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Attorney for Plaintiff
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.

COMPLAINT FOR:

1) **PATENT INFRINGMENT**
2) **LANHAM ACT**
3) **UTAH TRUTH IN ADVERTISING ACT**
4) **UNFAIR COMPETITION**
5) **UTAH UNFAIR PRACTICES ACT**
6) **UTAH UNFAIR COMPETITION ACT**

JURY TRIAL DEMANDED

Case No.: 2:12-cv-00531-PMW

Magistrate Judge Paul M. Warner

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, Catheter Connections 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 Catheter Connections' unique IV disinfection technology, Ivera (the Defendant herein) embarked on an unlawful campaign to copy and infringe Catheter Connections' innovative patented technology, exploiting and copying the ideas of its co-founder nurses. Such illegal and predatory tactics include: (i) filing a baseless lawsuit against Catheter Connections, (ii) aggressively promoting and preparing to sell a "me-too" copy of Catheter Connections' male luer cap product, (iii) displaying such "me too" product at numerous trade shows without the disclaimers that it is not for sale in the United States and has not been 510(k)-cleared, (iv) urging Catheter Connections' potential customers to wait and buy Ivera's copied device alleged to be available "soon", and (v) defaming Catheter Connections and its products.

Plaintiff Catheter Connections, Inc. ("Catheter Connections"), by and for its complaint against Defendant Ivera Medical Corporation ("Ivera" or "Defendant"), alleges 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 in Salt Lake City, Utah.

2. Ivera is a California corporation, which has alleged in at least ten pleadings filed in both State and Federal Courts that its principal place of business is 3525 Del Mar Heights Road, Suite 430, San Diego, California 92130. Only a UPS Store is located at 3525 Del Mar Heights Road, San Diego, California 92130. Inside that store there is a wall of mailboxes, including mailbox number 430. Bobby E. Rogers ("Rogers"), Ivera's CEO, testified in Ivera Medical Corporation v. Amsino International, Inc., Hospira, Inc. and Mark Godfrey, Los Angeles Superior Court, Case No. BC424826, that Ivera "doesn't really have a location", and

that the Del Mar Heights address is only a "mail drop" but that its contract manufacturer, PEDI, is located in California. Ivera has offered for sale and sold its "Curos® Port Protector" ("Curos"), a device different than its infringing device and for a different IV connector, in Utah and throughout the United States. Ivera is currently selling Curos in Utah and conducting a product trial in Murray, Utah. Ivera has, however, provided infringing devices to Intermountain Health Care (IHC) personnel in Murray and Salt Lake City, Utah and on information and belief, has provided such infringing devices to other medical personnel in Salt Lake City.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the patent infringement claim by virtue of 28 U.S.C. §1338(a) and 28 U.S.C. § 1331. This Court has diversity jurisdiction over all claims asserted in this action pursuant to 28 U.S.C. §1332, because the parties are citizens of different states and the amount in controversy exceeds the jurisdictional amount of $75,000, excluding interest and costs. This court has original jurisdiction over the unfair competition claim based upon 28 U.S.C. §1338(b). This Court has supplemental jurisdiction over the other pled claims by virtue of 28 U.S.C. §1367.

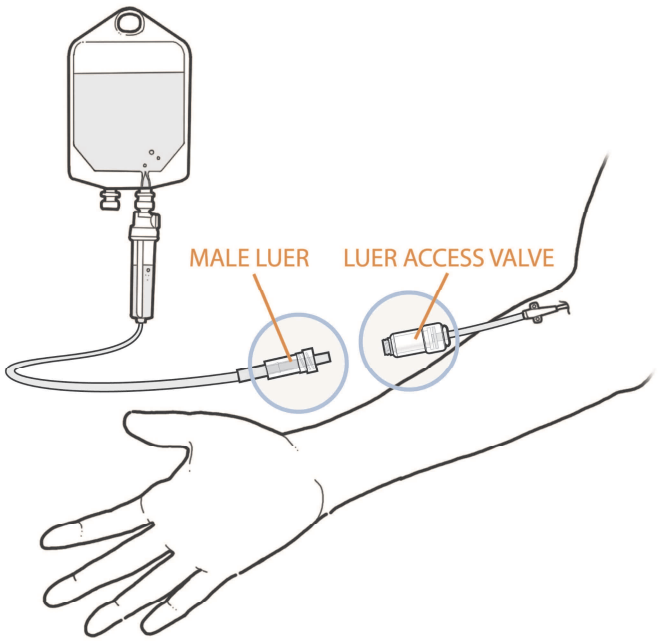
4. Venue is proper in this Court under 28 U.S.C. §1391(b), because Defendant has committed acts of patent infringement in, and has otherwise regularly conducted or conducts business within, Utah. Defendant is deemed to reside in this judicial district within the meaning of 28 U.S.C. §1391(a).

GENERAL ALLEGATIONS

Background of the Technology at Issue

5. 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:



6. 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.

7. 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.

8. 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.

9. 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.

10. Catheter Connections has developed and commercialized the DualCap System, shown below.

DualCap has a dark blue cap for disinfection and protection of the male luer and light blue cap for disinfection and protection of the LAV, for use when disconnecting an IV line. In addition to DualCap, the system includes two other medical devices: DualCap Duo™ and DualCap Solo™.

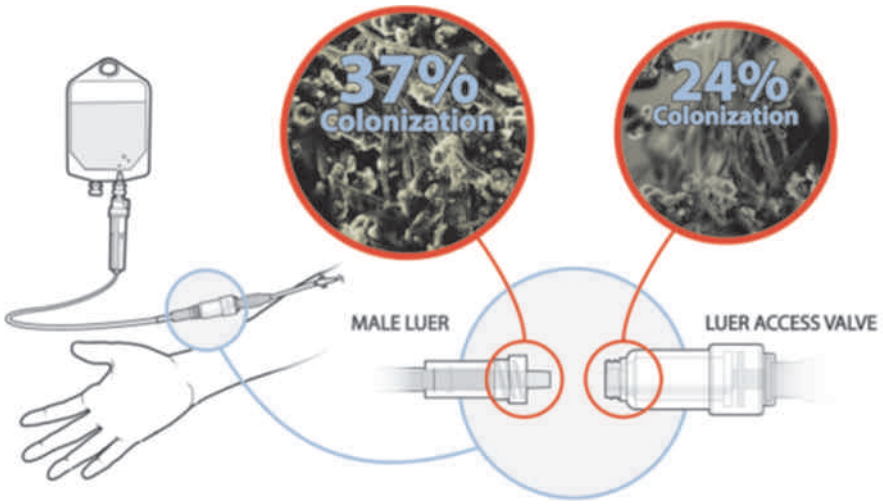
DualCap Duo is a sterile, single-use device containing two disinfecting caps — both for use on frequently accessed LAVs. It is the only device with two disinfectant caps for luer access valves conveniently located in one sterile package. DualCap Solo™ is a sterile, single disinfecting cap for use on the LAV.

