System”).

22. The commercialization of the V.A.C. System dramatically revolutionized wound care by providing effective treatment for chronic wounds.

23. Since its clearance and launch in 1995, KCI’s V.A.C. System has been used to treat millions of wounds worldwide. KCI continues to offer various models of the V.A.C. System for patient treatment, including in this District.

24. KCI has continued to research and develop improvements to the V.A.C. System to provide improved NPWT treatments for patients. The inventions of the Patents-in-Suit originated from KCI’s NPWT development efforts.

25. The ’915 Patent, entitled “Negative Pressure Assisted Tissue Treatment System,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on February 28, 2006. A copy of the ’915 Patent is attached hereto as Exhibit 1.

26. The ’915 Patent discloses, among other things, novel systems for stimulating the healing of tissue. One such system comprises a porous pad, an airtight dressing, an electric pump for applying negative pressure to a wound site, a conduit connecting the dressing to a canister that is removably connected to a wound site, and two filters (a hydrophobic filter and an odor vapor filter).

27. For example, claim 1 of the ’915 Patent recites:

A system for stimulating the healing of tissue, comprising:

a porous pad;

an airtight dressing;

a distal end of a conduit connected to the dressing;  
a canister removably connected to a proximal end of the conduit;  
an electric pump for applying negative pressure to a wound site;  
a hydrophobic filter positioned between said canister and said electric pump; and  
an odor vapor filter positioned between said hydrophobic filter and said electric pump.

28. The '315 Patent, entitled "Multi-Orientation Canister for Use with a Reduced Pressure Treatment System," was duly and legally issued by the PTO on June 24, 2014. A copy of the '315 Patent is attached hereto as Exhibit 2.

29. The '315 Patent discloses, among other things, novel canisters for use in reduced pressure tissue treatment. One such canister comprises a main chamber having an inlet, a filter chamber isolated from the filter chamber by one or more walls and having an outlet, a filter positioned within the filter chamber, and a first and second aperture extending through the one or more walls.

30. For example, claim 22 of the '315 Patent recites:

A canister for use in a reduced pressure tissue treatment, the canister comprising:  
a main chamber having an inlet adapted to receive fluid from a tissue site;  
a filter chamber isolated from the main chamber by one or more walls, the filter chamber having an outlet adapted to be fluidly coupled to a reduced pressure source;  
a filter positioned within the filter chamber; and

a first aperture and a second aperture extending through the one or more walls, the first aperture and the second aperture being sized to prevent the fluid, upon entrance into the main chamber, from incidentally contacting the filter.

31. The '683 Patent, entitled "Wound therapy and tissue management system and method with fluid differentiation," was duly and legally issued by the PTO on September 19, 2006. A copy of the '683 Patent is attached hereto as Exhibit 3.

32. The '683 Patent discloses, among other things, novel fluid-differentiating wound therapy and tissue management systems. One such system comprises (1) a fluid transfer element including a non-attaching patient contact surface, a first zone, a second zone, and a predetermined fluid flow path, (2) a cover placed over the transfer element, (3) a gradient source, and (4) an effluent conduit.

33. For example, claim 1 of the '683 Patent recites:

A fluid-differentiating wound therapy and tissue management system,  
which comprises:

a) a fluid transfer element including:

- 1) a non-attaching patient contact surface;
- 2) a first zone with a first fluid transfer coefficient;
- 3) a second zone with a second fluid transfer coefficient different from said first fluid transfer coefficient, said second zone being located adjacent to said first zone; and
- 4) a predetermined fluid flow path through said element guided by said fluid transfer coefficient differential between said first and second zones;

- b) a cover placed over said transfer element in contact therewith and including adhesive adapted for adhering said cover to a patient around the perimeter of said fluid transfer element;
- c) a gradient source for creating a gradient across said transfer element whereby fluids are moved through said transfer element;
- d) an effluent conduit connected to said transfer element and adapted for discharging effluent from the system; and
- e) said predetermined fluid flow path being towards said effluent conduit.

34. The '244 Patent, entitled "Super-Absorbent, Reduced Pressure Wound Dressings and Systems," was duly and legally issued by the PTO on August 5, 2014. A copy of the '244 Patent is attached hereto as Exhibit 4.

35. The '244 patent discloses, among other things, novel dressing assemblies. One such dressing assembly comprises a breathable, fluid restricted dry layer, a super-absorbent layer, and a drape.

36. For example, claim 7 of the '244 Patent recites:

A dressing assembly, comprising:

a breathable, fluid restricted dry layer having a first surface and a second surface;  
a super-absorbent layer having a first surface and second surface, the second surface of the super-absorbent layer disposed adjacent to the first surface of the breathable dry layer; and  
a drape disposed adjacent to the first surface of the super-absorbent layer;  
wherein the super-absorbent layer is adapted to increase rigidity with addition of fluid.

37. KCI Licensing is the sole owner and assignee of the Patents-in-Suit.

38. KCI Medical Resources is an exclusive licensee of the Patents-in-Suit pursuant to a written license agreement, which grants KCI Medical Resources certain exclusive rights in the Patents-in-Suit. KCI Medical Resources also has the right to join in or prosecute an action asserting the Patents-in-Suit.

39. Medical Holdings is an exclusive licensee of the Patents-in-Suit pursuant to a written license agreement, which grants Medical Holdings certain exclusive rights in the Patents-in-Suit. Medical Holdings also has the right to join in or prosecute an action asserting the Patents-in-Suit.

40. KCI Manufacturing is an exclusive licensee of the Patents-in-Suit pursuant to a written license agreement, which grants KCI Manufacturing certain exclusive rights in the Patents-in-Suit. KCI Manufacturing also has the right to join in or prosecute an action asserting the Patents-in-Suit.

41. KCI Import is an exclusive licensee of the Patents-in-Suit pursuant to a written license agreement, which grants KCI Import certain exclusive rights in the Patents-in-Suit. KCI Import also has the right to join in or prosecute an action asserting the Patents-in-Suit.

42. KCI USA is an exclusive licensee of the Patents-in-Suit pursuant to a written license agreement, which grants KCI USA certain exclusive rights in the Patents-in-Suit. KCI USA also has the right to join in or prosecute an action asserting the Patents-in-Suit.

#### **OVERVIEW OF THE S&N ACCUSED PRODUCTS**

43. KCI's claims of patent infringement are directed to S&N's NPWT products, including RENASYS TOUCH Negative Pressure Wound Therapy devices, RENASYS TOUCH Canisters, RENASYS Soft Port Dressings, and PICO devices.

44. S&N filed a request with the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360(k)) (“510(k)”), seeking clearance to market, among other things, RENASYS TOUCH Negative Pressure Wound Therapy devices (the “RENASYS TOUCH NPWT devices”) and RENASYS TOUCH Canisters in the United States. *See* Ex. 5.

45. On August 4, 2016, the FDA granted S&N clearance to market, among other things, RENASYS TOUCH NPWT devices and RENASYS TOUCH Canisters in the United States. *See* Exs. 5, 6.

