H. Dickson Burton (4004)
hdburton@traskbritt.com
Edgar R. Cataxinos (7162)
ERCataxinos@traskbritt.com
Andrew A. Hufford (14207)
aahufford@traskbritt.com
TRASKBRITT, P.C.
P.O. Box 2550
230 South 500 East, Suite 300
Salt Lake City, Utah 84110
Tele: (801) 532-1922

Vicki E. Farrar (7716)
vfarrar@cathconn.com
2455 E. Parleys Way, Suite 150
Salt Lake City, Utah 84109
Telephone: (435)729-9397

Attorneys 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 INFRINGEMENT** 2. **VIOLATIONS OF LANHAM ACT** 3. **UTAH UNFAIR COMPETITION** 4. **CALIFORNIA UNFAIR COMPETITION** 5. **UNFAIR COMPETITION** 6. **INTENTIONAL INTERFERENCE WITH ECONOMIC RELATIONS** 7. **UTAH TRUTH IN ADVERTISING ACT** 8. **UTAH UNFAIR PRACTICES ACT** **Case No. 2:14cv00070-DBP** **Magistrate Judge Dustin B. Pead** **JURY TRIAL DEMANDED**

NATURE OF THE ACTION

Plaintiff Catheter Connections, Inc. ("Catheter Connections" or "Plaintiff"), by and through its counsel, brings this complaint against Defendant Ivera Medical Corporation ("Ivera" or "Defendant"). This is a civil action for patent infringement, violation of § 43 of the Lanham Act, and unfair competition under Utah and California law.

Plaintiff Catheter Connections is a Salt Lake City, Utah, company founded by two nurses, James Mercer and Michael Howlett ("the Nurses"), who in 2006 conceived of a revolutionary idea for disinfecting *both* ends of an IV infusion line (the "male" luer and "female" luer access valve) using disinfectant caps. Despite a clear risk of contamination, clinicians had no safe or effective way to disinfect the male luer until the nurse inventors conceived of the "male cap." Their idea was further developed in cooperation with the University of Utah Research Foundation ("UURF"), and in 2012 Catheter Connections became the first company to obtain both patent protection *and* FDA clearance for disinfecting male luers. In addition, U.S. Patent No. 8,641,681 issued on February 4, 2014, and U.S. Patent No. 8,647,308 will issue on February 11, 2014 (collectively, "the Asserted Patents").[1] Both patents are directed to male caps and systems of medical luer connector caps. Catheter Connections is the legal owner of the Asserted Patents, which are valid and enforceable.

Defendant Ivera is a much larger manufacturer of IV-related products. Rather than investing in its own research and development, Ivera has chosen to shortcut this exploding market opportunity by stealing Catheter Connections' patented male cap. Ivera's motivation is clear: Catheter Connections' male cap is the missing link in a complex puzzle to assure patient

[1] Upon issuance of U.S. Patent 8,647,308, Catheter Connections will amend its Complaint to include further and appropriate causes of action.

safety during IV infusion. Without the male cap, any attempt at patient protection is incomplete, and a substantial risk of infection remains. Indeed, the male cap defines a new standard of patient care that hospitals—including Ivera's customers—are increasingly realizing.

Ivera is infringing and/or actively inducing others to infringe one or more claims of the Asserted Patents. Ivera is undercutting the price of its male cap to drive Catheter Connections out of the market, while falsely and illegally marketing its male cap as FDA-cleared. Ivera's infringement and tortious conduct have caused Catheter Connections to suffer lost sales, damage to reputation and brand distinction, and price erosion, while undermining the value of Catheter Connections' patents. Catheter Connections seeks injunctive relief and monetary damages.

PARTIES

1. Plaintiff Catheter Connections is a Delaware corporation, with its principal place of business at 2455 E. Parleys Way, Suite 150, Salt Lake City, Utah, 84109.

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 patent laws of the United States, specifically 35 U.S.C. §§ 271, 281, 283, 284 and 285. This Court has subject matter jurisdiction over the patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has diversity jurisdiction over all non-patent infringement claims under 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 claims under 28 U.S.C. § 1338(b). This Court has supplemental jurisdiction over the other pleaded claims under 28 U.S.C. § 1367.

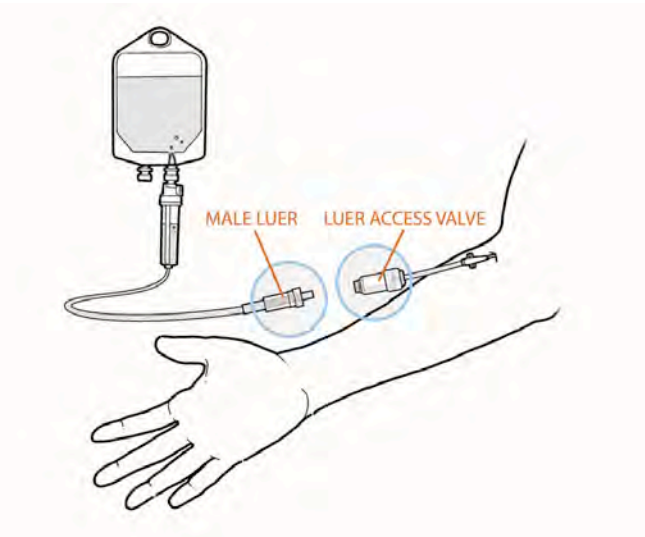
5. This Court has personal jurisdiction over Defendant because, on information and belief, Defendant is engaged in regular and substantial business in the State of Utah and the District of Utah. This court also has personal jurisdiction over Defendant under Utah Code Ann. § 78B-3-205(1)-(2) (2011) because, on information and belief, Defendant transacts business in Utah and contracts to supply services or goods in Utah.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b) because Defendant has committed acts of patent infringement in, and has otherwise regularly conducted or conducts business in the State of Utah and the federal district of Utah. Defendant is deemed to reside in this judicial district within the meaning of 28 U.S.C. § 1391(a).