11. The DualCap System fulfills an unmet need in healthcare. Not only does it protect and disinfect both ends of the infusion line, it helps standardize nursing care and makes compliance monitoring easy. Nurses now have the tools they need to keep the patient safe and protected from contaminated IV lines.

12. Catheter Connections is the only company with 510(k) premarket clearance to sell a device to protect and disinfect the male luer (K093229). Another company would be required to obtain appropriate 510(k) clearance from FDA in order to commercially distribute a substantially equivalent product. This 510(k) clearance is a significant and important marketing advantage for Catheter Connections.

First Clinical Evidence of the Need to Disinfect the Male Luer

13. The Nurses and Catheter Connections appreciated the need to disinfect and protect the male luer. Catheter Connections sponsored a clinical study at Loyola Medical University ("Loyola") in Maywood, Illinois. In this study, the LAVs and the male luers were collected from patients in five different ICUs at Loyola and cultured in Loyola's microbiology laboratory. The study found that the male luer was significantly more contaminated than the LAV. It also found cross-contamination – the same microbes in the patient's blood and on each connector. 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]." The results are set forth in a Poster that was presented in April 2011 at the Society for Healthcare Epidemiology of America (SHEA), which Ivera attended and is reproduced below:



Follow-On Clinical Evidence of the Need to Disinfect the Male Luer

14. Further scientific evidence of the need to protect and disinfect the male luer is found in the following recent studies conducted by Catheter Connections.

a. *IV Administration Sets are Vectors of Infection Because of Biofilm Contamination (Solomon 2012, Exhibit A*). While biofilm on luer access valves has been imaged for decades, Catheter Connections is the first and only one to detect and image biofilm on the male luer. The safety alert reports that biofilm is found on male luer connectors and was the first publication to provide images of biofilm on male luers. This safety alert also reports the clinical significance of this finding and the laboratory testing that confirms a contaminated male luer will contaminate an otherwise sterile access valve and the IV fluid, showing the need for DualCap.

b. *IV Stands and Medical Devices Hanging from IV Stands are Vectors of Infection (Solomon 2012, Exhibit B)*. This safety alert reports that contamination of IV stand surfaces can result in the transmission of organisms to other surfaces and even patients, contributing to hospital-acquired infections and infection breakouts. This report shows that any device hanging from an IV stand must be considered as a vector of infection, unless that device is protected from contamination such as in a sterile-barrier wrapper.

Clinical Evidence of Infection Reduction by DualCap

15. Catheter Connections' DualCap in use has reduced bloodstream infections. Based on hospital experience and clinical data on male luers, the only logical conclusion from these bloodstream reductions is that they occurred because both ends of the infusion line were

disinfected and protected. Clinical studies regarding the success of DualCap include:

a. *Scientific Poster: Pilot Study of the Effect of DualCap Disinfectant Devices on Rates of Central Line Associated Bloodstream Infections (Kamath et al; presented at Research Day 2012, April 26, 2012, Hines, IL, Exhibit C*). This poster reports on the results of a study using DualCap in two intensive care units (burn and heart-transplant). While the hospital's blood stream infection rates rose in the control units by 50%, the infection rate dropped by 46% in the study units. This study shows that DualCap use reduces the rate of blood stream infections, saving lives and protecting the hospital from liability and economic losses.

b. *Case Study: Device for Disinfecting Luer Access Valves and Male Luer Connectors (IV Administration Set End Connectors) is Reducing Central Line-Associated Bloodstream Infection (CLABSI) Risk (VA Medical Center, Salt Lake City, UT, May 2012, approved by VA for publication, Exhibit D*). This study reports a >80% reduction in bloodstream infections attributed to DualCap. This hospital tried other disinfecting caps, but infections continued. Since starting the use of the DualCap in April 2011, no infections have been reported.

Significant Time and Resources are Required for 510(k) Clearance

16. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. Section 321 *et seq.*, a medical device must be "approved" or "cleared" by FDA prior to introduction into interstate commerce. Medical devices may be "cleared" for marketing by FDA if the manufacturer shows that its device is "substantially equivalent" to a lawfully marketed "predicate device" under a premarket notification submission process, resulting in a "510(k)-cleared" device. See FDCA §§ 510(k) and 513(i); 21 C.F.R. Part 807. This federal law exists to protect our nation from harmful or otherwise unsafe medical devices.

17. In order to legally market and sell DualCap, Catheter Connections invested a significant amount of research, time, and money into the testing required for 510(k) clearance for each of its products. It performed extensive testing to show that its male luer disinfecting technology was safe and effective. In addition to standard biocompatibility and sterility requirements, to obtain 510(k) clearance of the male luer disinfectant cap, the FDA required the following:

a. Proof that no isopropyl alcohol (IPA) enters the fluid pathway of the IV male luer connector (IPA is toxic and a central nervous system depressant).

b. Proof that the critical surface areas of the male luer connector (the transverse surface and the luer taper surface) are both disinfected by IPA ─ demonstrated by using an *in vitro* model which inoculates both the transverse surface and the luer taper surfaces of a male luer.

c. Kill time studies for seven organisms (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, antibiotic-resistant bacteria MRSA and VRE, and yeasts such as *Candida albicans,* and *Candida krusei*).

d. Certifications from the relevant supply chain, demonstrating compliance with Latex-free and DEHP- free labeling.

18. Catheter Connections followed all FDA requirements for the clearance of its DualCap products, and has three 510(k) notifications: K093229, K112985, and K113842. While waiting for 510(k) clearance, when pictures or samples of non-510(k) cleared products were visible at trade shows, Catheter Connections always prominently displayed written materials stating that such products were not yet available for sale in the U.S., and it never accepted orders or sold such products until it received 510(k) clearance.

19. Upon information and belief, because Catheter Connections has the only 510(k) cleared device for male luer disinfection, Ivera must be using the DualCap as the "predicate device" in any 510(k) submission by Ivera for a male luer disinfecting cap (the "Ivera non-510(k)-cleared male luer cleansing cap"), asserting that its non-510(k)-cleared male luer cleansing cap is substantially equivalent to the DualCap dark blue cap for the male luer.

Ivera's 510(k)-Cleared Product Disinfects the Luer Access Valve Only

20. Ivera markets and sells Curos, a medical device it alleges disinfects and protects the entry port on certain types of valves used with IV lines.

21. According to the instructions for use and the 510(k) clearance from FDA, the Curos device is only indicated for use on an injection port and therefore can only be used on an injection port (also commonly referred to as a luer-activated valve, luer access valve, or needleless connector). Curos is not structured for use on the male luer connector at the end of

the IV tubing and is not approved by FDA for such use.

