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CATHETER CONNECTIONS, INC.

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

CATHETER CONNECTIONS, INC, a Delaware corporation Plaintiff, v. **IVERA MEDICAL CORPORATION**, a California corporation Defendant.	**SECOND AMENDED COMPLAINT** **JURY TRIAL DEMANDED** Case No.: 2:12-cv-00531-DN The Honorable David Nuffer

BACKGROUND

Catheter Connections is a start-up company in Salt Lake City, Utah, co-founded by nurses seeking to reduce deadly hospital-acquired infections. Each year in the United States, more than 500,000 patients suffer from IV catheter related blood stream infections and up to 1 in 4 die. In its mission to save the lives of these patients, Plaintiffs conceived, developed, and patented the DualCap System™, which includes DualCap® ─ the only 510(k)-cleared medical device that disinfects and protects the male luer connector at the end of the IV tubing ("male luer"). Contaminated male luers can be vectors of infection and by using DualCap nurses are able to safely disinfect the male luer before connecting it to the patient's IV catheter. Recognizing that a comprehensive infection control solution requires male luer disinfection and seeing the traction in the market place for Plaintiff's unique IV disinfection technology, Ivera (the Defendant herein) embarked on an unlawful campaign to copy and infringe Plaintiff's innovative patented technology, exploiting and copying the ideas of the co-founder nurses. Such illegal and predatory tactics include aggressively promoting and selling an infringing "me-too" copy of Catheter Connections' male luer cap product known as "Curos Tips™," and inducing

end users to infringe Catheter Connections' patent by using the Curos Tips™ device.)

Plaintiff Catheter Connections, Inc. ("Catheter Connections") alleges claims against Defendant Ivera Medical Corporation ("Ivera" or "Defendant"), as follows:

THE PARTIES

1. Catheter Connections is a Delaware corporation engaged in the development and sale of products to help prevent IV catheter related blood stream infections ("CRBSI") and central line associated bloodstream infections ("CLABSI") with its principal place of business at 2455 E. Parleys Way, Suite 150, Salt Lake City, Utah.

2. Ivera is a California corporation with its principal place of business at 3525 Del Mar Heights Road, Suite 430, San Diego, California 92130.

JURISDICTION AND VENUE

3. This is a civil action for patent infringement arising under the laws of the United States. This Court has jurisdiction over the patent infringement claim by virtue of 28 U.S.C. §1338(a) and 28 U.S.C. § 1331.

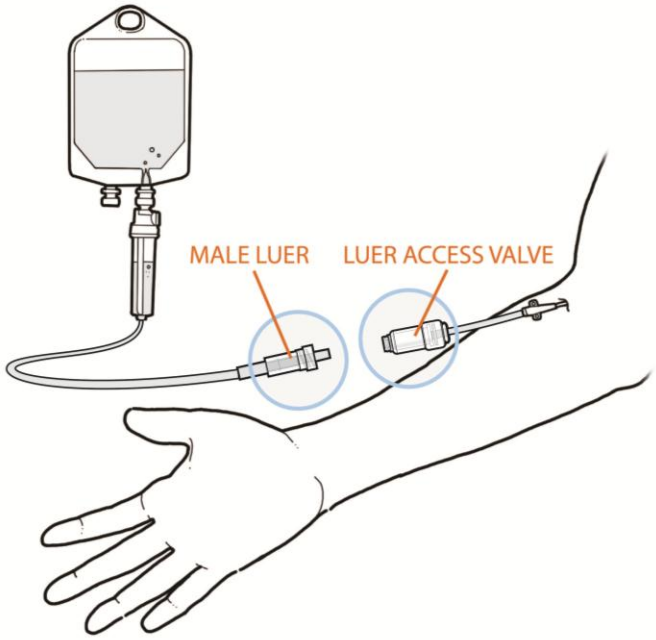
4. This Court has personal jurisdiction over Defendant because, on information and belief, Defendant is engaged in regular and substantial business in the State of Utah and the District of Utah.

5. 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, Utah. Defendant is deemed to reside in this judicial district within the meaning of 28 U.S.C. §1391(a).