BACKGROUND

7. Nearly 500,000 people acquire IV catheter-related blood stream infections ("CRBSI") in the United States each year, and up to 25% of these patients die. Hospitals lose billions of dollars in non-reimbursed expenses to treat these infections annually.

8. A typical IV infusion is illustrated below. As shown, one end of the IV line is typically attached to an IV fluid bag, medical equipment or other device and terminates in a "male luer." The other end of the IV line is attached to the patient and terminates with one or



more "luer access valves" ("LAV," "needleless connector," or "female luer"). The LAV can be accessed separately to withdraw or administer fluids or drugs using a needleless syringe, or the LAV can be attached to the male luer to administer fluids, etc. When not in use, the male luer and LAV are typically separated and may be exposed to air and contaminants from the patient or in the room.

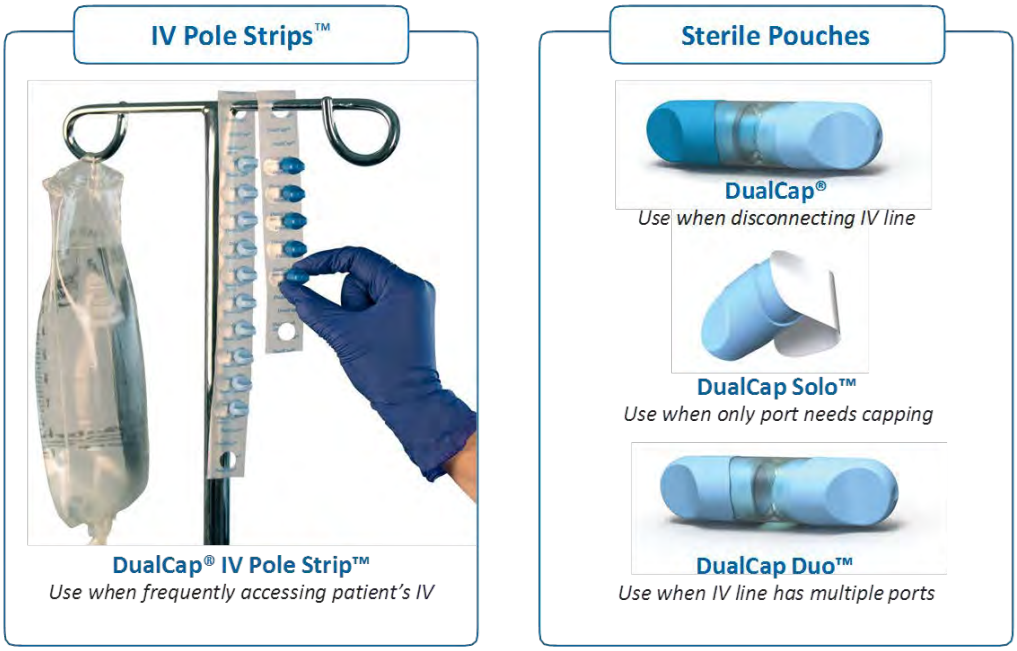
9. Current practice, reflected in the Centers for Disease Control and Prevention (CDC) Guidelines for the Prevention of Intravascular Catheter-Related Infections, "Infusion Nursing Society Standards of Practice," and other guidelines require that the LAV be disinfected prior to use. Nurses commonly scrub the surface of the LAV using an alcohol swab in an attempt to disinfect it before use. There are no similar guidelines or nursing practice recommendations addressing disinfection of the *male* luer, however. Historically, there was no way to disinfect the male luer without risking introduction of a toxic disinfectant (*e.g.*, isopropyl alcohol) into the open fluid pathway that enters the patient's blood. Thus, clinicians generally did not even consider disinfecting the male luer before accessing it in hospitals, infusion centers, or home IV programs.

10. James Mercer (RN, BSN) and Mike J. Howlett (RN, MS, CRNI), highly trained IV nurses working at the Veterans Affairs Hospital in Salt Lake City, recognized the risk presented by a contaminated male luer—a risk the entire industry had ignored. In early 2006, they conceived of a revolutionary idea for protecting both the male luer and the LAV using disinfecting caps. The Nurses then 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, which determined that the Nurses were

entitled to the entire right, title, and interest to the invention. The Nurses then donated the invention and associated rights to the University of Utah Research Foundation.