Ivera's Deceitful and Unlawful Acts at Trade Shows

22. Catheter Connections and Ivera routinely attend industry trade shows to promote their products to healthcare facilities, like hospitals, long-term acute care rehab hospitals, and homecare companies. These trade shows are attended by nurses, doctors, hospital executives, and group purchasing organization (GPO) executives, industry service providers, such as public relations experts, and members of the media. The clinician attendees typically take product samples back to their respective healthcare facilities so that they can be discussed with others and then, if desired, they "trial" the product and then may buy it. For medical device manufacturers, the purpose of attending these trade shows is to obtain qualified leads – end users to trial and purchase their products. Depending on the number of attendees at a show, a single manufacturer may obtain hundreds or even thousands of leads.

23. In 2012, Catheter Connections has attended three national trade shows. Ivera attends far more trades shows than Catheter Connections, as it has greater financial resources. According to Ivera's web site, it has attended six trade shows in 2012 and will attend eight more.

24. Rogers and Christine Arme, Ivera's VP of Clinical Integration, have requested and been provided with samples of DualCap at numerous industry trade shows, with the first request occurring at APIC 2010 (American Association of Infection Control) held in New Orleans, LA., July 12-14, 2010.

25. At SHEA 2011, Rogers told a Catheter Connections' investor, who identified himself as such, that the DualCap did not fit on certain needleless connectors, such as the MaxPlus by CareFusion and connectors made by Rymed, which statement, upon information and belief, Rogers knew was false and misleading at the time made.

Ivera Copies Catheter Connections' Male Luer Cap Invention and Unlawfully Promotes its Device without 510(k) Clearance and Disclaimers and Routinely Provides Rolling Dates of When its Non-510(k)-cleared Device will be Legally Available

26. Ivera is currently manufacturing a cap to protect and disinfect the male luer.

27. Despite having no 510(k) premarket clearance for Ivera's non-510(k)-cleared male luer cleansing cap, Ivera is routinely promoting its cap at industry trade shows with no placards or any other written materials at the point of display to advise that its product is not 510(k)-cleared, cannot lawfully be sold in the United States, that orders cannot lawfully be taken for the product, and that no contracts of sale for the device can lawfully be executed. Upon information and belief, such absences of warning literature are intentional upon the part of Ivera.

28. Ivera has shown the Ivera non-510(k)-cleared male luer cleansing cap at least at the following industry tradeshows, without any of the disclaimers identified in Paragraph 26 above:

a. *FANNP Conference (Florida Association of Neonatal Nurse Practitioners), October 11-12, 2011.* At this regional tradeshow, Ivera employee Al Kauper promoted the Ivera non-510(k)-cleared male luer cleansing cap, saying it would be released "soon." Kauper did not provide any information about 510(k)-clearance and he showed samples to Catheter Connections' representatives. There were no signs or other visible disclaimers about lack of 510(k)-clearance and that the product may not be legally offered for sale in the United States.

b. *Great Lakes Chapter - Infusion Nurses Society 2011 Fall Conference, Livonia, Michigan, October 25, 2011.* Ivera representatives Ted Beatty and Rick Hasseld of Med Alliance Group, Inc., promoted Ivera's non 510(k)-cleared male luer cleansing cap at this regional tradeshow. Beatty and Hasseld did not provide any information about 510(k)-clearance, and also showed a sample of the device to a Catheter Connections' employee, saying it would be available for purchase "soon". There were no signs or other visible written disclaimers about lack of 510(k)-clearance nor that the product could not be offered for sale in the United States.

c. *Gravens Neonatology Conference, Clearwater, Florida*, *January 24-26, 2012*. At this regional tradeshow, Ivera representative Jacob Mindlin of Tacy Medical promoted the Ivera non-510(k)-cleared male luer cleansing cap and showed samples to Catheter Connections' representatives . There were no signs or other visible written disclaimers about the lack of FDA-clearance and that the product could not be offered for sale in the United States.

d. *Southeast Florida Chapter of NANN (SEFANN) conference, Miami, Florida, March 8-9, 2012.* At this regional tradeshow, Ivera representative Jacob Mindlin of Tacy Medical promoted the Ivera non-510(k)-cleared male luer cleansing cap and showed samples to a Catheter Connections' representative. There were no signs or other visible written disclaimers about lack of FDA-clearance and that the product could not be offered for sale in the United States.

e. *Northern California Association for Vascular Access (NORVAN) Conference, Thunder Valley Casino, Lincoln, CA, April 20, 2012*. An Ivera representative promoted the Ivera non-510(k)-cleared male luer cleansing cap and showed samples of the device to Catheter Connections' representatives. The Ivera representative said that the Ivera non-510(k)-cleared male luer cleansing cap would be available for purchase in a "month".

f. *National Teaching Institute & Critical Care Exposition of the American Association of Critical Care Nurses (AACN) in Orlando, Florida, May 22-24, 2012.* Ivera displayed its non-510(k)-cleared male luer cleansing cap. Ivera's marketing manager, Jamie Kelly ("Kelly"), told a Catheter Connections' employee that the Ivera non-510(k)-cleared male luer cleansing cap does not have FDA-clearance, and there is nothing in writing available at the show about the Ivera non-510(k)-cleared male luer cleansing cap. There is no literature or signage with a disclaimer about lack of 510(k)-clearance or that its male luer cleansing cap is not "for sale" in the US. Kelly states that the Ivera non-510(k)-cleared male luer cleansing cap will be available for purchase this summer because a 510(k) premarket notification has been submitted and Ivera will get clearance from FDA in time to begin commercial distribution this summer. Attendees at the show told Catheter Connections that Ivera is saying that it will soon have a male luer cleansing cap and to use its male luer cleansing cap instead of Catheter Connections' cleared products.

29. Upon information and belief, it would have been impracticable if not impossible for Ivera to have orally made the disclaimers due to the lack of 510(k)-clearance for the Ivera non-510(k)-cleared male luer cleansing cap, as many trade show attendees just "glance" or look at the booth, do not interact with the displayers, and do not engage in one-on-one discussion with any one displaying the wares whereby such an oral disclaimer could have been made.

30. Upon information and belief the display of the Ivera non-510(k)-cleared male luer

cleansing cap at tradeshows is part of a national marketing strategy employed by Ivera and is not limited to the aforementioned tradeshows. Ivera's conduct is not based on isolated statements, they were widely disseminated to the relevant purchasing public. For instance, some of the tradeshows where the misleading promotions took place have thousands of attendees, such as the AACN Show where approximately 7,000 critical care clinicians attended.

31. Under the FDCA, a medical device pending 510(k) is considered to be a Class III device and cannot be introduced into interstate commerce without FDA approval of a "Premarket Approval Application," which upon information and belief, Ivera has not submitted and has no intention to submit.

