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IN THE UNITED STATES DISTRICT COURT, DISTRICT OF UTAH, CENTRAL DIVISION

CATHETER CONNECTIONS, INC , a Delaware corporation; and UNIVERSITY OF UTAH RESEARCH FOUNDATION , a Utah corporation	FIRST AMENDED COMPLAINT JURY TRIAL DEMANDED
Plaintiffs, v.	Case No.: 2:12-cv-00748-TC
IVERA MEDICAL CORPORATION , a California corporation	The Honorable Tena Campbell
Defendant.	

BACKGROUND

Plaintiffs Catheter Connections, Inc. ("Catheter Connections") and the University of Utah Research Foundation ("UURF"), by and through their respective counsels, file this First Amended Complaint alleging as follows:

THE PARTIES

1. Catheter Connections is a Delaware corporation with its principal place of business in Salt Lake City, Utah.

2. UURF is a Utah non-profit corporation with its principal place of business at 615 Arapeen Drive #310, Salt Lake City, Utah 84108.

3. Ivera Medical Corporation ("Defendant") is a California corporation, which has alleged that its principal place of business is 3525 Del Mar Heights Road, Suite 430, San Diego, California 92130.

4. Defendant has offered for sale and sold its "Curos® Port Protector" ("Curos"), a device different than the device accused of infringement herein, in Utah and throughout the United States. Defendant is currently selling Curos in Utah and conducting a product trial in Murray, Utah.

5. Defendant, additionally, has promised to provide devices accused of infringing United States Patent 8,231,587 herein to Intermountain Health Care (IHC) personnel in Murray and Salt Lake City, Utah.

6. On information and belief, Defendant has provided, is currently providing, and will continue to provide such devices accused of infringing United States Patent 8,231,587 to IHC personnel and to other medical personnel in Utah.

JURISDICTION AND VENUE

7. This is a civil action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 1, et seq.

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8. This Court has jurisdiction over the patent infringement claim by virtue of 28 U.S.C. §1338(a) and 28 U.S.C. § 1331.

9. This Court has personal jurisdiction over Defendant because Defendant is engaged in regular and substantial business in the State of Utah and the District of Utah.

10. Venue is proper in this Court under 28 U.S.C. §1391(b), because Defendant has committed acts of patent infringement in, and has otherwise regularly conducted or conducts business, within the State of Utah and the District of Utah. Defendant is deemed to reside in this judicial district within the meaning of 28 U.S.C. §1391(a).

GENERAL ALLEGATIONS

11. Plaintiffs conceived, developed, and patented the DualCap SystemTM, which includes DualCap®—the only United States Food and Drug Administration (FDA) 510(k)-cleared medical device that disinfects and protects the male luer connector at the end of IV tubing ("male luer").

12. On July 31, 2012, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent 8,231,587 ("the '587 Patent") for an invention titled "Disinfecting Caps For Medical Male Luer Connectors." (Exhibit 1).

 UURF is the owner by assignment of the '587 Patent and as such is a proper party to this action.

14. Catheter Connections is an exclusive licensee of the '587 Patent from UURF and, by virtue of the terms of its license from UURF, has the right to sue and to recover for past and future infringement thereof.

15. Ivera is a two-product company. One of the two products that Ivera makes, uses and has made and used is a male luer disinfecting cap (the "Ivera Cap"), the alleged infringing



Figure 1

device, shown in Figure 1, to protect and disinfect the male luer and to compete with the DualCap.

- 16. On information and belief, Ivera is currently offering to sell the Ivera Cap.
- 17. The Ivera Cap represents Ivera's attempt to copy the DualCap.

18. Defendant has shown and/or demonstrated the use of the Ivera Cap at least at the following industry tradeshows:

- a. FANNP Conference (Florida Association of Neonatal Nurse Practitioners), October 11-12, 2011.
- b. Great Lakes Chapter Infusion Nurses Society 2011 Fall Conference, Livonia, Michigan, October 25, 2011.
- c. Gravens Neonatology Conference, Clearwater, Florida, January 24-26, 2012.
- d. Southeast Florida Chapter of NANN (SEFANN) Conference, Miami, Florida, March 8-9, 2012.
- e. Northern California Association for Vascular Access (NORVAN) Conference, Thunder Valley Casino, Lincoln, CA, April 20, 2012.
- f. National Teaching Institute & Critical Care Exposition of the American Association of Critical Care Nurses (AACN) in Orlando, Florida, May 22-24, 2012.

At each of the FAANP, *Great Lakes Chapter - Infusion Nurses Society*, SEFANN, NORVAN and AACN industry tradeshows referenced above, Defendant's representatives told potential customers and other medical device developers that FDA 510(k) clearance for, and availability for purchase of, the Ivera Cap would be coming "soon," in "one month," and/or "this summer."