11. In 2008, the Nurses teamed up with Vicki Farrar, Don Solomon, Ph.D, and Robert Hitchcock, Ph.D, to form Catheter Connections to further develop, engineer, and commercialize the technology. In October, 2008, Catheter Connections received an exclusive license from UURF.[2] Catheter Connections has since developed and commercialized the DualCap System™ – five disinfectant cap products shown below in paragraph 12. The first product on the market, DualCap®, consists of two disinfecting caps nested together into a single device to help prevent infections.

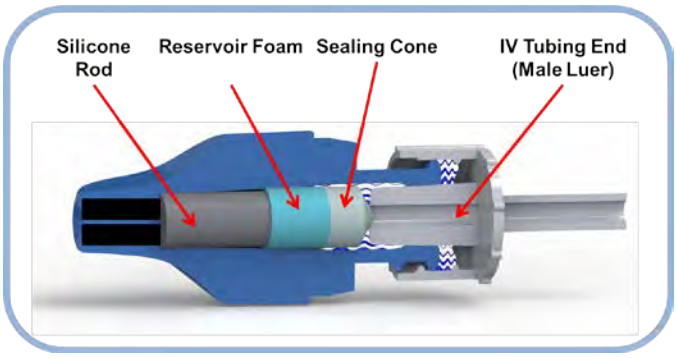
12. The dark blue cap in DualCap® (sold in a pouch and on IV Pole Strips™) is for disinfection and protection of the male luer. The light blue cap in each configuration are for disinfection and protection of the (female) LAV when disconnecting an IV line.



[2] In November 2013, UURF terminated the exclusive license and assigned all jointly-developed intellectual property to Catheter Connections.

13. 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.

14. 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.

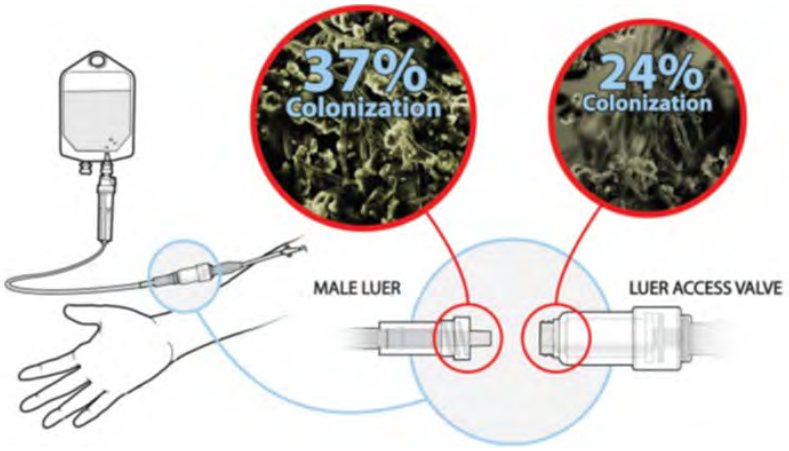


15. The DualCap™ System fulfills an unmet need in healthcare. Not only does it protect and disinfect both ends of the infusion line, it also helps standardize nursing care and makes compliance monitoring easy. Nurses now have the tools they need in a wide variety of packaging configurations to keep patients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

Clinical Evidence - Catheter Connections' Male Cap Works

16. 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]."

17. 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.

Substantial Time and Resources are Required for FDA 510(k) Clearance

18. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 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 the FDA if the manufacturer can show 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 patients from unsafe products.

19. In order to legally market and sell its products, Catheter Connections invested substantial time, research and money into studies to obtain 510(k) clearance for each product. It conducted extensive testing to show that its male luer disinfecting technology was safe and effective. In addition to standard biocompatibility and sterility requirements, Catheter Connections also had to demonstrate that no isopropyl alcohol enters the fluid pathway of the IV male luer connector. Catheter Connections followed all FDA requirements to gain clearance for this and all of its IV catheter-related products.

GPOs and the Medical Market

20. Group purchasing organizations ("GPOs") are a distinct feature of the medical market in which groups of hospitals join together to combine their purchasing power and enter into contracts with medical device suppliers for discounted prices. GPOs are in essence "agents" for their group hospitals, researching products and using group members' combined power to

negotiate discounts with prospective vendors. Nearly all U.S. hospitals use GPOs for procurement of medical equipment and supplies. Once a vendor is on a GPO contract, member hospitals are generally required to purchase products "on contract" from that vendor unless a product constitutes a "new technology," not otherwise available on contract. Securing one GPO contract thus dramatically impacts a company's economic prospects.

ALLEGATIONS

21. Ivera is a large manufacturer and supplier of IV-related medical products and a direct competitor of Catheter Connections. Instead of pursuing independent product development, Ivera has chosen to copy Catheter Connections' innovative technology and to file a nationwide string of lawsuits against Catheter Connections and its distributors in an attempt to drive them out of this exploding market.[3] Ivera's motivation is clear: the LAV (female) cap is a relatively simple and low-tech device, with many players already competing in the market. But the LAV cap is incomplete without an effective male cap partner. The company that controls the male cap market can thus gain a critical marketplace advantage at the very outset of the industry.