32. Under the FDA's enforcement policy (Compliance Policy Guide 300.600), a medical device pending 510(k) clearance can be displayed, but the device cannot be offered for sale or introduced into interstate commerce. Nor may orders for sale be taken or accepted prior to 510(k) clearance, even if made contingent upon clearance. Taking the name of a prospective customer and offering to contact that prospect once the device is 510(k)-cleared is the first step in offering a product for sale and fulfilling the sales order, which upon information and belief, is what FDA's promotion policy is designed to prohibit. See FDA CPG 300.600.

33. Upon information and belief, at each of the trade shows where Ivera displayed the Ivera non-510(k)-cleared male luer cleansing cap, Ivera representatives took the names of prospective customers either on a hard copy piece of paper or via an electronic contact information scanner. For example, at the AACN trade show described in paragraph 28f above, Ivera representatives used an electronic scanner to scan the trade show attendees' badges that visited the Ivera booth. Upon information and belief, Ivera offered to contact each attendee whose contact information it collected at every trade show it displayed the Ivera non-510(k)-cleared male luer cleansing cap to let such attendee know the Ivera non-510(k)-cleared male luer cleansing cap received FDA-clearance and was available for purchase. Ivera did not segregate its sales promotion activity for those visiting its trade show booths to learn about Curos, which is

510(k)-cleared, as opposed to the Ivera's non-510(k)-cleared male luer cleansing cap.

34. At the AACN trade show identified in paragraphs 28 and 30 above, there was "buzz" that FDA enforcement personnel from Bethesda, Maryland were walking the show on May 23, 2012 in connection with their enforcement duties. Around the time of this "buzz" on May 23, 2012, Ivera stopped prominently displaying its Ivera non-cleared FDA cap and instead at least one Ivera representative at its booth wore the product around his neck. Upon information and belief, this act was intended to mislead FDA personnel regarding the promotion of its non-510(k)-cleared cleansing device. By the next day of the show, May 24, 2012, Ivera was again prominently displaying the Ivera non-510(k)-cleared male luer cleansing cap without the required standard disclaimers that it is not 510(k)-cleared and is not for sale in the United States.

Ivera is Engaged in a Scheme to Mislead Buyers and to Stop Purchases of the Only 510(k)-cleared Product for Disinfecting IV Tubing Male Luer Connectors

35. Ivera promotes and displays its non-510(k)-cleared male luer cleansing cap with no disclaimers and no written information at all. Ivera, however, in conjunction with such displays provides only informational and promotional material about its Curos cap, which is 510(k)-cleared for disinfection of needleless IV injection ports, *but not IV tubing male luer connectors*. By providing written information *only* on the 510(k)-cleared Curos cap, Ivera is confusing and misleading potential buyers into falsely believing that the non-510(k)-cleared male luer cleansing cap is 510(k)-cleared and/or available for purchase.

36. On May 31, 2012, Ivera employee Al Kauper ("Kauper") made a marketing presentation and provided the Ivera non-510(k)-cleared male luer cleansing cap at no charge to personnel of South Miami Hospital in South Miami, Florida. Upon information and belief, Kauper did not provide any information, orally or in writing, about the FDA-clearance status of the Ivera non-510(k)-cleared male luer cleansing cap. What Kauper did provide to the hospital was the Ivera non-510(k)-cleared male luer cleansing cap and a green tote bag bearing Ivera's Curos cap logo with three pieces of Curos cap product literature inside such tote bag (attached

hereto as Exhibits E, F and G).

37. At the trade shows identified herein, Ivera's non-510(k)-cleared male luer cleansing cap is strategically placed right next to its 510(k)-cleared Curos cap and surrounded by literature on Curos. Upon information and belief, the promotional literature for Curos and the display of the Ivera non-510(k)-cleared male luer cleansing cap were strategically placed by Rogers, CEO of Defendant, and other Ivera personnel and sales representatives to falsely portray that the Ivera non-510(k)-cleared male luer cleansing cap is legally available for sale and is covered by the 510(k) clearance of the Curos cap.

38. Because potential buyers are lead to believe the Ivera non-510(k)-cleared male luer cleansing cap is or will be imminently available for purchase, they are dissuaded from purchasing the only 510(k)-cleared device for IV tubing male luer site disinfection ─ DualCap from Plaintiff. Because of Ivera's deceptive acts, some hospitals may think that the Ivera non-510(k)-cleared male luer cleansing cap is available now and others may be affirmatively misled by Ivera's misstatements into believing that it will be legally available soon, such that Ivera is choking off sales to Catheter Connections, the only company that can lawfully sell a male luer disinfection device now.

39. Upon information and belief, Ivera's scheme is national, involving both Ivera employees and its distributors, who are spreading misleading and confusing information about the Ivera non-510(k)-cleared male luer cleansing cap from coast to coast, including at least California, Florida, Michigan, Nevada, and Utah. Upon information and belief, starting in at least October of 2011, Ivera was displaying and promoting the Ivera non-510(k)-cleared male luer cleansing cap and giving misleading information about it would be available for purchase. Time estimates have included "soon", the "Spring [2012]", within a "month" and this "Summer [2012]" (See paragraphs 28 and 44 herein).

40. Upon information and belief, Ivera has never commented about its FDA-clearance status for the Ivera non-510(k)-cleared male luer cleansing cap until late April 2012 when Ivera

representatives at the Ivera exhibit booth in the Infusion Nursing Society Annual Conference and Industrial Exhibition (April 30 – May 2, 2012, Las Vegas, Nevada) stated that a 510(k) for the Ivera non-510(k)-cleared male luer cleansing cap had been submitted.

Plaintiff's Claims Against Ivera are Based upon Ivera's Intentional Deception of Consumers and do not Require Interpretation of any FDA Regulation

41. Catheter Connections' claims that Ivera's non-510(k)-cleared male luer cleansing cap is misbranded, adulterated and unlawfully offered for sale does not challenge 510(k)-clearance or labeling, areas which are regulated by the FDCA. Nor does Catheter Connections seek an interpretation of the FDA regulations. While many of Ivera's acts may very well be unlawful under the FDCA, it is Ivera's scheme of intentionally deceiving clinicians and hospitals by choosing, for marketing reasons, to provide misleading, deceptive and confusing information regarding Ivera's non-510(k)-cleared male luer cleansing cap that is actionable. Catheter Connections' claims are directed at Rogers' and Ivera's strategic marketing campaign, which is voluntary and misleading, even if it complies with the minimum requirements set forth by the FDA regulations. Accordingly, neither the Lanham Act nor any of the statutory or common law claims alleged herein are dependent upon violations of the FDCA by Ivera.