GENERAL ALLEGATIONS

Background of the Technology at Issue

6. CRBSI and CLABSI, infections arising from IV infusion therapy, are life threatening and costly. Current practice, reflected in the Centers for Disease Control and Prevention (CDC), Infusion Nursing Society Standards of Practice, and other guidelines require that the luer access valve ("LAV"), a needleless connector attached to the patient's IV catheter, be disinfected with an antiseptic prior to use. Nurses commonly use an alcohol swab to scrub the surface of the LAV in an attempt to disinfect it before use. None of the guidelines or nursing practice recommendations provides any guidance that specifically addresses disinfection of the male luer at the end of the IV administration line. A typical infusion is illustrated below:



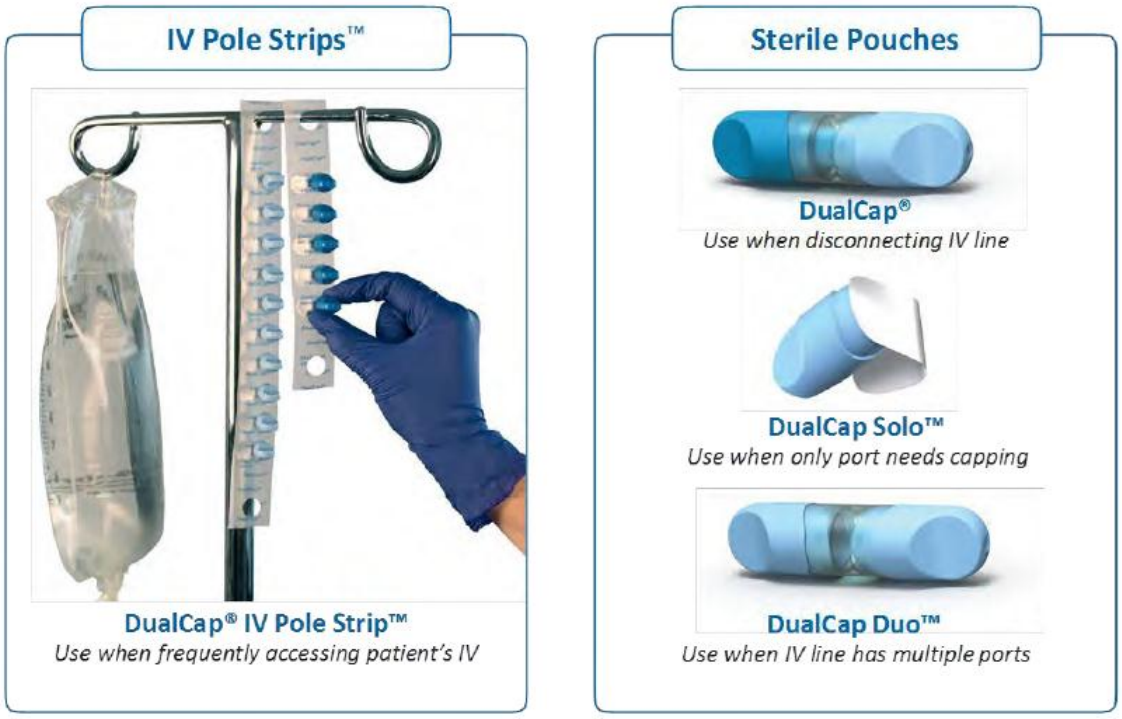
7. Historically, there has been no way of disinfecting the male luer without risking introduction of toxic antiseptic into the fluid that enters the patient's bloodstream. Prior to DualCap, there was no recommendation or guideline requiring the swabbing of the male luer at

the end of the IV tubing with alcohol, as it is an open fluid pathway into the patient. It has not been common to attempt to disinfect the male luer in daily practice in hospitals, infusion centers, or in home IV programs.

8. Michael J. Howlett ("Howlett"), RN, MS, CRNI and James Mercer ("Mercer"), RN, BSN are nurses with over 40 years of IV infusion experience between them. While working at the George E. Whalen Veterans' Affairs Medical Center in Salt Lake City, Utah (the "VA Hospital"), they conceived of the idea of disinfecting and protecting both ends of an IV infusion line ─ the LAV and the male luer.