Curos X10 Prototype Male Cap

22. Catheter Connections was the first company to bring a cap to the market that was effective for disinfecting the male luer. For a time, it was the only player in the market. Realizing the importance of getting a male cap on the market quickly, Ivera designed a series of at least

[3] *Ivera Medical Corporation v. Catheter Connections, Inc*., 12-cv-0954 (S.D. Ca. 4.18.12); *Ivera Medical Corporation v. Catheter Connections, Inc.*, 12-cv-1587 (S. D. Ca. 6.26.12); *Ivera Medical Corporation v. New Alliance of Independent Medical Distributors, Inc, et. al*, 13-cv-00387 (W.D.Tx, 5.10.13) (transferred to S.D. Ca. 13-cv-02607); *Ivera Medical Corporation v. New England Medical Specialties, Inc.*, 13-cv-00086 (D.Ct. 5.23.13) (transferred to S.D. Ca. 13-cv-02063); *Ivera Medical Corporation v. The Bimeco Group*, 13-cv-00086 (N.D. Ga. 5.23.13) (transferred to S.D. Ca. 3:13-cv-02063); *and Ivera Medical Corporation v. Catheter Connections, Inc*., 13-cv-02452 (S.D. Ca. 1.2.14).

eight prototype male caps ("DiPerno Design," X7, X8, X 9, X10, X11, X12 and X13) using Catheter Connections' male cap and published patent applications as a template.

23. Upon information and belief, beginning at least as early as December 2011, Ivera began providing free samples of its prototype male caps to, among others, Intermountain Medical Center in Murray, Utah, part of the 22-hospital system of Intermountain Healthcare . Ivera also provided free samples and promoted its prototype male caps to personnel at South Miami Hospital in South Miami, Florida. Upon information and belief, Ivera represented to prospective customers that it would soon have 510(k) clearance for its male cap, and encouraged these prospective customers not to evaluate Catheter Connections caps until then.

24. On April 17, 2012, Ivera submitted a 510(k) premarket application for its male cap. Ivera listed Catheter Connections' DualCap® as a "predicate" device in its 510(k) application (certifying that its male cap was "substantially equivalent" to the DualCap®). Upon information and belief and Ivera's representations, all tests supporting the Ivera male cap 510(k) application were based on testing conducted on the X10 prototype.

25. Catheter Connections is also the owner by assignment of U.S. Patents 8,172,825 (issued May 8, 2012); 8,231,587 (issued July 31, 2012); and 8,328,767 (issued December 11, 2012), with claims encompassing male disinfecting caps and methods for disinfecting male luer connectors. On June 5, 2012, Catheter Connections was forced to file a complaint for infringement of the '825 Patent and false advertising against Ivera in the United States District Court for the District of Utah.[4] Later that year, Catheter Connections filed similar complaints for

[4] *Catheter Connections v Ivera Medical Corp*., 2:12-CV-00531-DN (D. Utah, Central Division), filed June 5, 2012, for patent infringement, false advertising, unfair competition and violation of Utah laws concerning competition, unfair practices and truth in advertising. Amended Complaint, Catheter Connections, Inc. and University of Utah Research Foundation v Ivera, filed August 7, 2012. Consolidated with '587 case below in November, 2012. This

infringement of its '587 Patent[5] and '767 Patent in the same district.[6] These complaints (collectively, the "related male cap litigation") were based on Ivera's making, using, selling, offering for sale, and/or importing into the United States, an Ivera device which infringed one or more claims of the '825, '587 and/or '767 Patents – specifically, the Curos/X10 prototype or Curos/X13.

26. On July 2, 2013, in a hearing for the related male cap litigation, Ivera admitted that it studied Catheter Connections' patents and claimed to have "worked around" Catheter Connections' patents. However, even before that time, the applications for the Asserted Patents were published and available to the public, including Ivera.

27. Upon information and belief, Ivera regularly monitors pending Catheter Connections' patent applications in the U.S. Patent and Trademark Office and is fully aware of their current status, including when they publish, the scope of any allowed claims, and when they are going to issue as patents. This is true of each of the Asserted Patents.

IVERA'S INFRINGING PRODUCTS

Curos Tips™/X13 Male Caps

28. Ivera continued to modify its X10 prototype. The result is the Curos Tips™ male cap (internally called the X13). A photograph of the Curos Tips™/X13 male cap and a longitudinally-sectioned Curos Tips™/X13 male cap are shown below. Ivera's Curos Tip™/X13 is an unsuccessful design-around of Catheter Connections' prior patents. This design-around,

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case was stayed for 60 days so the parties could engage in settlement talks; the stay ended December 6, 2013, with resolution of all claims except the infringement claim.

[5] *Catheter Connections and University of Utah Research Foundation v. Ivera Medical Corp.*, 2:12-CV-00748 (D. Utah, Central Division), filed July 31, 2012, for patent infringement. Amended Complaint filed October 5, 2012. This case was dismissed without prejudice after settlement.

[6] *Catheter Connections and University of Utah Research Foundation v. Ivera Medical Corp.*, 2:12-CV-01127-PMW (D. Utah, Central Division), filed December 11, 2012, for patent infringement. This case was dismissed without prejudice after settlement.

which included the elimination of a foam pad and other design modifications to the X10, has resulted in an Ivera male cap that is functionally inferior both to Ivera's X10 prototype *and* Catheter Connections' patented male cap.