19. At the AACN tradeshow, on or about May 22, 2012, Charity Williams ("Williams"), CBO and In-house Counsel for Catheter Connections, visited Ivera's booth and saw the Ivera Cap being displayed and used. Williams observed that alcohol was present in the Ivera Caps at Ivera's booth and was being used as an antiseptic agent for the Ivera Cap to disinfect the male luer, which is the intended purpose of the Ivera Cap.

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20. An Ivera sales representative at the booth at the AACN tradeshow recognized Williams and asked Williams if she would like to photograph the Ivera Cap. The Ivera sales representative allowed Williams to photograph the Ivera Cap, and even held an Ivera Cap mated to a male luer connector in position for Williams to photograph.

21. Figure 2, below, is a photograph taken by Williams of the Ivera Cap as displayed in use at Ivera's booth at the AACN tradeshow on or about May 22, 2012. The Ivera Cap is the green cap on the right of Figure 2. As shown in Figure 2, the Ivera Cap was attached to a male luer-lock connector, wherein a skirt of the male luer-lock connector was engaged to an external surface of the Ivera Cap.

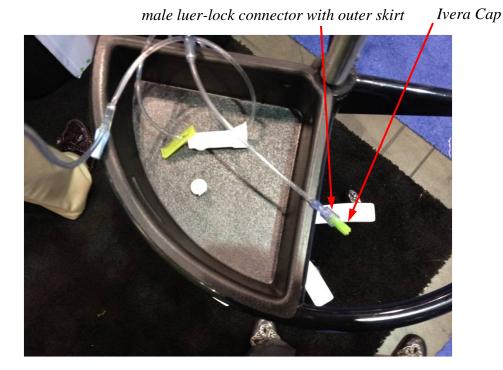


Figure 2

22. Figure 3, below, is another photograph taken by Williams of the Ivera Cap as displayed in use at Ivera's booth at the AACN tradeshow. The right hand is that of the Ivera representative that was using the Ivera Cap.



Figure 3

23. Figure 4, below, is yet another photograph taken by Williams of the Ivera Cap attached to a male luer connector as displayed at Ivera's booth at the AACN tradeshow. The Ivera Cap, made by Ivera, is being "used" in the photo below.



Figure 4

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24. Figure 5, below, is an additional photograph taken by Williams of the Ivera Cap as displayed in use at Ivera's booth at the AACN tradeshow. In the photograph of Figure 5, the Ivera Cap is being held by an Ivera representative.



Figure 5

25. Ivera has represented to Catheter Connections that the Ivera Cap would be available for purchase in the summer of 2012.

26. In addition to displaying and demonstrating the Ivera Cap in at least the foregoing tradeshows, Defendant, via its representatives, has used the Ivera Cap to demonstrate it for hospital personnel in the United States, and has provided the Ivera Cap to hospital personnel ("Third Parties") in the United States, including but not limited to IHC in Murray, Utah and South Miami Hospital in South Miami, Florida.

27. On or about the last week of May 2012, Curt Gallatin ("Gallatin"), a representative of the BiMeco Group, a distributor for Catheter Connections in the southeastern United States, met with hospital personnel and registered nurses ("the Nurses") of South Miami

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Hospital in South Miami, Florida. When Gallatin arrived at this meeting, Al Kauper ("Kauper"), an Ivera employee, was already meeting with the Nurses. With Gallatin present, Kauper showed the Ivera Cap to the Nurses and gave them five (5) Ivera Caps on a strip. The Nurses gave Gallatin the Ivera Caps they received from Kauper, which Gallatin sent via Federal Express to Catheter Connections.

28. The Ivera Cap provided by Kauper to the Nurses is illustrated in Figures 6 through 10 below.



Figure 6



Figure 7



Figure 8



Figure 9





29. The Ivera Cap infringes at least claim 1 of the '587 Patent. Specifically, the Ivera Cap used at the AACN tradeshow embodies, as recited in claim 1 of the '587 Patent, a maledisinfecting cap for applying an antiseptic agent to a medical male luer-lock connector, of the type including a post having a lumen through which fluid flows and an internally helically threaded skirt surrounding the post, the cap comprising:

a. a receiving portion defining a chamber into which the post of the male luer-lock connector can be received, the chamber having only a single opening, the receiving portion defining an external surface having means for engaging helical threads of the internally threaded skirt wherein the receiving portion is configured to fit within the skirt of the male luer-lock connector when the post is received into the receiving portion;

b. a compressible absorbent pad containing the antiseptic agent disposed in the chamber;

c. a sealing member movably disposed within the chamber and configured to sealingly engage with the lumen when the post is received into the receiving portion to prevent flow of the antiseptic agent into the lumen while permitting the flow of the antiseptic agent past the sealing member to the post of the male luer-lock connector, wherein a portion of the sealing member proximal to the opening of the chamber defines

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a dome or cone, and the sealing member is located between the pad and the lumen when the post is received into the receiving portion; and

d. a gripping portion.