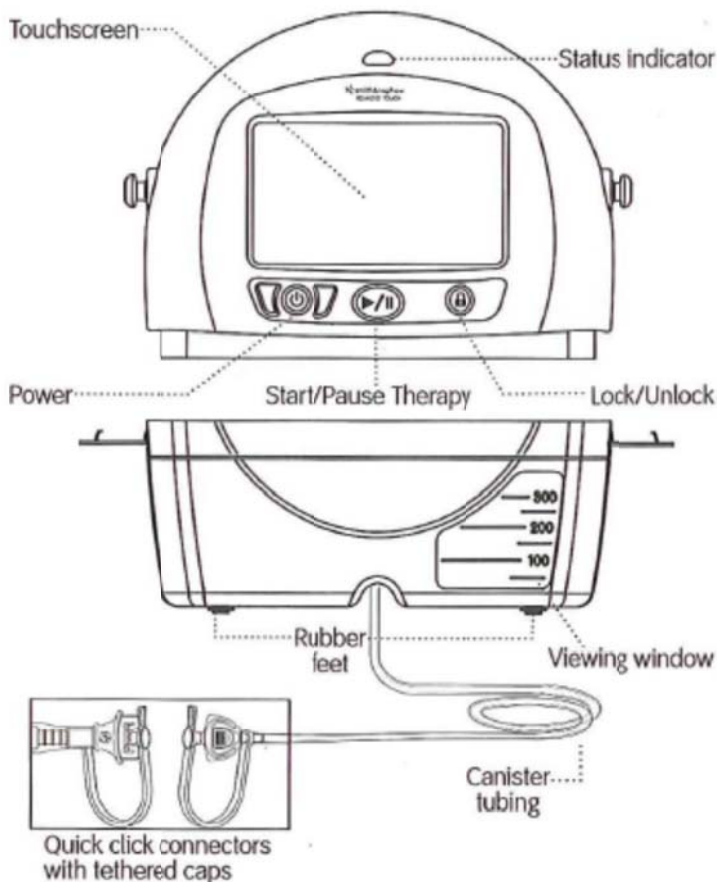
46. S&N also requested and received 510(k) clearance from the FDA to market various wound dressing kits, including the RENASYS Foam NPWT Wound Dressing Kit with Soft Port and RENASYS AB Abdominal Dressing Kit with Soft Port (collectively, “RENASYS Soft Port Dressings”) in the United States. *See* Exs. 7, 8.

47. S&N also requested and received 510(k) clearances from the FDA to market various single-use NPWT products, including the PICO devices, in the United States. *See* Exs. 10, 11.

48. Each of the RENASYS TOUCH NPWT devices made, used, sold, and/or offered for sale in the United States and/or imported into the United States by S&N contains, among other things, an electric pump for applying reduced (*i.e.*, negative) pressure to a wound site, a processing unit, and a speaker. *See, e.g.*, Ex. 12 at 5 (“RENASYS TOUCH is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy), as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.”); *see also id.* at 20-27 (describing audible alarms). Negative pressure is applied through a conduit from the pump to a sealed dressing applied to the wound site, such as the RENASYS Soft Port Dressings. *See, e.g., id.* at 5. The application of negative

pressure to the wound site removes fluids and exudate that are directed from the wound site through a conduit of the RENASYS Soft Port Dressings to the RENASYS TOUCH Canister. *See, e.g., id.* at 5. Below is a diagram of the RENASYS TOUCH NPWT device and Canister.

Device and canister overview



Ex. 13 at 12.

49. The RENASYS TOUCH Canister is a reservoir that holds fluids and exudate removed from a wound site by application of negative pressure. The RENASYS TOUCH Canister is designed to interface with the RENASYS Soft Port Dressings and the RENASYS TOUCH NPWT device. *See, e.g.,* Ex. 13 at 24 (describing the process for attaching and detaching a RENASYS TOUCH Canister to a RENASYS TOUCH NPWT device); *see also id.* at 25 (describing use of “quick click” connectors), Ex. 14 (same). The RENASYS Soft Port

Dressing's conduit couples to the RENASYS TOUCH Canister, providing fluid communication between the wound site and the canister. *See, e.g.*, Ex. 13 at 24; Ex. 14. The RENASYS TOUCH Canister also couples to the RENASYS TOUCH NPWT device, providing fluid communication between the device, canister, conduit, and wound site to enable the application of negative pressure (generated by the pump) on the wound site. *See, e.g.*, Ex. 13 at 24. The RENASYS TOUCH Canister prevents the contamination of the pump by fluids and exudate (removed from the wound and contained in the canister) through hydrophobic filters located at the interface between the canister and the RENASYS TOUCH NPWT device.

50. Each of the RENASYS TOUCH Canisters made, used, sold, and/or offered for sale in the United States and/or imported into the United States by S&N contains, among other things: a main chamber, a filter chamber, a hydrophobic filter, an odor vapor filter, and a first and second aperture extending through one or more walls, which isolate the filter chamber from the main chamber. The exemplary images below show the filter chamber and filters of a RENASYS TOUCH Canister.

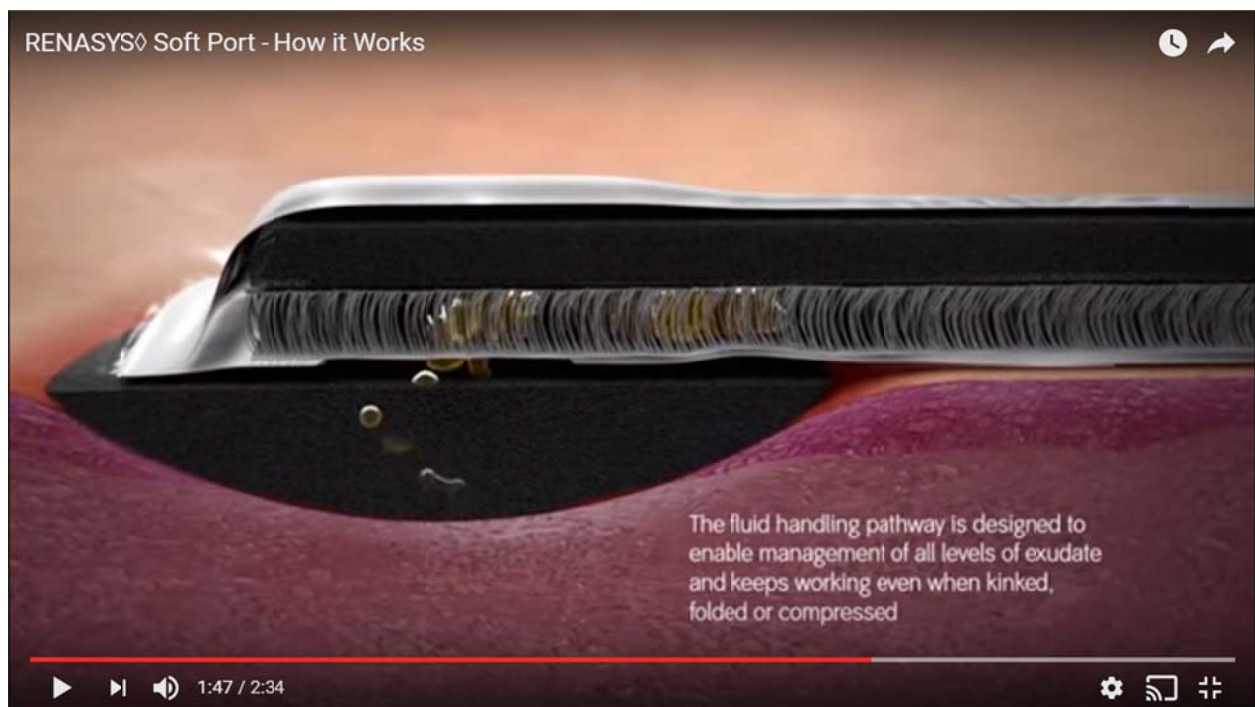




Ex. 15 at 4-5.

51. On information and belief, the RENASYS Soft Port Dressings are designed for use with, compatible for use with, and intended to be used with RENASYS TOUCH NPWT devices and RENASYS TOUCH Canisters. *See, e.g.*, Ex. 13 at 24 (describing the process for attaching and detaching a RENASYS TOUCH Canister to a RENASYS TOUCH NPWT device); *see also id.* at 25 (describing use of “quick click” connectors); Ex. 14 (same); *see also* Ex. 12 at 7 (“Device is only to be used with Smith & Nephew authorized components.”).