Ivera Urges Hospitals and Other Potential Customers Not to Buy DualCap Representing the Ivera Non-510(k)-cleared Male luer Cleansing Cap is Coming Soon

42. Catheter Connections and Ivera are competitors. Upon information and belief, Ivera is a much larger company than Catheter Connections. Upon information and belief, Ivera has at least 6 sales and marketing employees and has told those in the investment community that its value is $100 million. Ivera began selling Curos approximately two years before Catheter Connections launched DualCap. The only way that Catheter Connections can effectively compete against larger competitors like Ivera is on the basis of its innovative products and patent protected technology.

43. Ivera routinely, systematically, and aggressively urges hospitals that are

considering the purchase of Catheter Connections' DualCap not to purchase DualCap. When these hospitals raise the fact that only Catheter Connections has an 510(k)-cleared product to protect and disinfect the male luer, Ivera tells them that the Ivera non-510(k)-cleared male luer cleansing cap is coming "soon" or in a particular season, and that it will be significantly less expensive than Catheter Connections' product no matter what the price of the Catheter Connections' product.

44. Ivera has stated that its non-510(k)-cleared male luer cleansing cap will be available "soon" since at least as early as the fall of 2011 through the present. Upon information and belief, in its discussions with hospitals, Ivera is silent on the fact Catheter Connections has a patent on its male luer technology and that the hospitals who use Ivera's non-510(k)-cleared male luer cleansing cap may be infringing that patent. Discussions to this effect include:

a. A clinician at the VA Hospital in Reno, Nevada advising a Catheter Connections' representative, on November 4, 2011 that Ivera promised such hospital the Ivera non-510(k)-cleared male luer cleansing cap and that it is "expected to be ready to use in early Spring [2012] so they should hold off on evaluating DualCap".

b. Sharon Sumner, RN, ICP, Infection Control of Intermountain Medical Center ("IMC"), Murray, Utah told Catheter Connections' CEO Vicki Farrar, on November 15, 2011, that Ivera said it is coming out with a male luer cleansing cap soon, and that Ivera is urging Intermountain Health Care to trial its non-510(k)-cleared male luer cleansing cap. To convince IMC and its parent organization, Intermountain Health Care ("IHC") that it would have a male luer cleansing cap and to induce them not to purchase DualCap, Ivera gave samples of the Ivera non-510(k)-cleared male luer cleansing cap to Ms. Sumner who has shown it to others at IHC, including its purchasing agent, and has relayed the information that the Ivera non-510(k)-cleared male luer cleansing cap is "coming soon" and IHC should not trial DualCap and wait for the Ivera product instead.

Catheter Connections' Patent

45. United States Patent 8,172,825 ("the '825 Patent") entitled "Methods of Disinfecting Medical Connectors" (Exhibit H) was duly and legally issued by the United States

Patent and Trademark Office ("USPTO") on May 8, 2012.

46. The significance of Catheter Connections male luer technology has been recognized by world renown infectious disease experts who submitted declarations to the USPTO regarding the importance in clinical care of now being able to safely disinfect male luer connectors with DualCap and prior to Catheter Connections, the risk of contaminated male luers was simply overlooked.

47. The '825 Patent is assigned to the University of Utah Research Foundation ("UURF"). Catheter Connections is the exclusive licensee of the '825 Patent and, without limitation, has the right to sue and to recover for past and future infringement thereof.

48. Ivera, through its manufacturer, has for some time, and continues to the present time, to make Ivera's non-510(k)-cleared male luer cleansing cap in the United States.

49. Ivera has for some time, and continues to promote and distribute and provide for use by others the Ivera non-510(k)-cleared device in the United States.

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

51. Upon information and belief, Ivera is fully aware of the '825 Patent.

52. Catheter Connections has invested in a large patent portfolio in order to compete against much larger companies like Ivera and to protect the novel ideas of the Nurses and its position in the market.

Rogers is Responsible for Ivera's Actions

53. Rogers, the Chief Executive Officer of Ivera, is, upon information and belief, the "person most knowledgeable" about Ivera, as he testified under the California equivalent of FRCP 30(b)6) in Ivera Medical Corporation, Plaintiff v. Amsino International, Inc., Hospira, Inc. and Mark Godfrey, and Does 1 to 10, Exclusive Defendant, Los Angeles Superior Court, Case No. BC 424826 ("Ivera Trade Secret Case").

54. In the Ivera Trade Secret Case, Rogers testified that he is an "approximately 50

percent shareholder" of Ivera, with the next biggest shareholder being Eddie Rodriquez, his attorney, who owns 4% of Ivera.

55. Upon information and belief, Rogers is aware of Catheter Connections' intellectual property, including both its issued, allowed, and pending patents. Rogers saw the DualCap at APIC 2010 (American Association of Infection Control) held in New Orleans, LA., July 12-14, 2010.

56. Then, at the 2011 Annual Scientific Meeting of the Society for Healthcare Epidemiology of America (SHEA) held in Dallas, Texas, April 1-4, 2011, Rogers visited the Catheter Connections' trade show booth, where he inspected the DualCap® on display and told Catheter Connections' personnel that the DualCap did not infringe his intellectual property and that Catheter Connections had done a good job with the design.

57. Rogers again recently told Catheter Connections that its DualCap does not infringe Ivera's intellectual property. While attending the Infusion Nurses Society 2012 Annual Convention and Industrial Exhibition in Las Vegas, Nevada, Rogers told Charity Williams, Catheter Connections Chief Business Officer and In-house Counsel ("Williams"), that he had seen "[Catheter Connection]'s press release" and "did we understand that [he] only had issue with the DualCap Solo" and that he had "absolutely no problem with DualCap" as he "thinks it navigates the IP nicely".

58. Upon information and belief, like most decisions at Ivera, Rogers made the decision not to have any disclaimers when the Ivera non-510(k)-cleared male luer cleansing cap was prominently displayed at trade shows. During the American Association of Critical-Care Nurses, NTI-National Teaching Institute & Critical Care Exposition ("AACN Show") in Orlando, Florida May 22 – 24, 2012, Rogers stood by and watched Williams examine the Ivera non-510(k)-cleared male luer cleansing caps that were on display, take pictures of the same and discuss the same with Ivera's marketing manager.

Ivera is Dumping the Ivera Non-510(k)-cleared Male Luer Cleansing Cap by Providing it at No Charge to Hospitals

59. Upon information and belief, Ivera is dumping the Ivera non-510(k)-cleared male luer cleansing cap into the market. Upon information and belief, in January 2012, Ivera began a six-month product evaluation trial of its Curos at Intermountain Medical Center, Murray, Utah ("IMC"); IMC is a hospital in the 22-hospital system of Intermountain Healthcare ("IHC"). Upon information and belief, Ivera provided numerous Ivera Non-510(k)-cleared Male luer cleansing cap at no charge to IMC and IHC personnel as early as December 2011, with the promise that additional, no charge, or free, Ivera non-510(k)-cleared male luer cleansing caps would be provided for IMC's use for a period of at least three months. Upon information and belief, Ivera is trying to secure an agreement from IHC for the purchase and use of its Curos and the Ivera non-510(k)-cleared male luer cleansing cap and has been aggressively lobbying IHC not to buy Catheter Connections' products.