9. While working as nurses at the VA Hospital, Howlett and Mercer (collectively, "the Nurses") conceived of the original idea for what is now DualCap – two disinfecting caps nested together into a single device to prevent infections. The Nurses had prototypes and drawings made and worked on the initial engineering. As required by the Department of Veterans Affairs' Federal Regulations, the Nurses disclosed their invention to the federal government. After reviewing the circumstances of the invention, it determined that the Nurses were entitled to the entire right, title, and interest in and to the invention and released invention rights to them. The Nurses then donated the invention and associated rights to the UURF.

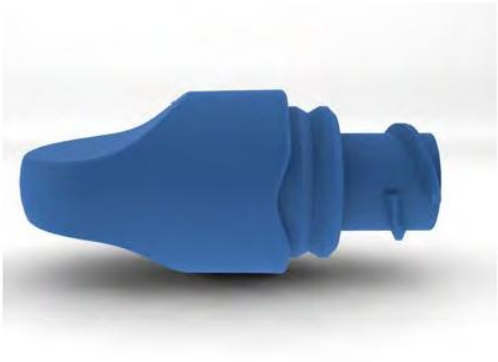
10. The Nurses then teamed up with Vicki Farrar, Don Solomon, PhD, and Robert Hitchcock, PhD, to form Catheter Connections in 2008 to further develop, engineer, and commercialize the technology. To this end, Catheter Connections received an exclusive license from UURF in October 2008, which was terminated in November 2013 when Catheter Connections received an assignment from UURF for previously licensed technology, including the patent in suit.

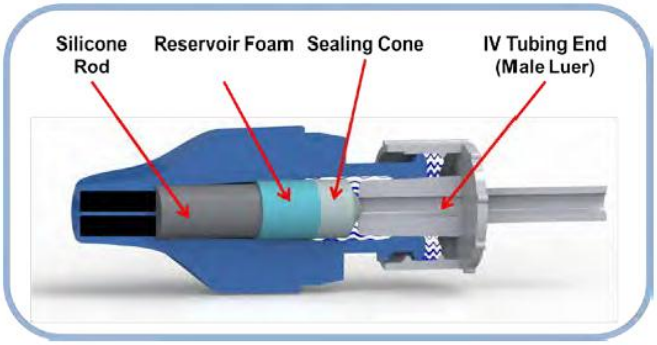


11. Catheter Connections has since developed and commercialized the DualCap System™ – five disinfectant cap products shown below. The first product on the market, DualCap®, consists of two disinfecting caps nested together into a single device to help prevent infections. The dark blue cap in DualCap® (sold in a pouch and on IV Pole Strips™) is for disinfection and protection of the male luer. The light blue cap in each configuration are for disinfection and protection of the (female) LAV when disconnecting an IV line.

12. Catheter Connections' light blue LAV cap competes against several other LAV caps, known as "female caps," including: SwabCap®, by Excelsior Medical Corporation; Curos® Port Protector, by Ivera; and EffectIV™, by Hospira, Inc. These competitive LAV caps reached the market before Catheter Connections, while Catheter Connections was developing the first male cap in the industry.

13. Disinfecting the male luer is more challenging than disinfecting the LAV because of the risk of introducing toxic disinfectants into the male luer's open fluid pathway. After extensive research and development and after testing several different materials, however, Catheter Connections solved the problem with its now-patented male cap, seen below.



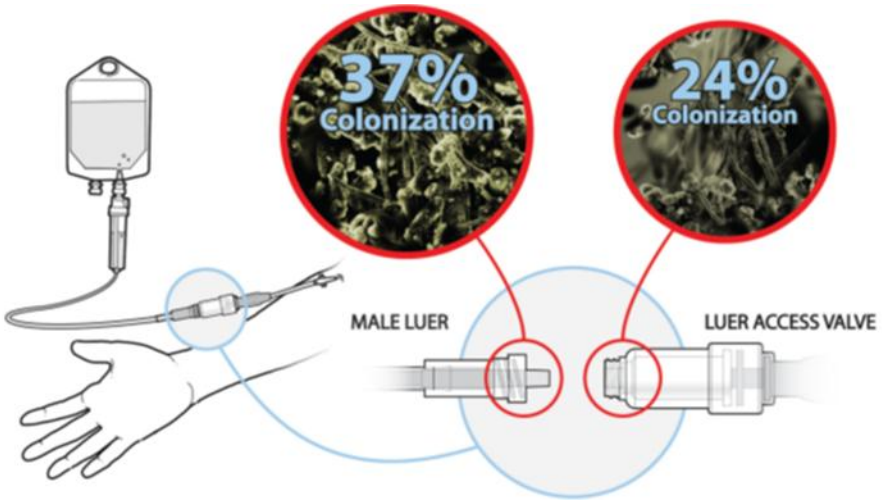


14. The DualCap™ System fulfills an unmet need in healthcare. Not only does it protect and disinfect both ends of the infusion line, it also helps standardize nursing care and makes compliance monitoring easy. Nurses now have the tools they need in a wide variety of packaging