30. Each and every element of at least claim 1 of the '587 Patent reads on, and is embodied by, the Ivera Cap.

31. On information and belief, Defendant will continue to make and use the Ivera Cap that infringes the '587 Patent.

32. On or about June 5, 2012, Catheter Connections sued Ivera in the United States District Court for the District of Utah for patent infringement of United States Patent 8,172,825 ("the '825 Patent"), in which case Catheter Connections alleged that Ivera infringed the method claimed in the '825 Patent by using the Ivera Cap. *See Catheter Connections, Inc. v. Ivera Medical Corp.*, No. 2:12-cv-00531-DN (D. Utah filed June 5, 2012) (Complaint). (Exhibit 2).

33. At least as early as about June 7, 2012, Ivera, through its counsel, Jonathan Hangartner ("Hangartner"), has been aware that Catheter Connections was suing Ivera for infringement of the '825 Patent based on Ivera's use of the Ivera Cap. *See Catheter Connections*, No. 2:12-cv-00531-DN (Waiver of Service of Summons). (Exhibit 3).

34. Prior to June 19, 2012, Catheter Connections had been seeking a contract for the purchase of its' FDA-cleared male luer cleansing caps from Florida Hospital for Children, located in Orlando, FL.

35. On or prior to June 19, 2012, and after Catheter Connections had already sued Ivera for patent infringement of the '825 Patent for its manufacture and use of the Ivera Cap, on information and belief, the President of Ivera told Florida Hospital for Children that Ivera "will" have its Ivera Cap 510(k)-cleared "this summer."

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36. On information and belief, on or prior to June 19, 2012, an Ivera representative told Florida Hospital for Children that "for sure" the Ivera Cap would be 510(k)-cleared the summer of 2012 and that, if the hospital wanted, the President of Ivera would fly in to discuss.

37. On information and belief, on or prior to June 26, 2012, Ivera had advised Florida Hospital for Children that Ivera would receive FDA approval for the Ivera Cap within thirty (30) days and that the Ivera Cap would be available "before the end of the Summer."

38. On information and belief, on or prior to June 26, 2012, Ivera had acknowledged to Florida Hospital for Children that Catheter Connections had already sued Ivera for patent infringement of the '825 Patent, but stated that Ivera believed the lawsuit was baseless, and that, according to Ivera, Florida Hospital for Children should purchase the Ivera Cap instead of Catheter Connections' male luer-cleansing cap.

39. On information and belief, Ivera has continued to use the Ivera Cap after issuance of the '587 Patent.

40. On information and belief, on or about October 2, 2012, Ivera displayed the Ivera Cap to customers at the Amerinet tradeshow in St. Louis, Missouri.

41. On information and belief, Ivera will offer the Ivera Cap for sale at a price less than Catheter Connections' DualCap.

<u>COUNT ONE</u> <u>Infringement of U.S. Patent 8,231,587</u>

42. The preceding paragraphs of this Complaint are incorporated and reasserted herein.

43. Defendant is making and using products in the United States, including at least the Ivera Cap, which directly infringe at least claim 1 of the '587 Patent.

44. On information and belief, Defendant will continue to, inter alia, make and use products, including at least the Ivera Cap, that directly infringe at least claim 1 of the '587 Patent.

45. Plaintiffs have suffered damages by reason of Defendant's infringement of the '587 Patent, and will suffer additional damages and will be irreparably injured unless the Court enjoins Defendant from continuing such infringement.

PRAYER FOR RELIEF

Wherefore, Plaintiffs pray for judgment against Defendant as follows:

1. A finding that Defendant has infringed the '587 Patent.

2. For temporary, preliminary and permanent injunctive relief prohibiting Defendant, its agents, or anyone working for, in concert with or on behalf of Defendant from infringing the '587 Patent.

3. For an award of damages adequate to compensate Plaintiffs for the damages they have sustained as a result of Defendant's bad acts, including damages for Defendant's infringement, and prejudgment interest.

4. For monetary damages in an amount according to proof at trial;

5. For an Order directing Defendant to cease making, using, selling and distributing all infringing products, whether in the possession of Defendants, its distributors or retailers, and that all offending products or materials be seized or destroyed.

6. A finding that this case is an exceptional case justifying an award of attorneys' fees against Defendant. 35 U.S.C. § 285.

7. A finding that this case is an exceptional case justifying an award of treble damages against Defendant. 35 U.S.C. § 284.

8. For costs of court.

9. For such further equitable and legal relief that this Court deems reasonable and appropriate under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues properly triable by jury.

Dated: October 5th, 2012

Respectfully Submitted,

By: /s/ Edgar R. Cataxinos EDGAR R. CATAXINOS Attorney for Plaintiff Catheter Connections, Inc.

Dated: October 5th, 2012

Respectfully Submitted,

By: <u>/s/ R. Parrish Freeman</u> R. PARRISH FREEMAN Attorney for Plaintiff Univ.of Utah Research Foundation

CERTIFICATE OF SERVICE

I hereby certify that on the 5^{th} day of October, 2012, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sent notification of such filing to the following:

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Sanif