60. Upon information and belief, the Ivera non-510(k)-cleared male luer cleansing cap has been provided to other hospitals. On May 31, 2012, Ivera employee Kauper did a sales presentation and provided the Ivera non-510(k)-cleared male luer cleansing cap at no charge to personnel of South Miami Hospital in South Miami, Florida. Upon information and belief, Kauper did not provide any information, orally or in writing, about the FDA-clearance status of the Ivera Non-510(k)-cleared Male luer cleansing cap.

Ivera is Urging its Current Customers and Prospects To Buy the Ivera Non-510(k)-cleared Male Luer Cleansing Cap

61. Upon information and belief, Ivera has approached each of its current customers to notify each such customer of the "soon-availability" of Ivera non-510(k)-cleared male luer cleansing cap and to urge it buy such medical device and not consider purchasing the DualCap. Upon information and belief, Ivera has also approached prospective customers like the VA Hospital in Reno, Nevada promising them in November 2011 that the Ivera non-510(k)-cleared

male luer cleansing cap was expected to be ready to use in early Spring [2012] so they should hold off on evaluating DualCap.

Ivera's Improper Use of Litigation

62. On April 18, 2012, Ivera sued Catheter Connections alleging patent infringement of two of its patents. Ivera v. Catheter Connections, 3:12-cv-0954-H (WVG) (S.D. Ca.).

63. Prior to instituting suit, Ivera had repeatedly advised Catheter Connections that it did not infringe its patents and that Catheter Connections had "navigated the IP nicely". Ivera, prior to filing suit, provided no cease and desist demand, no letter, no phone call, not even a whisper that it believed there was infringement of any of its claims in its patents.

64. Ivera has a lengthy history of filing suits against its competitors. According to publicly available information, to date, Ivera has filed multiple lawsuits against its competitors in numerous State and Federal Courts (See Exhibit I for table of the lawsuits).

65. Upon information and belief, Ivera and its contingency fee attorney are fully aware that Ivera's patents are not infringed by Catheter Connections and suit was filed for improper purposes, including but not limited to interfering with Catheter Connections market penetration, market traction, financings, and business focus. Upon information and belief, the litigation was filed to coerce a license from Catheter Connections to the '825 patent covering the male luer technology which Ivera is infringing.

66. Upon information and belief, Ivera sued in Southern District of California to cause Catheter Connections undue burden and expense, knowing full well that Catheter Connections' evidence relevant to the issues of non-infringement, anticipation, obviousness, claim construction and (if applicable) damages is in Utah, and that all employees and all third-party witnesses reside and work in Utah (except one that splits time between Catheter Connections' offices in Salt Lake City and a home office located in Orange County, California), and all are not within the subpoena power of the Southern District Court of California.

67. Upon information and belief, Ivera has forum shopped in the past, by filing suit in

the Eastern District of Texas against Hospira, Inc. and Excelsior Medical Corporation, knowing its contacts with that forum ─ one regulatory person ─ were tenuous. In the proceeding against Hospira, Case No. 6:10-cv-545 (E.D.Tex., 10.13.10), Ivera disingenuously and unsuccessfully argued against the motion to transfer out of the Eastern District of Texas.

Count One

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

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

69. At the AACN Show, which took place on May 22-24, 2012, (and after the May 8, 2012 grant of U.S. Patent 8,172,825), Defendant had made, used, and demonstrated its non-510(k)-cleared male luer cleansing caps as shown in the photograph reproduced in paragraph 26, which caps and associated demonstrations infringe the '825 Patent.

70. Approximately 7,000 critical care clinicians (primarily nurses) attended the AACN Show.

71. As can be seen from the photograph in paragraph 26 above, Defendant's display at the AACN Show included a method of disinfecting a male luer connector of the type including a post having a lumen through which fluid flows, and included providing a male-disinfecting cap including a receiving portion having a sidewall defining a chamber into which the post of the male luer connector can be received; a biasing member disposed in the chamber; a sealing member disposed in the chamber; and an antiseptic agent disposed in the chamber; and moving the cap in relation to the male luer connector so that (i) the post is received into the chamber, (ii) the biasing member urges the sealing member toward the post to cover the lumen and maintain the sealing member against the lumen, and, (iii) while the sealing member covers the lumen so as to inhibit at least the antiseptic agent from entering the lumen, at least a portion of the antiseptic agent is caused to come into contact with the post.

72. At the AACN Show, there was no literature or signage with a disclaimer about the lack of 510(k)-clearance for Defendant's non-510(k)-cleared male luer cleansing caps or that the caps were not "for sale" in the US.

73. Defendant's marketing manager stated that the Defendant's non-510(k)-cleared male luer cleansing caps would be available this summer because a 510(k) application had been submitted. Upon information and belief, Defendant is telling everyone with whom it discussed the matter at the AACN Show, that Defendant would soon have a 510(k)-cleared male luer cleansing cap and to use Defendant's male luer cleansing caps instead of the 510(k)-cleared cap of Plaintiff.

74. This display and demonstration by Defendant at the AACN Show constituted an act of direct infringement of the '825 Patent under 35 U.S.C. §271(a).

75. Upon information and belief, Defendant's infringement of the '825 Patent has been deliberate, willful, and with full knowledge of the '825 Patent because Rogers acknowledged that he had seen Plaintiff's press release relating to the '825 Patent.

76. Upon information and belief, Defendant's infringement of the '825 Patent has continued with Defendant's hospital demonstrations of the non-510(k)-cleared male luer cleansing caps as described herein. Plaintiff has 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.

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

Count Two

Violation of §43 of the Lanham Act – 15 U.S.C. §1125a

78. The preceding paragraphs of this complaint are incorporated and reasserted herein.

79. At all relevant times, Plaintiff has been engaged in the business of manufacturing and marketing to the medical community. Plaintiff's key product is DualCap.

80. Plaintiff is the only company currently legally providing a cap for cleansing the male luer at the end of the IV tubing to the medical community that disinfects and protects the male luer from contamination of microbes that cause CRBSI and CLABSI. Plaintiff has enjoyed this position by virtue of its proprietary technology as well as clearance from the United States FDA to market DualCap in the United States for protection and disinfection of the male luer. Such clearances are legally required to market such a medical device in the United States.

81. Plaintiff has invested, and continues to invest, significant time, money, and other resources in developing, improving and refining DualCap.

82. Beginning at least as early as October 2011, Ivera has, in interstate commerce promoted, sold, prepared or offered to sell, the Ivera non-510(k)-cleared male luer cleansing cap for the protection and disinfection of the male luer.