Curos Strip Dispensers

29. Ivera packages its LAV caps (marketed as the "Curos® Port Protectors") on a dispenser called the Curos Strip that can be hung from an IV pole, similar to Catheter Connections' DualCap® IV Pole Strips™. Photographs of Ivera's Curos Strip are shown below:

30. After Ivera began selling the Curos Tips™/X13 male cap and Curos Strip, Catheter Connections' Asserted Patents issued, with broader claims than the '825, '587 and '767 Patents. Ivera has not obtained Catheter Connections' permission or license to make, use, sell, offer for sale, or import into the United States any of the technology embodied in the Asserted Patents.

IVERA'S "BAIT AND SWITCH" ON THE FDA

31. Ivera used the Catheter Connections' DualCap® as a "predicate" device in its 510(k) application for the Curos Tips™ product (certifying to the FDA that its male cap was "substantially equivalent" to the DualCap®). However, upon information and belief, all testing and specifications used in that application were based on the Ivera X10 prototype, not the X13-based device that is now being marketed by Ivera.

32. Ivera received 510(k) clearance (K121171) from the FDA for its "Curos Tips™" male cap on November 26, 2012, and proceeded to promote this clearance to prospective customers, while continuing to package and sell the non-cleared Curos Tip™/X13.

33. Thus, Ivera has illegally placed the Curos Tips™/X13 on the market without FDA premarket notification to market that cap. Instead of submitting a new 510(k) premarket notification for the newer Curos Tips™/X13, Ivera is relying on its premarket notification for the X10, which is an earlier and structurally distinct prototype.

34. Because the Curos Tips™/X13 raises potential safety and efficacy issues, Ivera cannot rely on the 510(k) premarket clearance previously granted for its X10, and Ivera has no valid 510(k) premarket clearance for the marketing and sale of its Curos Tips™/X13.

35. While there is no private cause of action to enforce the FDA's medical device 510(k) clearance regulations, Ivera's "bait and switch" tactics with its own 510(k) have harmed

Catheter Connections' ability to compete on a level playing field in a market that was largely created by Catheter Connections' own innovations, while cheating the FDA and threatening consumer safety and confidence in the very products that should be promoting improvements in public health.

Ivera is Misrepresenting its Curos Tips™/X13 to Consumers

36. Ivera contends that the X10 was never offered for sale, but it was shown at trade shows and provided to hospitals and sales representatives during testing.

37. Ivera represents to existing and potential customers that Curos Tips™/X13 is a cheaper but equivalent version of Catheter Connections' male cap. In its advertising, Ivera represents that its alcohol stays on the outside of the luer and does not get into the patient's infusion line, thus implying it does not get into the patient's bloodstream: "For effective disinfection, Curos Tips™ are designed to keep the alcohol precisely where it is needed – on the exterior of the male luer." This is false. It is indisputable that the alcohol in Curos Tips™ leaks into the infusion line, which Ivera has acknowledged is clinically unacceptable.

38. Ivera's actions cause confusion in the marketplace by misleading customers (including hospitals, clinics, home care providers, and others) into believing that they are getting a male cap from Ivera that functions like Catheter Connections' product, at a cheaper price.

39. Catheter Connections devotes significant resources – technical research and development – to develop cutting edge products with a superior look, feel and functionality from its competitors. Ivera's deliberate misrepresentations and efforts to equate its own inferior products with Catheter Connections' products threaten to undermine Catheter Connections' market share, brand identity, and reputation.

Ivera's Curos Tips™/X13 Male Caps Raise Potential Safety and Efficacy Issues

40. Aside from the question of infringement, the design and operational changes to Curos Tips™/X13 raise potential safety and efficacy issues requiring at least a new 510(k) premarket notification.

41. Significant differences between the X10 and X13 include a change of the control mechanism and/or key operating principle of how Ivera's male cap: 1) dispenses the alcohol to disinfect the male luer connector to which it is attached; and 2) effectively diminishes the flow of alcohol to the male luer to prevent alcohol from contaminating the lumen of the IV line.

42. Ivera eliminated the foam pad in pre-production prototypes in a failed attempt to design around Catheter Connections' earlier '587 and '767 Patents.

43. Because of its missing foam pad, poor design, and inferior material construction, however, the Curos Tips™/X13 leaks varying amounts of toxic isopropyl alcohol into the patient's infusion line with normal use. This finding has been confirmed in multiple tests, but has so far apparently been ignored by Ivera.

IVERA'S UNFAIR COMPETITIVE BEHAVIOR

44. Only two companies are currently manufacturing male caps in the United States—the innovator, Catheter Connections, and the imitator, Ivera. Until Ivera deliberately and blatantly copied Catheter Connections by creating a functionally inferior male cap, the market for male caps belonged to Catheter Connections.

45. Ivera is a much larger company than Catheter Connections, with significantly more resources and market share. Ivera launched a disinfecting cap for the LAV two years before Catheter Connections came to market with its innovative male cap, giving Ivera a built-in customer base for its Curos Tips™ knock-off.