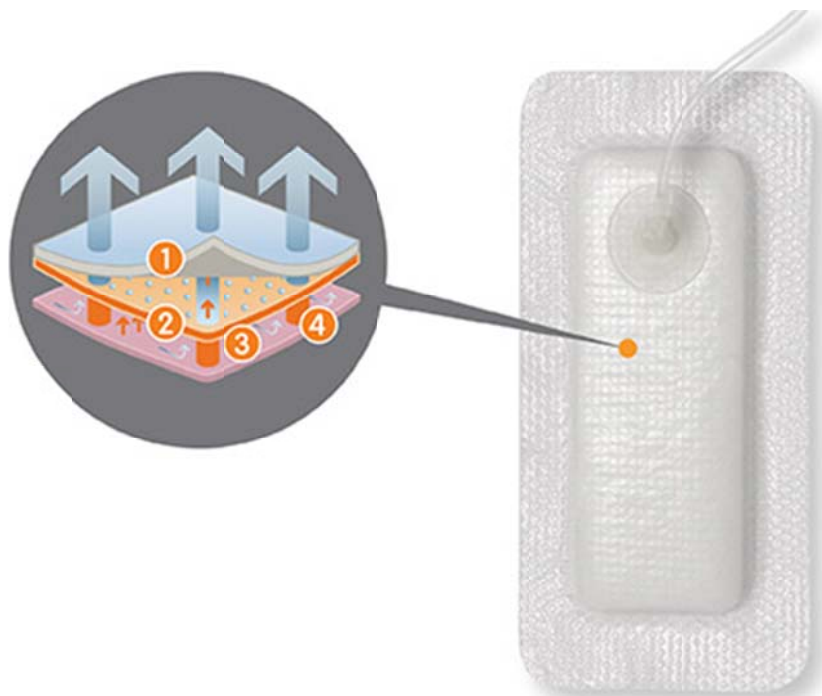
52. Each of the RENASYS Soft Port Dressings made, used, sold, and/or offered for sale in the United States and/or imported into the United States by S&N contains, among other things: (1) a fluid transfer element including a non-attaching patient contact surface, a first zone, a second zone, and a predetermined fluid flow path; (2) a cover placed over the transfer element and including adhesive; (3) a gradient source, and (4) an effluent conduit.



“Renasys Soft Port – How It Works, available at <https://www.youtube.com/watch?v=H-r29Ym7vzc> (last visited October 6, 2016).

53. Each of the PICO devices made, used, sold, and/or offered for sale in the United States and/or imported into the United States by S&N contains, among other things: (1) a

delivery manifold operable to transfer reduced pressure; (2) a first encapsulating envelope at least partially enclosing the delivery manifold and having a patient-facing side; (3) a reduced-pressure-interface site formed proximate a second end of a reduced-pressure bridge; (4) an aperture formed on the patient-facing side of the first encapsulating envelope, wherein reduced pressure is transferable to the tissue site via the aperture; and (5) a moisture-removing device on at least a portion of the first encapsulating envelope. The image below from S&N's website shows the PICO dressing and what purports to be an exemplary representation of a cross-section of the dressing.



Ex. 16 at 3.

### **COUNT I**

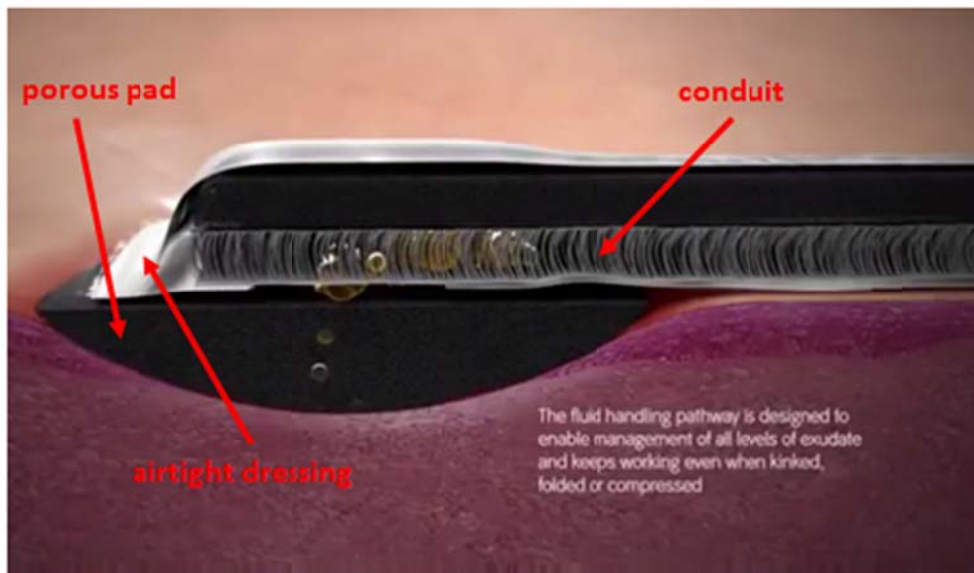
#### **Infringement Of The '915 Patent**

54. Paragraphs 1 through 53 are incorporated by reference as if fully stated herein.

55. S&N, either alone or in conjunction with others, has infringed and continues to infringe, one or more claims of the '915 Patent, including at least exemplary claim 1, under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, certain wound therapy products (collectively, “the '915 Accused Products”), including, for example and without limitation, RENASYS TOUCH NPWT devices, RENASYS TOUCH Canisters, and RENASYS Soft Port Dressings.

56. For example, S&N infringes exemplary claim 1 of the '915 Patent by making, using, offering to sell, and/or selling in the United States and/or importing into the United States the '915 Accused Products. The '915 Accused Products are a system for stimulating the healing of tissue comprising:

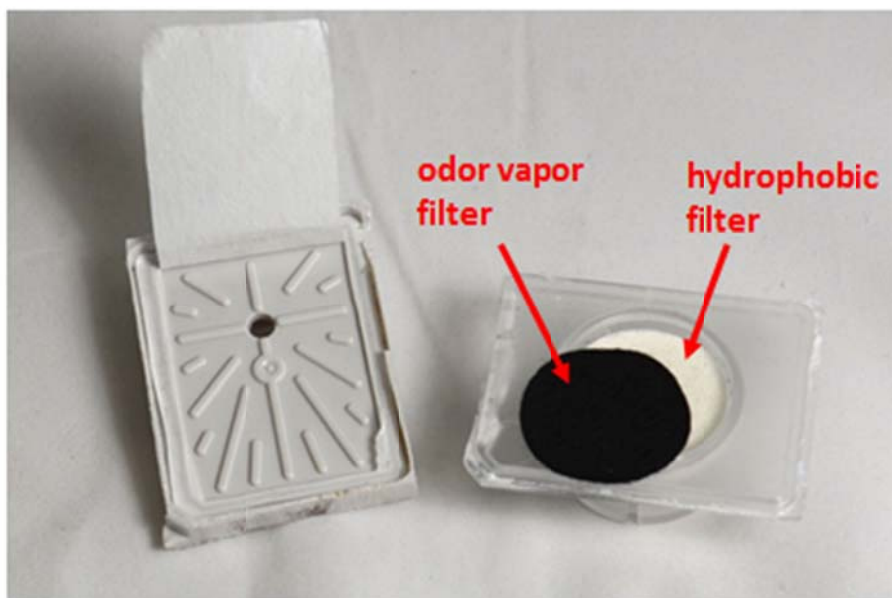
(1) a porous pad such as shown in the image below:



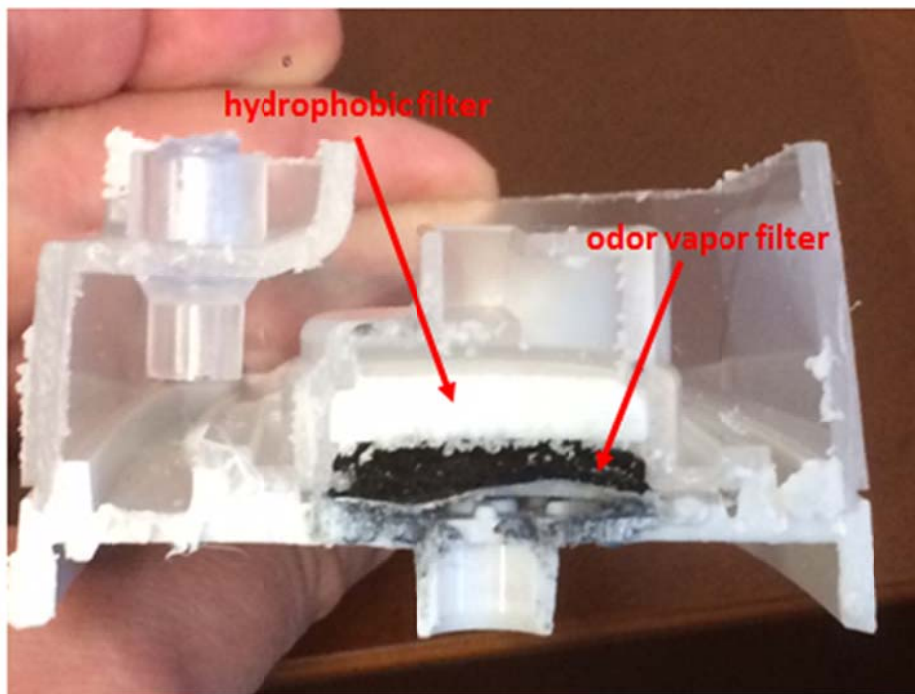
(see, e.g., Ex. 17 at 2 (annotations added); Ex. 7 at 1);