Clinical Evidence of the Need to Disinfect the Male Luer

15. The Nurses and Catheter Connections recognized the need to find an effective disinfection strategy for the male luer. Between October, 2009 and June, 2010, Catheter Connections sponsored a clinical study at Loyola Medical University in Maywood, Illinois ("Loyola") to evaluate how significant this risk was. LAVs and male luers were collected from patients from five Loyola intensive care units and cultured in Loyola's microbiology laboratory. The researchers surprisingly discovered that the male luer was significantly more contaminated than the LAV (37% colonization for the male luer compared to only 24% colonization for the

LAV). Significantly, they also found cross-contamination of microorganisms between the two connectors and the patient's blood. Their results were presented in a poster session at the Society for Healthcare Epidemiology of America (SHEA) Conference in April 2011, which conference was attended by representatives from Ivera and other industry competitors. The study concluded: "Colonization of male luers may have greater significance due to its potential to introduce microorganisms into the flow tract, which cannot be disinfected by scrubbing the [LAV]."



16. Hospitals using Catheter Connections' DualCap® with both the male cap and LAV cap, report improved safety and/or significantly fewer IV catheter-related blood stream infections than hospitals using other caps or no protection at all. These hospitals include Loyola University Medical Center, the Veteran Affairs Hospital in Salt Lake City, LDS Hospital in Salt Lake City, Utah, and Primary Children's Medical Center in Salt Lake City, Utah. *See, e.g.*, Kamath *et al*. 2012; Drews 2013; Ward 2013. The only logical conclusion is that the reduction in infections occurred because both ends of the infusion line were disinfected and protected. Thus,

Catheter Connections' patented technology has the potential to create an entirely new standard of care in the medical industry.

Ivera is offering for sale its infringing Curos Tips™ device

17. Upon information and belief, Ivera has been using, demonstrating for use, offering for sale, and selling the current version of its Ivera male cap device, known as Curos Tips™, since at least as early as December 2012.

18. Upon information and belief, Ivera markets its products to clinicians, and accordingly end users of the Curos Tips™ device are those who work in clinical or medical settings such as hospitals, including nurses and medical assistants.

19. The "Directions For Use" provided to consumers of Curos Tips™ instructs users to use the product in an infringing manner. A copy of the Directions For Use has been attached as Exhibit A and is incorporated herein. The Directions For Use provided by Ivera to users states that "Curos Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips™ will disinfect the male luer (3) minutes after application and should cover the luer until removed. The effectiveness of Curos Tips™ was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. Curos Tips™ may be used in the home or healthcare facility."

20. The Direction For Use are very clear and specific about how the Curos Tips™ male cap device should be used. The Directions For Use only instructs use of the product in a manner that would infringe the '825 Patent.

21. The "Instructions for Use" section of the Directions For Use instructs users as follows: "1. Peel the Curos Tip from the foil strip. 2. Once removed, push and twist the Curos Tip onto the end of the male luer. 3. The Curos Tip must remain on the male luer for a minimum

of three (3) minutes and may remain on as a cover until removed. 4. A new Curos Tip should be placed on the male luer after each use. 5. Discard the Curos Tip after use."

22. Upon information and belief, Ivera specifically intends for its consumers to follow these instructions and to use the device to infringe the '825 Patent. At least some consumers do follow these instructions and use the device in an infringing manner.

23. The Directions For Use includes the following image of a gloved user connecting the Curos Tips™ to a male luer connector:

24. The directions quoted herein demonstrate that use of the Curos Tips™ male cap device constitutes an act of direct infringement of the '825 Patent.

25. The Directions For Use provides only instructions for a user to infringe and no inconsistent direction or inconsistent indication of how an end user would use the product.