GPO Contracts

46. Until Ivera copied Catheter Connections' male cap and promoted its infringing knockoff product to the GPOs, member hospitals were free to purchase Catheter Connections' male cap under a "new technology" exception. Because Ivera now has an infringing male cap, however, their male cap is now covered by some of Ivera's GPO contracts and member hospitals are generally required to purchase Ivera's male cap. The inferiority of Ivera's cap and the fact that Catheter Connections' owns patents covering that technology are irrelevant to the GPO process, giving Ivera an undeserved and unfair competitive advantage.

47. For example, Provena Mercy Medical Center in Aurora, Illinois, a member of the Premier GPO, was one of Catheter Connections' first customers for the DualCap® product. Provena recently advised Catheter Connections that because Ivera's Curos Tips™ were now on Premier's sole source contract, Provena would no longer be able to buy the DualCap® product from Catheter Connections.

48. Hospitals and GPOs do not have the time, expertise or resources to conduct the testing required to show that Ivera's male cap is functionally inferior to Catheter Connections' male cap, or that Ivera's male cap leaks alcohol into the infusion line. Upon information and belief, Ivera is representing to hospitals that its male cap performance is equivalent to Catheter Connections' male cap. It is not.

49. Upon information and belief, at least three additional GPO bids are expected to occur for disinfecting caps in the first part of 2014, substantially raising the risk that Ivera's ongoing infringement of the Asserted Patents will seriously harm Catheter Connections' ability to compete in the market.

50. Ivera represents itself as a "minority" business and has been awarded GPO contracts on this basis for its LAV cap. GPOs are typically required to offer or participate in programs for minorities. Upon information and belief, Curos Tips™/X13 is now also on several such GPO contracts where Ivera has "minority"/diversity supplier status, including contracts with MedAssets, Novation, and HealthTrust Purchasing Group. Ivera also has a sole source contract with Premier, Inc.

51. To further squeeze Catheter Connections out of the market, Ivera is undercutting the price of Catheter Connections' male cap. Upon information and belief, Ivera is offering its Curos Tips™/X13 male caps to at least some customers near or below its own cost, in an attempt to harm competition and to drive Catheter Connections out of the market.

52. Ivera's infringement and other tortious activity has caused Catheter Connections to lose sales and business opportunities, undermined its reputation as an innovator, and eroded its brand distinction and the price of Catheter Connections' products—not only for its male caps but also for its LAV caps and the DualCap™ product lines.

53. Catheter Connections also faces potential damage to its reputation as a result of sales of Ivera's inferior male cap. Customers are likely to associate Ivera's product with Catheter Connections' patented products, and any reliability issues with Ivera's male cap are likely to forever harm the perceived value of Catheter Connections' product and technology.

54. Competition is healthy, but stealing technology and cheating the FDA is not. Ivera has a long history of suing its competitors and using the Federal courts as its marketing department. There is no doubt of the harm caused by its infringement of the '681 patent and violation of FDA rules that are in place to protect patients from unsafe products. The injury to

Catheter Connections' business is great, so the Court is being asked for the extraordinary remedy of a preliminary injunction to immediately stop Ivera from selling Curos Tips™.

COUNT ONE
Infringement of U.S. PATENT 8,641,681

55. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

56. Catheter Connections is the exclusive owner and assignee of the entire right, title and interest in and to U.S. Patent 8,641,681 (the "681 Patent).

57. The '681 Patent", entitled "Disinfecting Caps for Medical Male Luer Connectors." The '681 Patent was duly and legally issued by the United States Patent and Trademark Office on February 4, 2014.

58. The '681 Patent is valid and enforceable.

59. Ivera has infringed and continues to infringe the '681 Patent by making, using, selling, and /or offering to sell products in the United States, including the Curos Tips™, that embody one or more claims of the patented invention.

60. Specifically, the Curos Tips™ infringe at least claims 1 and 12 of the '681 Patent by incorporating all the elements of "a male-disinfecting cap for disinfecting a male luer-lock connector…" as recited in those claims.

61. Upon information and belief, Ivera's infringement of the '681 Patent has been deliberate, willful, and with full knowledge of the '681 Patent, and Ivera has taken no steps to take the infringing Curos Tips™ off the market.

62. Ivera's activities directly infringe, induce infringement and/or contribute to infringement of at least one claim of the '681 Patent without authority or license from Catheter Connections, and in violation of Catheter Connections' rights, either literally or under the doctrine of equivalents.

63. Ivera's infringing activities entitle Catheter Connections to an award of damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by Ivera, together with interest and costs.

64. Ivera's infringement of Catheter Connections' rights in the '681 Patent is causing Catheter Connections irreparable injury and will cause further irreparable injury unless Defendant is preliminarily and permanently enjoined under 35 U.S.C. § 283.

65. 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 Section 43(a) of the Lanham Act – 15 U.S.C. § 1125(a)

66. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

67. At all relevant times, Catheter Connections has been engaged in the business of manufacturing medical devices and marketing to the medical community.

68. Catheter Connections was the first company to provide a medical device for the disinfection and protection of the male luer connectors used at the end of the IV tubing. This male cap protects patients from the microbes that cause blood stream infections.

69. Catheter Connections has invested, and continues to invest, significant time, money, and other resources in developing, improving and refining its male luer disinfecting cap.

70. Beginning at least as early as December 3, 2012, Ivera has, in interstate commerce, promoted, sold, and offered to sell, Curos Tips™/X13 for the protection and disinfection of the male luer.