(2) an airtight dressing such as shown in the image above (see, e.g., Ex. 7 at 1 (“transparent wound drape”));

- (3) a distal end of a conduit connected to the dressing (such as shown in the image above);
- (4) a canister removably connected to a proximal end of the conduit (*see, e.g.*, Ex. 13 at 25 (“Connect the dressing to the canister tubing by pushing the quick click connectors together.”));
- (5) an electric pump for applying negative pressure to a wound site (*see, e.g.*, Ex. 13 at 6 (“The RENASYS TOUCH is a therapy system that is applied to your wound and may help promote wound healing by removing fluid, including wound exudates and infectious materials.”));
- (6) a hydrophobic filter positioned between said canister and said electric pump



- (Ex. 15 at 5-6 (annotations added)); and
- (7) an odor vapor filter positioned between said hydrophobic filter and said electric pump



(Ex. 15 at 5-6).

57. On information and belief, S&N has made and continues to make the '915 Accused Products in the United States, including at facilities in Oklahoma City, Oklahoma. *See* Ex. 18 at 3 (“The majority of the NPWT components are bought in from third parties and assembled in the Advanced Surgical Devices Oklahoma City facility.”). On information and belief, and based upon S&N’s 510(k) clearance to market the ‘915 Accused Products in the United States, S&N has used and/or offered for sale the ‘915 Accused Products in the United States, including at least at the 2016 Vizient Clinical Connections Summit on September 29, 2016 in Dallas, Texas.

58. On information and belief, S&N has had knowledge of the ‘915 Patent since at least September 10, 2013, when U.S. Patent No. 8,529,548 (“‘548 Patent”) issued to S&N. The ‘915 Patent is identified on the face of S&N’s ‘548 Patent.

59. On information and belief, S&N has had knowledge of the '915 Patent and its infringement of that patent since the filing and service of this complaint.

60. Despite its knowledge and notice of the '915 Patent and its infringement of that patent, S&N has continued to make, use, offer for sale, and/or sell the '915 Accused Products in the United States, and/or import the '915 Accused Products into the United States. Accordingly, S&N's infringement has been and continues to be willful.

61. On information and belief, S&N is inducing and/or will induce infringement of one or more claims of the '915 Patent under 35 U.S.C. § 271(b). S&N has received 510(k) clearance to market the '915 Accused Products in the United States. On information and belief, S&N actively, knowingly, and intentionally induces, and will continue to actively, knowingly, and intentionally induce, infringement of the '915 Patent by selling or otherwise supplying the '915 Accused Products; with the knowledge and intent that third parties will use the '915 Accused Products supplied by S&N to infringe the '915 Patent; and with the knowledge and intent to encourage and facilitate third party infringement through the dissemination of the '915 Accused Products and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the '915 Accused Products, through its websites and other sources.

62. On information and belief, S&N specifically intends and is aware that the ordinary and customary use of the '915 Accused Products would infringe the '915 Patent. For example, S&N sells and provides the '915 Accused Products, which when used in their ordinary and customary manner intended by S&N, infringe one or more claims of the '915 Patent, including at least exemplary claim 1. S&N further provides product manuals and other technical information, such as the manuals attached as Exhibits 12 and 13 to this Complaint, that cause

S&N customers and other third parties to operate the '915 Accused Products for their ordinary and customary use. On information and belief, S&N customers and other third parties directly infringe and/or will directly infringe the '915 Patent, including at least exemplary claim 1, through the normal and customary use of the '915 Accused Products. By providing instruction and training to customers and other third parties on how to use the '915 Accused Products in an infringing manner, S&N specifically intends to induce infringement of the '915 Patent, including at least exemplary claim 1. S&N accordingly induces and/or will induce S&N customers and other users of the '915 Accused Products to use the '915 Accused Products in their ordinary and customary way to infringe the '915 Patent, knowing, or at least being willfully blind to the fact, that such use constitutes infringement of the '915 Patent.

63. KCI has been and continues to be damaged by S&N's infringement of the '915 Patent.

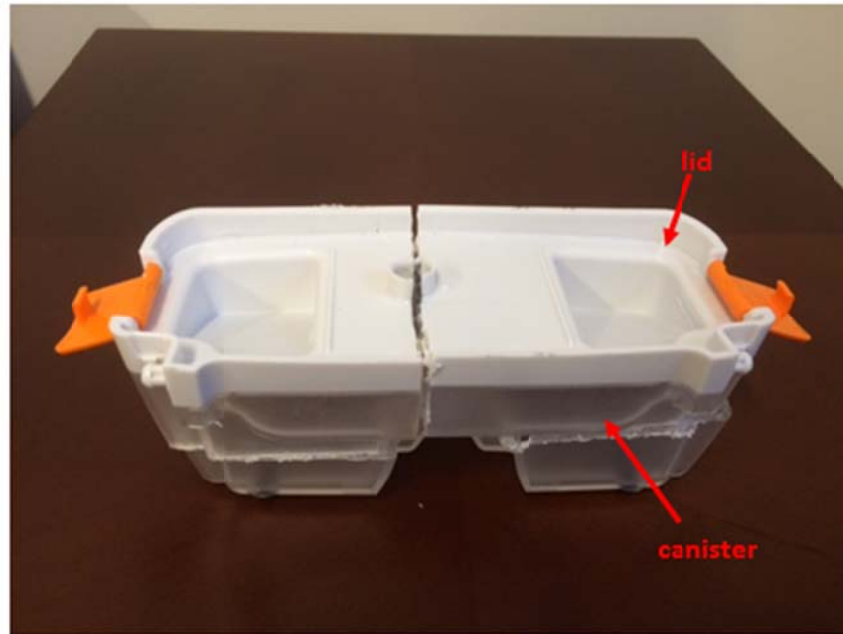
64. S&N's conduct in infringing the '915 Patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

## **COUNT II**

### **Infringement Of The '315 Patent**

65. Paragraphs 1 through 53 are incorporated by reference as if fully stated herein.

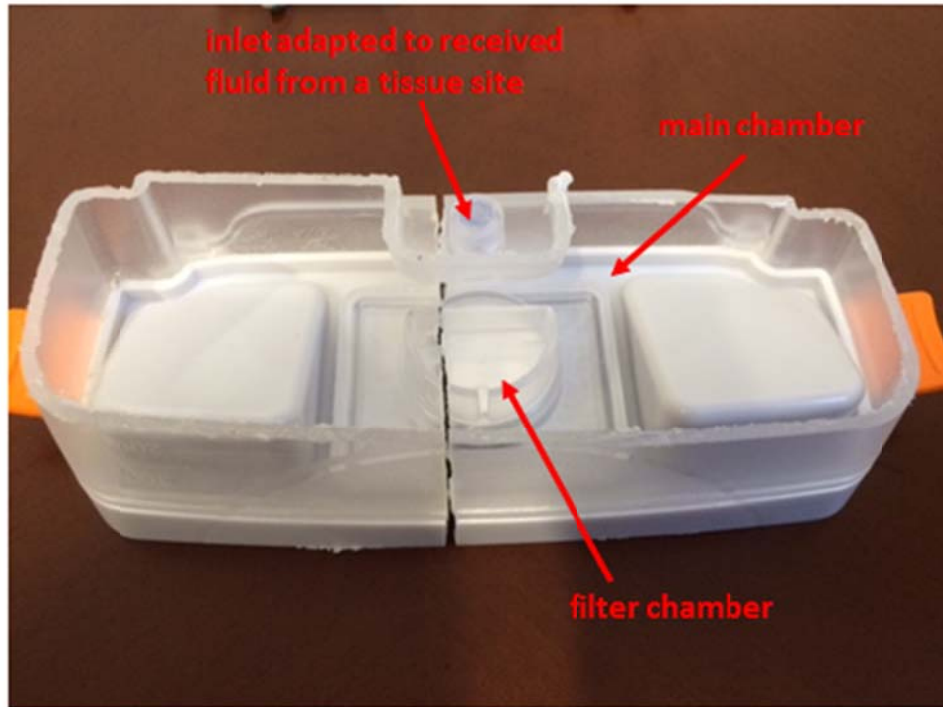
66. S&N, either alone or in conjunction with others, has infringed and continues to infringe, one or more claims of the '315 Patent, including at least exemplary claim 22, under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, certain wound therapy products (collectively, "the '315 Accused Products"), including, for example and without limitation, RENASYS TOUCH Canisters, including both 300mL and 800 mL capacity canisters.