83. Beginning at least as early as October 2011, Ivera has represented that the Ivera non-510(k)-cleared male luer cleansing cap will be 510(k)-cleared "soon", and that it will be cheaper than Plaintiff's DualCap.

84. The representations in paragraphs 28, 35-44, 61, and 83 above regarding the availability of the Ivera non-510(k)-cleared male luer cleansing cap are false and untrue and are likely to deceive the public because Ivera has no 510(k)-clearance of the Ivera non-510(k)-cleared male luer cleansing cap and cannot possibly accurately predict a clearance date.

85. Ivera made the above alleged false descriptions and representations knowing at all times that they were false and untrue and that there was no factual basis therefor.

86. Ivera's false descriptions and representations have confused and misled, and will continue to confuse and mislead, a substantial number of persons who receive these descriptions and representations believing the non-510(k)-cleared male luer cleansing cap is available, is 510(k)-cleared, and has the qualities and attributes as described.

87. These false descriptions and representations are not forward-looking statements of opinion, they are intentional misrepresentations.

88. By the actions alleged herein, Defendant has violated §43(a), 15 U.S.C. §1125(a), by using false or misleading descriptions and representations of facts in commercial advertising or promotion in connection with goods in interstate commerce.

89. By telling prospective purchasers that Ivera's non-510(k)-cleared male luer cleansing cap would be available soon, Ivera is attempting to and might have succeeded in persuading customers not to buy DualCap, which was already available, leaving them open to consider and possibly purchase Ivera's competing product later.

90. By reason of Defendant's acts alleged herein, Plaintiff has and will suffer damage to its business, reputation and good will and the loss of sales and profits Plaintiff would have made but for Defendant's acts, all to Plaintiff's damage in an amount in excess of $75,000.

91. By reason of the foregoing, defendant has been improperly and unjustly enriched at the expense of Plaintiff in an amount not as yet ascertained, in a sum to be proven at trial, so that Defendant can make appropriate restitution to Plaintiff, in excess of the minimum jurisdiction of this Court.

92. Defendant threatens to continue to do the acts complained of herein, and unless restrained and enjoined, will continue to do so, all to Plaintiff's irreparable damage. It would be difficult to ascertain the amount of compensation which could afford Plaintiff adequate relief for such continuing acts, and a multiplicity of judicial proceedings would be required. Plaintiff's remedy at law is not adequate to compensation it for the injuries threatened.

Count Three

Unfair Truth in Advertising Act (Utah Code Ann. § 13-11a-3)

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

94. Under the FDCA, a medical device must be "approved" or "cleared" by FDA prior to its introduction into interstate commerce. Otherwise, the device is deemed "adulterated" and/or "misbranded".

95. Medical devices are approved for marketing under a premarket approval application. FDCA § 515. Medical devices are cleared for marketing as "substantially equivalent" to a lawfully marketed "predicate device" under a premarket notification submission (a "510(k) notification") FDCA §§ 519(k), 513(i).

96. As part of the FDA's approval and clearance process, the manufacturer must submit data or information to the FDA to support the safety and effectiveness of the device for its "intended use" in the intended patient population as stated in the proposed labeling. FDCA §§ 513(i)(1)(A) &(E)(510(k)), § 55 (d)(2)(PMA).

97. Under the FDCA, a device is "misbranded" if it lacks a 510(k) for the use, a 510(k) is needed and the device is introduced into interstate commerce, or if the labeling or advertising is "misleading". A device is "adulterated" if it lacks a PMA for the use, and a PMA is required. FDCA § 502.

98. Section 513(f)(1) of the FDCA automatically classifies a newly marketed device into Class III (thus needing PMA) unless it is within a type of device that has been classified in Class I or II, and is substantially equivalent to another device within such type. The newly marketed device remains in automatic Class III status "until the effective date of an order" by the FDA classifying it in Class I or II (i.e., a 510(k) clearance). Accordingly, any device shipped in commerce before the sponsor has received the 510(k) clearance order is charged by FDA as an illegal Class III device that has no approved PMA.

99. Section 201 of FDCA provides:

> In determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. 21 U.S.C. § 321(n)**.**

100. The FDA governs the allowed promotion of medical devices before and after clearance or approval. The FDA has special rules applicable to trade show promotion for medical devices. The FDA's current policy is:

> Although a firm may advertise or display a device that is the subject of a pending 510(k) – in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device – a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use". Compliance Policy Guide (CPG) §300.600, issued 7.7.78, reissued 10.1.80, 9.24.87

101. Trade show disclaimers are standard in the industry. Where a device is the subject of a pending 510(k) premarket notification to the FDA, typical disclaimers are those set forth in paragraph 26 above. Indeed, for some trade shows, exhibitors are required by the trade show to make standard disclaimers in order to exhibit.

102. Ivera failed to display disclaimers at the trade shows when it promoted and showed the Ivera non-510(k)-cleared male luer cleansing cap, which misleads and deceives the end-user into believing it may be cleared, that it is in compliance with FDA regulations, and that, like Plaintiff's DualCap, it is available for purchase.

103. Upon information and belief, with the exception of discussions with Catheter Connections representatives and employees, Ivera did not orally advise those attending the trade shows where its non-510(k)-cleared device was displayed of any disclaimers.

104. Upon information and belief, many potential end-users at the trade shows where Ivera displayed its non-cleared FDA cap may have reasonably believed that it was for sale in the

United States and that Ivera was prepared to take orders that might result in contracts for the sale of the device. Moreover, upon information and belief, such end-users would have no idea why the Ivera non-510(k)-cleared male luer cleansing cap was not 510(k)-cleared, such as whether additional studies were required by FDA, whether FDA has safety and efficacy concerns, whether FDA has doubts about the devices claimed substantial equivalence to the predicate device, or whether FDA intends to require a PMA instead of a 510(k).

105. Upon information and belief, Ivera has knowledge of established FDA law and policy regarding the promotion and sale of the Ivera non-510(k)-cleared male luer cleansing cap.

106. While there is no private right of action to sue to enforce FDCA, including its seizure, injunctive, monetary, and criminal penalties for violations, these laws reflect standard, acceptable practices in promoting, offering to sell, and advertising a medical device that has not received FDA premarket clearance. Upon information and belief, failure to follow these laws and policies is misleading and confusing to the end-users, many of whom are not familiar with the FDCA.

107. Based on the foregoing conduct, Ivera is using in commerce false, deceptive, or misleading statements, representations, and descriptions of fact.

108. Ivera's conduct causes the likelihood of confusion or misunderstanding as to its legal right to introduce Ivera's non-510(k)-cleared device into interstate commerce, and its ability to take orders or be prepared to take order that might result in contracts for sale of the device. See Utah Code Ann. § 13-11a-3(b).