71. Beginning at least as early as December 3, 2011, Ivera has represented to consumers, including representatives from hospitals, clinics, the medical supply industry, and

individual consumers, that its Curos Tips™/X13 works as effectively as Catheter Connections' product, but is cheaper.

72. Ivera's representations that Curos Tips™ functions like Catheter Connections' product are false and untrue and are likely to deceive the public because Ivera's cap leaks alcohol into the infusion line.

73. Ivera's false descriptions and representations have confused and misled, and are likely to continue to confuse and mislead, a substantial number of persons who receive these descriptions and representations believing Curos Tips™/X13 does not leak toxic alcohol into the infusion line.

74. Beginning at least as early as November 26, 2012, Ivera has represented and promoted to prospective customers, clinicians, and others in the medical device industry that its Curos Tips™/X13 has 510(k) premarket clearance ("approval") from the FDA, when in fact its 510(k) clearance was obtained for an earlier, different prototype male cap (the X10).

75. These false and deceptive descriptions and representations are likely to influence the purchasing decisions of a substantial segment of Ivera's audience.

76. 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.

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

78. 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.

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

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

81. Unless restrained and enjoined, Ivera is likely to continue to do the acts alleged herein, to Catheter Connections' irreparable harm. It would be extremely difficult, if not impossible, to ascertain the compensation that could afford Catheter Connections adequate relief for these continuing acts. The harmful effects of Ivera's wrongful activity the marketplace and on Catheter Connections ability to compete cannot readily be compensated by money damages alone. A remedy at law is thus not adequate to compensate Catheter Connections for the harm caused by Ivera's continuing wrongful behavior.

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

82. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

83. 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 the value of Catheter Connections' intellectual property, including without limitation, the '681 Patent, and the DualCap™ System.

84. This intentional business act or practice does not relate to the departure and hiring of an employee by a competitor.

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

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

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

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

COUNT FOUR
California Unfair Competition (Cal. Bus. Prof. Code § 17200 et seq.)

89. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

90. Ivera is engaged in business within the State of California.

91. Ivera is participating in an intentional business act or practice that is unlawful and unfair.

92. Ivera is participating in acts of unfair, deceptive, untrue or misleading advertising.

93. Ivera is representing in its advertising and promotions to prospective customers that its Ivera Curos Tips™/X13 have received 510(k) clearance, and do not leak alcohol into the catheter line, when in fact, these representations are deceptive, untrue and/or misleading.

94. Ivera's conduct in this regard violates Cal. Bus. Prof. Code § 17200.

95. Ivera's conduct in this regards significantly threatens or harms competition.

96. Ivera should be enjoined from continuing acts of unfair competition, pursuant to Cal. Bus. Prof. Code § 17203.

COUNT FIVE
Common Law Unfair Competition

97. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

98. Ivera is a much larger company than Catheter Connections, with annual sales revenue and number of employees far exceeding those of Catheter Connections.

99. Catheter Connections' male cap is unique, proprietary and patented. Catheter Connections has invested substantial time, resources, and effort into developing this product, which hospitals widely associate with Catheter Connections.

100. Ivera committed the above-mentioned acts of infringement and other tortious acts in bad faith, with the intent of unlawfully and unfairly competing with Catheter Connections and trading off of Catheter Connections' name, goodwill, and reputation.

101. Catheter Connections has also been damaged by Ivera's conduct, in that it has lost sales and customers due to Ivera's conduct alleged herein.

102. Catheter Connections is entitled to an award of actual damages in an amount to be proven at trial.

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

104. Catheter Connections has been, and will continue to be, irreparably harmed by the conduct of Ivera.

105. Catheter Connections 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.

COUNT SIX
Common Law Intentional Interference with Economic Relations

106. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

107. Catheter Connections had existing or potential economic relations with third parties, including, but not limited to, Provena Mercy Medical in Aurora, Illinois; Kaiser

Permanente San Rafael, in San Rafael, California; and the Durham VA Medical Center in Durham, North Carolina.

108. Ivera intentionally interfered with Catheter Connections' existing and/or potential economic relations.

109. Ivera used improper means to interfere with Catheter Connections' existing or potential economic relations, including deceit and/or misrepresentation.

110. On information and belief, Ivera's marketing has consistently played up the similarities between Catheter Connections' product and its copy, Curos Tips™, even though the products have significant functional and safety differences.

111. In the alternative, Ivera interfered with Catheter Connections' existing or potential economic relations for the improper purpose of injuring Catheter Connections, including but not limited to, depriving Catheter Connections of its intellectual property and driving Catheter Connections out of the marketplace.

112. Ivera's interference with Catheter Connections' existing or prospective economic relations has caused injury to Catheter Connections in an amount to be determined at trial.

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

113. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

114. A medical device must be "approved" or "cleared" by the FDA prior to its introduction into interstate commerce.

115. Ivera represents that Curos Tips/X13 has received FDA 510(k) "approval" or clearance and advertises this through its press releases and other marketing efforts.

116. Ivera fails to advertise that it is the prototype, the X10, that received 510(k) premarket clearance, not the Curos Tips™/X13.