(Ex. 15 at 1 (exemplary photograph of a RENASYS TOUCH Canister that has been sectioned for examination) (annotations added).)

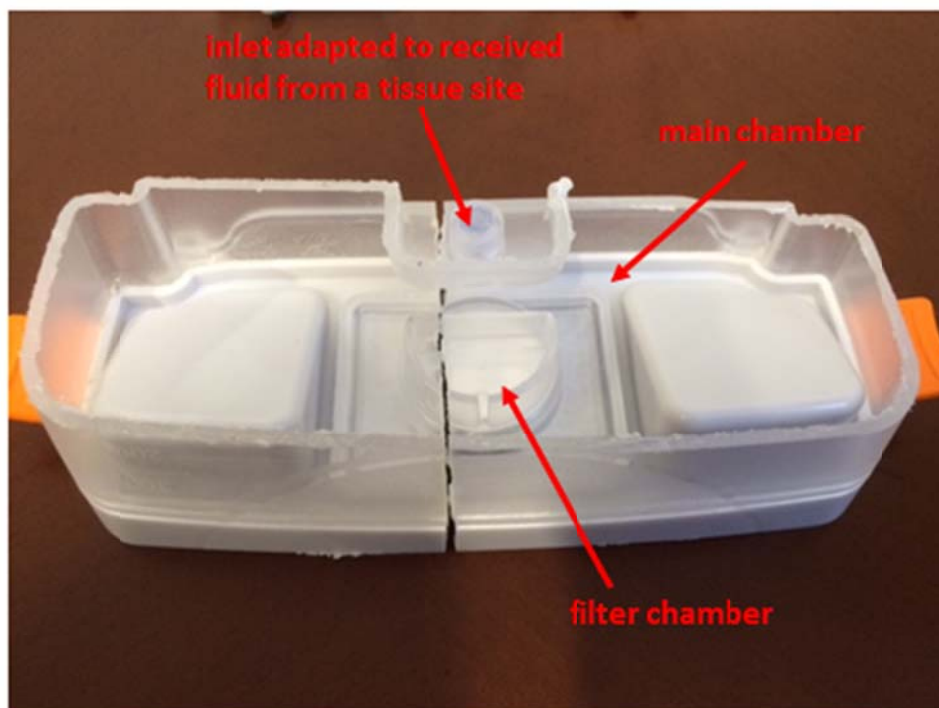
67. For example, S&N infringes exemplary claim 22 of the '315 Patent by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, the '315 Accused Products. The '315 Accused Products are canisters for use in a reduced (or negative) pressure tissue treatment (*e.g.*, RENASYS TOUCH NPWT Device) comprising:

a main chamber having an inlet adapted to receive fluid from a tissue site (*e.g.*, a RENASYS Soft Port Dressing can connect to the inlet)



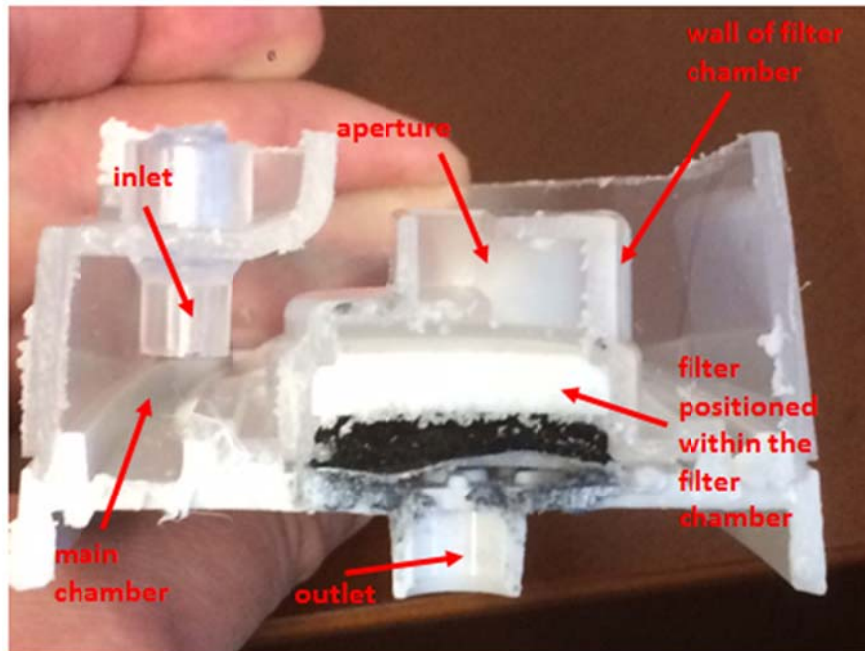
(*see id.* at 2 (annotations added));

a filter chamber isolated from the main chamber by one or more walls, the filter chamber having an outlet adapted to be fluidly coupled to a reduced pressure source (*e.g.*, the pump of a RENASYS TOUCH NPWT device)



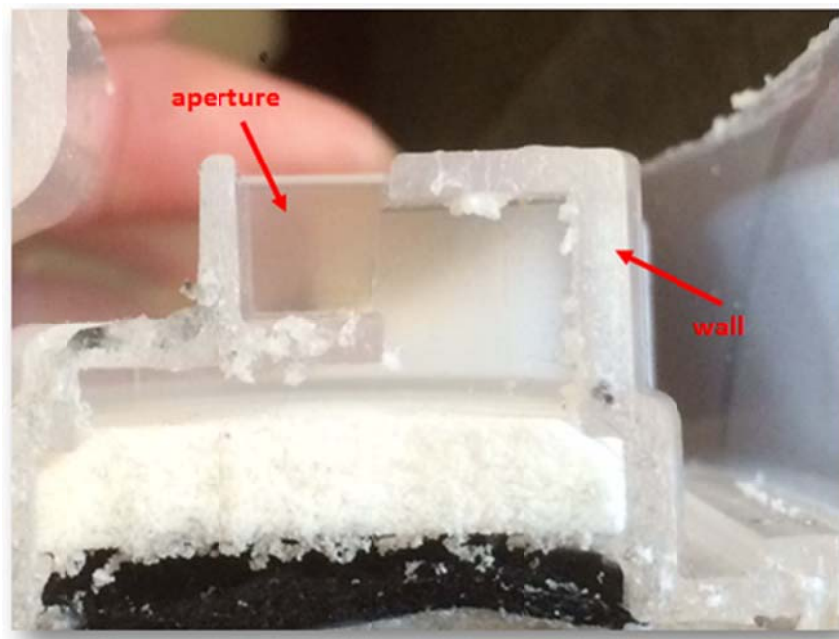
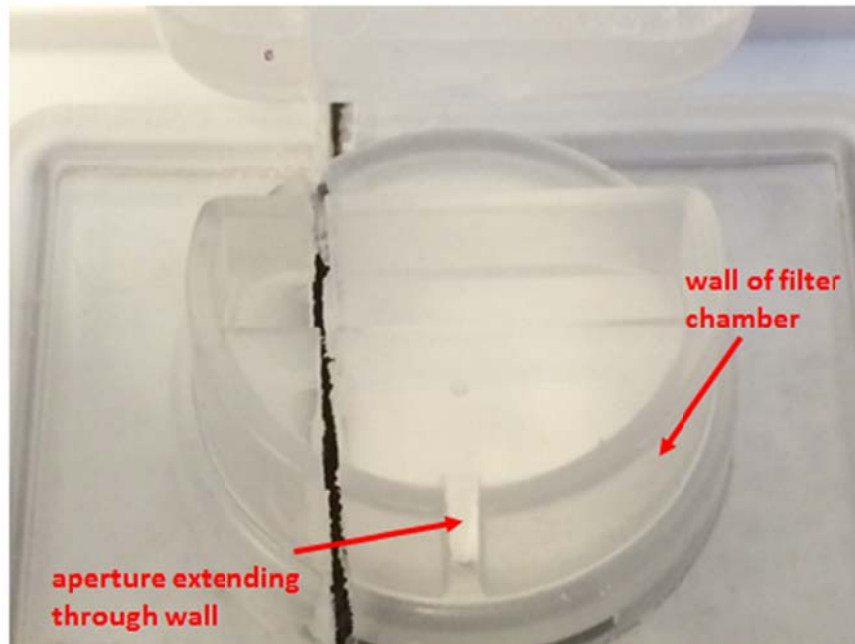
(*id.* at 1-2 (annotations added));