26. The Curos Tips™ male cap device was made to be used in the manner directed in the Directions For Use.

27. The use of the Curos Tips™ as directed by Ivera's Directions For Use infringes a number of claims of the '825 Patent. For example, using the Curos Tips™ male cap device as

directed by the Directions For Use infringes claims including, but not limited to, 1, 2, and 4-10 of the ‘825 Patent.

28. Upon information and belief, Ivera was aware of the ‘825 Patent at least as early as March 2012.

Patent Infringement Claim (Count One)

For a joint claim for patent infringement against Defendant, Catheter Connections alleges as follows:

COUNT ONE

Infringement of U.S. Patent 8,172,825

29. The allegations of paragraphs 1 through 28 of this First Amended Complaint are incorporated and reasserted herein. Catheter Connections is the exclusive owner and assignee of the entire right, title and interest in and to United States Patent No. 8,172,825 (“the ‘825 Patent), which was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on May 8, 2012, for an invention titled “Methods for Disinfecting Medical Connectors.” A true and correct copy of the ‘825 patent is attached hereto as Exhibit B.

30. Ivera has infringed and continues to infringe the ‘825 Patent by making, using, selling, and /or offering to sell the Curos Tips™ product that embodies one or more claims of the patented invention.

31. Ivera, through its manufacturer, has for some time, and continues to the present time, to make its Curos Tips™ male cap device in the United States.

32. Ivera has for some time, and continues to promote and distribute and provide for use by others in the United States its Curos Tips™ male cap device.

33. A press release announcing a Notice of Allowance for the patent of Plaintiff's male luer technology now covered in the '825 Patent was issued on March 8, 2012.

34. Catheter Connections filed the Complaint for patent infringement of the '825 Patent on May 2, 2012, shortly after the '825 Patent issued. On June 7, 2012, Ivera filed a waiver of the service of summons acknowledging receipt of the Complaint, which attached a copy of the '825 Patent.

35. Upon information and belief, Ivera was fully aware of the '825 Patent when it began selling or offering to sell its Curos Tips™ device at least as early as December 2012.

36. Upon information and belief, Defendant has been and will continue to be using, demonstrating the use of, offering to sell, and selling its Curos Tips™ device, constituting direct infringement of at least claims 1, 2, and 4-10 of the '825 Patent under 35 U.S.C. §271(a).

37. Upon information and belief, Defendant has been and is contributory infringing and/or actively inducing others, including end users, to infringe at least claims 1, 2, and 4-10 of the '825 Patent, and sells the Curos Tips™ device with the knowledge and intent that they will be used by end users and that such uses infringes the '825 Patent, and the intent that such caps are especially designed to be and are used in a manner which infringes the '825 Patent under 35 U.S.C . §271(b). As evidenced by, *inter alia*, the Directions For Use, such caps are, and are known and intended by Defendant to be, especially made and adapted for use in practicing a method of use that infringes the '825 Patent, constituting a material art of the invention of the patent, and not being staple items or commodities of commerce suitable for substantial noninfringing use.

38. Upon information and belief, Defendant's infringement of the '825 Patent has been deliberate, willful, and with full knowledge of the '825 Patent.

39. Plaintiffs have suffered damages by reason of Defendant's deliberate and willful infringement of the '825 Patent, and will suffer additional damages and will be irreparably injured unless the Court enjoins Defendant from continuing such infringement.

40. This case is an exceptional case justifying an award of attorneys' fees and treble damages against Defendant. 35 U.S.C. §§ 284 & 285.

PRAYER FOR RELIEF

Wherefore, Plaintiffs prays for judgment against Defendant as follows:

1. For judgment that Defendant has infringed the '825 Patent.

2. For compensatory and prejudgment interest thereon for Defendant's acts of direct or indirect infringement or inducing infringement of the '825 Patent.

3. For temporary, preliminary and permanent injunctive relief prohibiting Defendant, its agents, or anyone working for, in concert with or on behalf of Defendant from directly or indirectly infringing or inducing the infringement of the '825 Patent of Plaintiffs.

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

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

6. For costs of court.

7. 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: March 3, 2014

Respectfully Submitted,

By: /s/ Kerry L. Timbers

KERRY L. TIMBERS
Attorney for Plaintiff
CATHETER CONNECTIONS, INC.

CERTIFICATE OF SERVICE

I hereby certify that on the 3rd day March, 2014, 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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