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

118. Upon information and belief, Ivera has knowledge that federal law requires that it submit a new 510(k) for the CurosTips™/X13 before they can be legally marketed.

119. Upon information and belief, end-users, including clinicians, hospitals and general consumers, would not know that Ivera is improperly and unlawfully relying on its 510(k) clearance for the X10 – not the Curos Tips™/X13—to market its male caps and to make its safety and efficacy representations.

120. While there is no private right of action to sue to enforce the FDCA, 21 U.S.C. § 337(a)—including seizure, injunctive, monetary, and criminal penalties for violations— Catheter Connections is not seeking to enforce the FDCA. Instead, it is seeking damages caused by Ivera's unlawful anticompetitive conduct. Even without the FDCA, Ivera's actions are unlawful as it is marketing a product based on false and misleading information.

121. Ivera's conduct has caused a likelihood of confusion or misunderstanding as to the clearance status ("approval") and functionality of its goods.

122. Ivera's conduct causes a likelihood of confusion as to its legal right to introduce Curos Tips™ into interstate commerce, and its ability to take orders or be prepared to take orders that might result in contracts for sale of the device. *See* Utah Code Ann. § 13-11a-3(1)(b).

123. Ivera has disparaged DualCap® by false or misleading representations of fact.

124. Catheter Connections followed all FDA requirements for the clearance of its male cap, which is cleared by two 510(k) notifications: K123967 and K09329. Ivera's conduct is

unfair to Catheter Connections, which, after a significant investment of time, resources and effort obtained the required 510(k)-clearance to introduce its male cap into interstate commerce.

125. Catheter Connections' male cap does not leak alcohol into the infusion line. Ivera's price comparisons between Curos Tips™ and Catheter Connections' product are comparisons between non-identical goods, yet the dissimilar aspects have not been clearly and conspicuously disclosed in Ivera's advertisements or other promotions, or discussions with the end user.

126. Ivera's conduct causes comparisons between its own sale or discounted price for Curos Tips™ and Catheter Connections' male cap without clearly and conspicuously disclosing the functional and safety differences.

127. As a result of Ivera's conduct, Catheter Connections 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.

128. As a result of Ivera's conduct, and given the likelihood of irreparable harm to Catheter Connections resulting from this conduct, Catheter Connections 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.

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

129. The preceding paragraphs are incorporated by reference, as if set forth fully herein.

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

131. Ivera advertises Curos Tips™ to clients in Utah.

132. Ivera advertises that the Curos Tips™ are "designed to keep the alcohol precisely where it is needed—on the exterior of the male luer."

133. Ivera advertises that its Curos Tips™ have received FDA 510(k) premarket clearance.

134. Both of these representations are false.

135. Ivera is not prepared to supply Curos Tips™ as advertised to clients in Utah.

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

137. Ivera's conduct has caused, and continues to cause, injury to Catheter Connections.

138. Catheter Connections 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.

139. Ivera's conduct in this regard has damaged Catheter Connections. Ivera should be enjoined pursuant to Utah Code Ann. § 13-5-14.

PRAYER FOR RELIEF

Wherefore, Plaintiffs prays for judgment against Defendant as follows:

a. That Defendant has infringed one or more claims of the ‘681 Patent.

b. For compensatory and prejudgment interest thereon for Defendant’s acts of infringement of the ‘681 Patent.

c. For temporary, preliminary and permanent injunctive relief prohibiting Defendant, and its officers, directors, agents, servants, or anyone working for, in concert with or on behalf of Defendant from infringing the ‘681 Patent.

d. For immediate preliminary injunctive relief prohibiting Defendant, and its officers, directors, agents, servants, or anyone working for, in concert with or on behalf of Defendant from making, using, selling, offering for sale, or importing into the United States the Curos Tips™ product.

e. 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 Ivera male cap.

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

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

h. That Defendant be adjudged to have violated Utah's Unfair Practices Act, UCA §13-5-1 *et seq.*; that Ivera's conduct in this regard has damaged Catheter Connections;

i. That Defendant should be enjoined under Utah Code Ann. § 13-5-14.

j. That Catheter Connections 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.

k. That Defendant be adjudged to have violated California's Unfair Competition Law, Cal. Bus. Prof. Code § 17200 et seq.

l. That Defendant should be enjoined from continuing acts of unfair competition, pursuant to Cal. Bus. Prof. Code § 17203.

m. That Defendant violated Utah's Unfair Practices Act, UCA §13-5a-101 *et seq.*, for which damages should be awarded to Catheter Connections 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).

n. That Defendant violated Utah's Truth in Advertising Act, UCA § 13-11a-1 *et seq*.

o. That Defendant intentionally interfered with Catheter Connections' present or potential economic relations.

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

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

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

s. For costs of court.

t. Restitutionary relief against Ivera and in favor of Catheter Connections, including disgorgement of wrongfully obtained profits and any other appropriate relief.

u. 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 this 4th day of February, 2014.

/s/ H. Dickson Burton
H. Dickson Burton
Edgar R. Cataxinos
Andrew A. Hufford
TRASKBRITT, P. C.
P.O. Box 2550
230 South 500 East, Suite 300
Salt Lake City, Utah 84110

Attorneys for Plaintiff