a filter positioned within the filter chamber



(*id.* at 6 (annotations added)); and

a first aperture and a second aperture extending through the one or more walls, the first aperture and the second aperture being sized to prevent the fluid, upon entrance into the main chamber, from incidentally contacting the filter as shown above and in the images below:



(*id.* at 3, 7 (annotations added)).

68. On information and belief, S&N has made and continues to make the '315 Accused Products in the United States, including at facilities in Oklahoma City, Oklahoma. *See* Ex. 18. On information and belief, and based upon S&N's 510(k) clearance to market the '315 Accused Products in the United States, S&N has used and/or offered for sale the '315 Accused

Products in the United States, including at least at the 2016 Vizient Clinical Connections Summit on September 29, 2016 in Dallas, Texas.

69. On information and belief, S&N has had knowledge of the '315 Patent and its infringement of that patent since at least the filing and service of this complaint.

70. Despite its knowledge and notice of the '315 Patent and its infringement of that patent, S&N has continued to make, use, offer for sale and/or sell the '315 Accused Products in the United States, and/or import into the United States the '315 Accused Products. Accordingly, S&N's infringement has been and continues to be willful.

71. KCI has been and continues to be damaged by S&N's infringement of the '315 Patent.

72. S&N's conduct in infringing the '315 Patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

### **COUNT III**

#### **Infringement Of The '683 Patent**

73. Paragraphs 1 through 53 are incorporated by reference as if fully stated herein.

74. S&N, either alone or in conjunction with others, has infringed and continues to infringe, one or more claims of the '683 Patent, including at least exemplary claim 1, under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, certain wound therapy products (collectively, "the '683 Accused Products"), including, for example and without limitation, RENASYS TOUCH NPWT devices, RENASYS TOUCH Canisters, and RENASYS Soft Port Dressings.

75. For example, S&N infringes exemplary claim 1 of the '683 Patent by making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, the '683 Accused Products, which comprise a fluid-differentiating wound therapy and tissue management system, including the following:

- a) a fluid transfer element, such as shown below



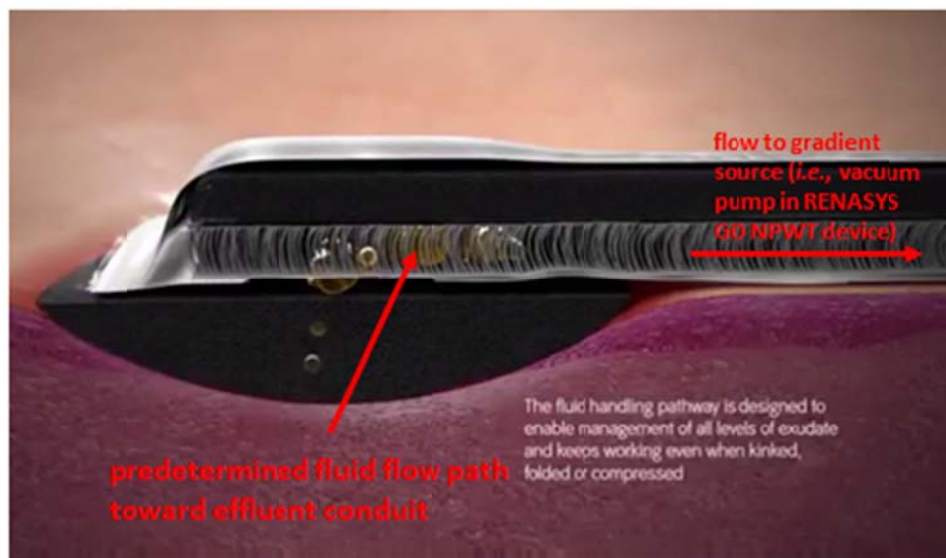
(Ex. 17 at 1 (annotations added), that includes:

- 1) a non-attaching patient contact surface



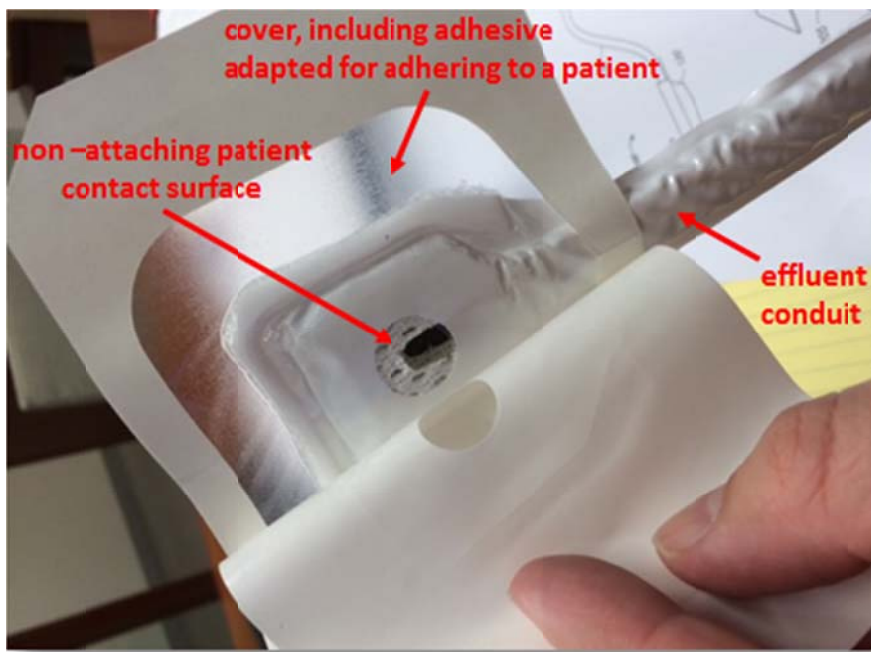
(see, e.g., Ex. 19 at 2 (annotations added));

2) a first zone with a first fluid transfer coefficient



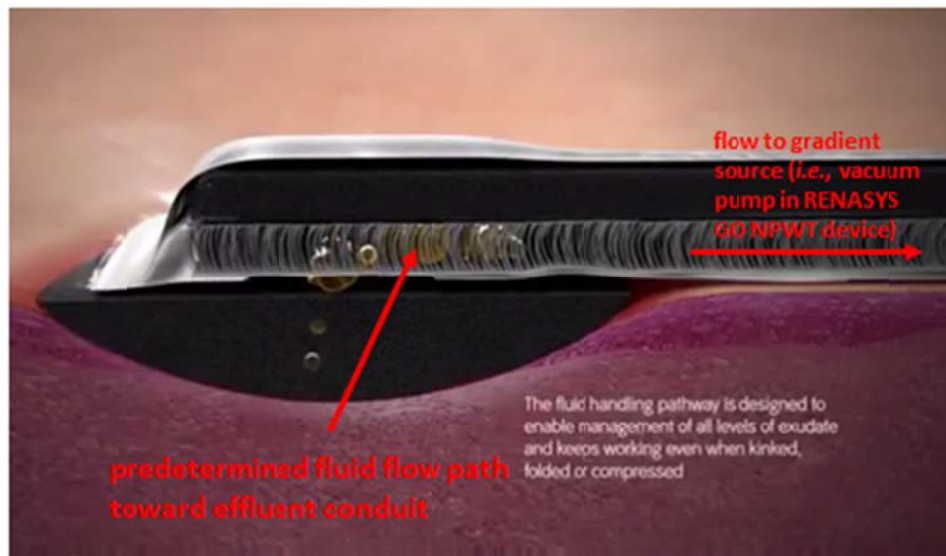
(see, e.g., Ex. 17 at 2 (annotations added) (showing cross-section of two-layer transfer element and wound filling material, all of which, on information and belief, have different fluid transfer coefficients));