109. Ivera's conduct has caused a likelihood of confusion or misunderstanding as to the certification of its goods.

110. Ivera's conduct has disparaged Plaintiff's DualCap by false or misleading representations of fact.

111. Ivera's conduct causes comparisons between its own sale or discount price for the Ivera non-510(k)-cleared male luer cleansing cap and DualCap without clearly and

conspicuously disclosing that fact.

112. Plaintiff's DualCap contains two disinfectant caps – one for the male luer and one for the LAV. Ivera's price comparisons between Ivera's non-510(k)-cleared male luer cleansing cap and DualCap are comparisons between non-identical goods, yet the dissimilar aspects have not been clearly and conspicuously disclosed in its advertisements or other promotions, or discussions with the end user.

113. Plaintiff followed all FDA requirements for the clearance of its DualCap System, which is cleared by three 510(k) notifications: K093229, K112985, and K113842. Ivera's conduct is unfair to Plaintiff, who at significant time, resources and effort obtained the required 510(k)-clearance to introduce DualCap into interstate commerce.

114. As a result of Ivera's conduct, and given the likelihood of irreparable harm to Plaintiff resulting from this conduct, Plaintiff is entitled to preliminary and permanent injunctive relief enjoining Ivera and its officers, agents, and employees, together with all persons acting in concert with them, from engaging in unfair or deceptive trade practices.

115. As a result of Ivera's conduct, Plaintiff is entitled to an award of its actual damages due to the unfair or deceptive trade practices, statutory damages, costs, attorneys' fees, and pre- and post-judgment interest. See Utah Code Ann. §13-11a-4.

Count Four

Common Law Unfair Competition

116. The preceding paragraphs of this complaint are incorporated and reasserted herein.

117. Ivera is a much larger company than plaintiff, and its dollars in sales and its number of employees far exceeds those of Plaintiff.

118. Plaintiff's male luer cleansing cap is unique, proprietary and patented and Plaintiff has invested significant time, resources, and effort into developing its male luer cleansing cap, which hospitals widely-recognize as being Plaintiff's idea.

119. Ivera committed the above-mentioned acts in bad faith, with the intent of unlawfully and unfairly competing with Plaintiff and trading off of Plaintiff's name, goodwill, and reputation.

120. Plaintiff has been, and continues to be, irreparably harmed by the conduct of Ivera.

121. Plaintiff is entitled to preliminary and permanent injunctive relief enjoining Ivera and its officers, agents, and employees, together with all persons acting in concert with them, from engaging in these unfair acts of competition.

122. Plaintiff has also been damaged by Ivera's conduct, in that it has lost sales and customers due to Ivera's misbranded and infringing FDA non-cleared product.

123. Plaintiff is entitled to an award of actual damages in an amount to be proven at trial.

124. Ivera has engaged in these activities knowingly, willfully, and with actual malice. As a result, Plaintiff is entitled to an award of actual and punitive damages in an amount to be proven at trial.

Count Five

Utah Unfair Practices Act (Utah Code Ann. § 13-5-1 et seq.)

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

126. Ivera is engaged in business within the State of Utah.

127. Ivera advertises the non-510(k)-cleared male luer cleansing cap to clients in Utah.

128. Ivera is not prepared to supply the non-510(k)-cleared male luer cleansing cap to clients in Utah.

129. Ivera's conduct in this regard violates Utah Code Ann. §13-5-8.

130. Ivera's conduct in this regard has damaged Plaintiff and should be enjoined under Utah Code Ann. §13-5-14.

131. Plaintiff is also entitled to three times the amount of its actual damages or $2,000.00, whichever is greater, plus court costs under Utah Code Ann. §13-5-14.

Count Six

Utah Unfair Competition Act (Utah Code Ann. § 13-5a-101 et seq.)

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

133. As previously pled herein, Ivera is participating in an intentional business act or practice that is unlawful and unfair, which act or practice leads to a material diminution in value of intellectual property; and involves infringement of the '825 Patent. This intentional business act or practice does not relate to the departure and hiring of an employee by a competitor.

134. Ivera's conduct in this regard violates Utah Code Ann. §13-5a-102.

135. Ivera's conduct in this regard has damaged Plaintiff in an amount to be determined at trial, which damages should be awarded to Plaintiff under Utah Code Ann. § 13-5a-103(1)(b)(i).

136. For Ivera's conduct in this regard, Plaintiff should be awarded its costs and attorney fees in this regard under Utah Code Ann. § 13-5a-103(1)(b)(ii).

137. If the court determines that the circumstances are appropriate, punitive damages should be awarded to Plaintiff for Ivera's conduct in this regard under Utah Code Ann. § 13-5a-103(1)(b)(iii).

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for judgment against Defendant as follows:

1. 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 '825 Patent of Plaintiff.

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 engaging in false or misleading promotion of its non-510(k)-cleared device.

3. For an order requiring Defendant to correct any erroneous impressions persons may have derived concerning Defendant's or Plaintiff's competing products.

4. That Defendant be adjudged to have violated 15 U.S.C. §1125(a) by unfairly competing against Plaintiff by using false, deceptive or misleading statements of fact regarding Plaintiff's products.

5. That Defendant be adjudged to have violated 15 U.S.C. §1125(a) by unfairly competing against Plaintiff by using false, deceptive or misleading statements of fact regarding Defendant's products in comparison to Plaintiff's products.

6. That Defendant be adjudged to have violated Utah's Unfair Practices Act, UCA §13-5-1 *et seq*. Ivera's conduct in this regard has damaged Plaintiff and should be enjoined under Utah Code Ann. §13-5-14, and for which Plaintiff is entitled to three times the amount of its actual damages or $2,000.00, whichever is greater, plus court costs under Utah Code Ann. §13-5-14.

7. That Defendant be adjudged to have violated Utah's Unfair Practices Act, UCA §13-5a-101 *et seq*., for which damages should be awarded to Plaintiff under Utah Code Ann. § 13-5a-103(1)(b)(i), costs and attorney fees under Utah Code Ann. § 13-5a-103(1)(b)(ii), and if the court determines that the circumstances are appropriate, punitive damages under Utah Code Ann. § 13-5a-103(1)(b)(iii).

8. That Defendant be adjudged to have violated Utah's Truth in Advertising Act, UCA §13-11a-1 *et seq*.

9. That Plaintiff be awarded damages Plaintiff has sustained in consequence of Defendant's violations of Section 43(a) of the Lanham Act, 15 U.S.C. §1125.

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

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

12. For costs of court.

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

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues properly triable by jury.

Dated: June 5th, 2012

Respectfully Submitted,

By: /s/ Vicki E. Farrar
VICKI E. FARRAR
Attorney for Plaintiff
CATHETER CONNECTIONS, INC.