- 3) a second zone with a second fluid transfer coefficient different from said first fluid transfer coefficient, said second zone being located adjacent to said first zone (*see, e.g.*, Ex. 17 at 2 (shown above, annotations added) (showing cross-section of two-layer transfer element and wound filling material, all of which on information and belief have different fluid transfer coefficients));
  - 4) a predetermined fluid flow path through said element guided by said fluid transfer coefficient differential between said first and second zones (*see, e.g.*, Ex. 17 at 2 (shown above, annotations added) (showing that the RENASYS Soft Port Dressings has a predetermined flow path, which, on information and belief, is the result of the fluid transfer coefficient differential between the two zones));
- b) a cover placed over said transfer element in contact therewith and including adhesive adapted for adhering said cover to a patient around the perimeter of said fluid transfer element



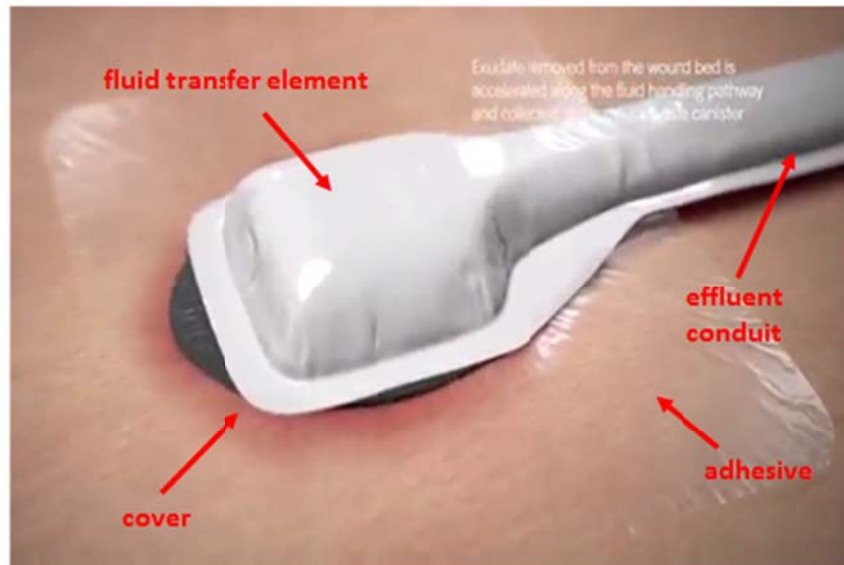
(see, e.g., Ex. 19 at 2 (annotations added));

- c) a gradient source for creating a gradient across said transfer element whereby fluids are moved through said transfer element



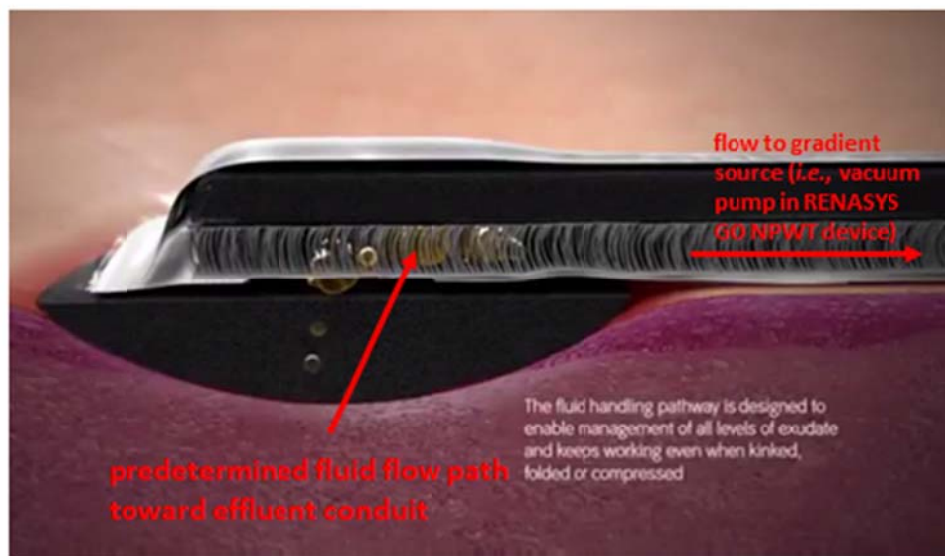
(see, e.g., Ex. 17 at 2-3 (annotations added) (showing that the RENASYS TOUCH NPWT device creates a negative pressure gradient such that fluids are moved through the transfer element));

- d) an effluent conduit connected to said transfer element and adapted for discharging effluent from the system



(see, e.g., Ex. 17 at 1 (annotations added) (showing that the effluent conduit permits the discharge of effluent into the RENASYS TOUCH canister)); and

- e) said predetermined fluid flow path being towards said effluent conduit



(see, e.g., Ex. 17 at 2 (annotations added)).

76. On information and belief, S&N has made and continues to make the '683 Accused Products in the United States, including at facilities in Oklahoma City, Oklahoma. *See* Ex. 18. On information and belief, and based upon S&N's 510(k) clearance to market the '683 Accused Products in the United States, S&N has used and/or offered for sale the '683 Accused Products in the United States, including at least at the 2016 Vizient Clinical Connections Summit on September 29, 2016 in Dallas, Texas.

77. On information and belief, S&N has had knowledge of the '683 Patent since at least April 28, 2009, when U.S. Patent No. 7,524,315 ("315 Patent") issued to S&N. The '683 Patent is identified on the face of S&N's '315 Patent.

78. On information and belief, S&N has had knowledge of the '683 Patent and its infringement of that patent since the filing and service of this complaint.

79. Despite its knowledge and notice of the '683 Patent and its infringement of that patent, S&N has continued to make, use, offer for sale and/or sell the '683 Accused Products in the United States, and/or import into the United States the '683 Accused Products. Accordingly, S&N's infringement has been and continues to be willful.

80. S&N induces and/or will induce infringement of one or more claims of the '683 Patent under 35 U.S.C. § 271(b). S&N has received 510(k) clearance to market the '683 Accused Products in the United States. S&N actively, knowingly, and intentionally induces, and/or will actively, knowingly, and intentionally induce, infringement of the '683 Patent by selling or otherwise supplying the '683 Accused Products; with the knowledge and intent that third parties will use the '683 Accused Products supplied by S&N to infringe the '683 Patent; and with the knowledge and intent to encourage and facilitate third party infringement through the dissemination of the '683 Accused Products and/or the creation and dissemination of

promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the '683 Accused Products, through its websites and other sources.

81. S&N specifically intends and is aware that the ordinary and customary use of the '683 Accused Products would infringe the '683 Patent. For example, S&N sells and provides the '683 Accused Products, which when used in their ordinary and customary manner intended by S&N, infringe one or more claims of the '683 Patent, including at least exemplary claim 1. S&N further provides product manuals and other technical information, such as the manuals attached as Exhibits 12 and 13 to this Complaint, that cause S&N customers and other third parties to operate the '683 Accused Products for their ordinary and customary use. On information and belief, S&N customers and other third parties directly infringe and/or will directly infringe the '683 Patent, including at least exemplary claim 1, through the normal and customary use of the '683 Accused Products. By providing instruction and training to customers and other third parties on how to use the '683 Accused Products in an infringing manner, S&N specifically intends to induce infringement of the '683 Patent, including at least exemplary claim 1. S&N accordingly has induced and continues to induce S&N customers and other users of the '683 Accused Products to use the '683 Accused Products in their ordinary and customary way to infringe the '683 Patent, knowing, or at least being willfully blind to the fact, that such use constitutes infringement of the '683 Patent.

82. KCI has been and continues to be damaged by S&N's infringement of the '683 Patent.

83. S&N's conduct in infringing the '683 Patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

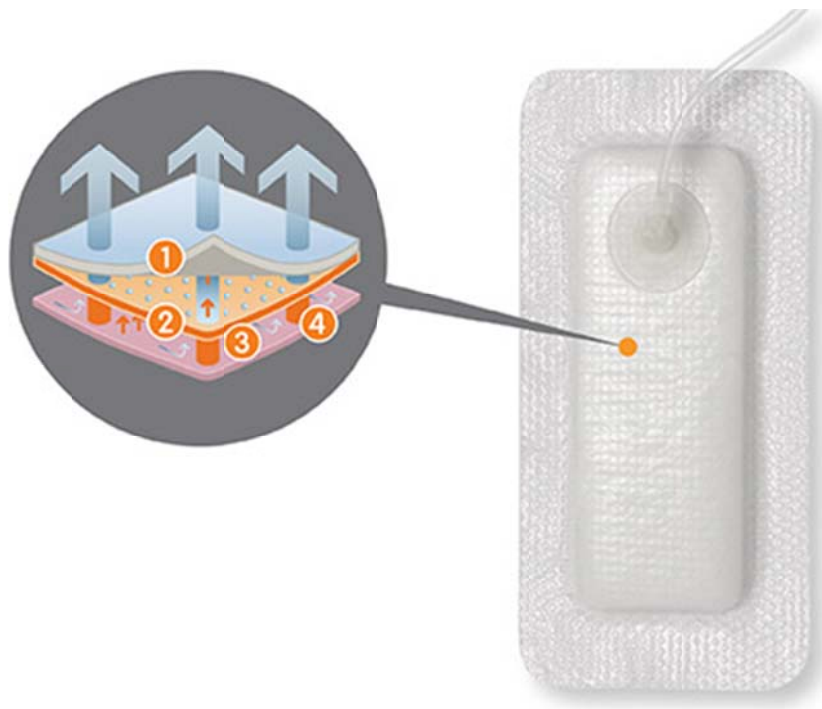
## **COUNT IV**

### **Infringement Of The '244 Patent**

84. Paragraphs 1 through 53 are incorporated by reference as if fully stated herein.

85. S&N, either alone or in conjunction with others, has infringed and continues to infringe, one or more claims of the '244 Patent, including at least exemplary claim 7, under 35 U.S.C. § 271, either literally and/or under the doctrine of equivalents, by using, offering to sell, and/or selling in the United States and/or importing into the United States certain wound therapy products (collectively, "the '244 Accused Products"), including, for example and without limitation, the PICO devices.

86. For example, S&N infringes exemplary claim 7 of the '244 Patent by using, offering to sell, and/or selling in the United States and/or importing into the United States the '244 Accused Products, which include a dressing assembly as shown below:



See Ex. 16 at 3.

87. The dressing assembly includes the following:

a breathable, fluid restricted dry layer, such as the “airlock layer,” having a first surface and a second surface (*see, e.g.*, Ex. 16 at 2-3 (an “[a]irlock layer maintains open airflow and allows even distribution of negative pressure across the dressing”) (shown as (3) in the figure above));

a super-absorbent layer, such as the “absorbent layer,” having a first surface and a second surface, the second surface of the super-absorbent layer disposed adjacent to the first surface of the breathable dry layer (*see, e.g., id.* (a “[p]roprietary absorbent layer [that] moves exudate away from the wound and initiates evaporation”) (shown as (2) in the figure above));

a drape, such as the “top film layer,” disposed adjacent to the first surface of the super-absorbent layer (*see, e.g., id.* (a “[t]op film layer with a high moisture vapor transmission rate (MVTR) [that] allows one-way transpiration of exudate vapor”) (shown as (1) in the figure above));

wherein the super-absorbent layer is adapted to increase rigidity with addition of fluid (*see, e.g., id.* (the proprietary absorbent layer is constructed of “super absorbent crystals,” which, on information and belief, increases rigidity with addition of fluid); *see also, e.g.*, “PICO Application and Mode of Action,” *available at* <http://www.possiblewithpico.com/introduction> (last visited October 6, 2016)).

88. On information and belief, S&N has made and continues to make the '244 Accused Products in the United Kingdom. *See* Ex. 18. On information and belief, and based upon S&N's 510(k) clearance to market the '244 Accused Products in the United States, S&N

has used, sold, and/or offered for sale in the United States, and/or imported into the United States, the '244 Accused Products in the United States.

89. On information and belief, S&N has had knowledge of the '244 Patent since at least December 29, 2015, when U.S. Patent No. 9,220,822 ("822 Patent") issued to S&N. The '244 Patent is identified on the face of S&N's '822 Patent.

90. On information and belief, S&N has had knowledge of the '244 Patent and its infringement of that patent since the filing and service of this complaint.

91. Despite its knowledge and notice of the '244 Patent and its infringement of that patent, S&N has continued to use, offer for sale and/or sell in the United States, and/or import into the United States, the '244 Accused Products. Accordingly, S&N's infringement has been and continues to be willful.

92. S&N has induced infringement, and continues to induce infringement, of one or more claims of the '244 Patent under 35 U.S.C. § 271(b). S&N has received 510(k) clearance to market the '244 Accused Products in the United States. S&N actively, knowingly, and intentionally induced, and continues to actively, knowingly, and intentionally induce, infringement of the '244 Patent by selling or otherwise supplying the '244 Accused Products; with the knowledge and intent that third parties will use the '244 Accused Products supplied by S&N to infringe the '244 Patent; and with the knowledge and intent to encourage and facilitate third party infringement through the dissemination of the '244 Accused Products and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the '244 Accused Products, through its websites and other sources.

93. S&N specifically intended and was aware (and continues to specifically intend and be aware) that the ordinary and customary use of the '244 Accused Products would infringe the '244 Patent. For example, S&N sells and provides the '244 Accused Products, which when used in their ordinary and customary manner intended by S&N, infringe one or more claims of the '244 Patent, including at least exemplary claim 7. S&N further provides product manuals and other technical information, such as the manuals, videos, and instructions such as those attached as Exhibit 16 (*available at* <http://www.smith-nephew.com/key-products/advanced-wound-management/pico/>) to this Complaint, that cause S&N customers and other third parties to operate the '244 Accused Products for their ordinary and customary use. On information and belief, S&N customers and other third parties have directly infringed the '244 Patent, including at least exemplary claim 15, through the normal and customary use of the '244 Accused Products. By providing instruction and training to customers and other third parties on how to use the '244 Accused Products in an infringing manner, S&N specifically intended (and continues to intend) to induce infringement of the '244 Patent, including at least exemplary claim 7. S&N accordingly has induced and continues to induce S&N customers and other users of the '244 Accused Products to use the '244 Accused Products in their ordinary and customary way to infringe the '244 Patent, knowing, or at least being willfully blind to the fact, that such use constitutes infringement of the '244 Patent.

94. KCI has been and continues to be damaged by S&N's infringement of the '244 Patent.

95. S&N's conduct in infringing the '244 Patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, KCI respectfully requests that this Court enter judgment against S&N as follows:

- A. That S&N has infringed the Patents-In-Suit;
- B. That KCI be awarded damages adequate to compensate it for S&N's past infringement and any continuing or future infringement up until the date such judgment is entered, including pre- and post-judgment interest, costs, and disbursements as justified under 35 U.S.C. § 284;
- C. That any award of damages be enhanced under 35 U.S.C. § 284 as result of S&N's willful infringement;
- D. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that KCI be awarded reasonable attorneys' fees;
- E. A preliminary and permanent injunction preventing S&N, and those in active concert or participation with S&N, from directly and/or indirectly infringing the Patent-In-Suit;
- F. A judgment requiring that, in the event a permanent injunction preventing future acts of infringement is not granted, KCI be awarded a compulsory ongoing licensing fee; and
- G. That KCI be awarded such other and further relief at law or equity as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff KCI hereby demands a trial by jury on all claims and issues so triable.

Dated: October 7, 2016

Respectfully submitted,

FARNAN LLP

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