Paper No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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IVERA MEDICAL CORPORATION

Petitioner

v.

CATHETER CONNECTIONS, INC.

alleged Patent Owner

Patent No. 8,647,326

PETITION FOR INTER PARTES REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 ET. SEQ.

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CERTIFICATE OF SERVICE 1

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Pat. No. 8,647,326 ("the '326 patent").
1002	Declaration of Dr. Karl Leinsing.
1003	U.S. Pat. No. 8,197,749 ("Howlett '749").
1004	U.S. Application Ser. No. 12/610,033 ("Solomon '033 application").
1005	Provisional App. No. 60/880,541 ("Howlett '541 provisional").
1006	U.S. Published App. No. 2008/0019889 ("Rogers '889").
1007	Curos Strip Information.
1008	U.S. Pat. No. 7,780,794 to Rogers ("Rogers '794 patent").
1009	Office Action of January 14, 2013.
1010	Response and Amendment of February 14, 2013.
1011	Final Rejection of February 28, 2014.
1012	Interview Summary of March 26, 2013.
1013	Response and Amendment of September 20, 2012.
1014	U.S. Publication App. No. 2008/0147047 ("Davis").
1015	U.S. Publication App. No. 2007/0282280 ("Tennican").
1016	Chart comparing Rogers '889 claims to the Rogers '438 provisional and the Rogers '805 application.
1017	Provisional Appl. No. 60/850,438 ("Rogers '438 provisional").
1018	U.S. Published Application No. 2007/0112333 ("Hoang").
1019	U.S. Pat. No. 7,282,186 to Lake ("Lake").
1020	Response and Amendment of April 25, 2013.

1021	U.S. Pat. No. 6,394,983 ("Mayoral").
1022	U.S. Pat. No. 6,605,076 ("Jepson").
1023	U.S. Pat. No. 5,658,260 ("Desecki").
1024	U.S. Pat. No. 5,620,427 ("Kipp").
1025	Notice of Allowance of October 3, 2013.
1026	U.S. Application Ser. No. 11/705805 ("the Rogers '805 application").
1027	Non-Final Rejection of March 13, 2014, in U.S. Application Ser. No. 14/207458.
1028	Amendment of June 2, 2014, in U.S. Application Ser. No. 14/207458.

NOTICE OF LEAD AND BACKUP COUNSEL

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NOTICE OF EACH REAL-PARTY-IN-INTEREST

The real-party-in-interest for this Petition is Ivera Medical Corporation.

NOTICE OF RELATED MATTERS

U.S. Patent No. 8,647,326 ("the '326 patent") has been asserted in the U.S. District Court of New Jersey in Case No. 1-14-cv-00852, in *Excelsior Medical Corporation v. Ivera Medical Corporation*, filed February 11, 2014.

NOTICE OF SERVICE INFORMATION

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GROUNDS FOR STANDING

Petitioner hereby certifies that the patent for which review is sought is available for inter partes review and that the Petitioner is not barred or estopped from requesting an inter partes review challenging the patent claims on the grounds identified in the petition.

STATEMENT OF PRECISE RELIEF REQUESTED

The Petitioner respectfully requests that claims 1-9, 12, and 14-16 of U.S. Patent No. 8,647,326 ("the '326 patent") (Ex. 1001) be canceled based on the following grounds of unpatentability, explained in detail in the next section:

Ground 1. Claims 1, 4-9, 12 and 14-16 are invalid under 35 U.S.C. § 102 over Rogers '889.

Ground 2. Claims 2 and 3 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Mayoral.

Ground 3. Claims 1, 4-9, 12 and 14-16 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Lake.

Ground 4. Claims 2 and 3 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Lake, in further view of Mayoral.

Ground 5. Claims 1, 4-9, 12, and 14-16 are invalid under 35 U.S.C. § 103(a) over Hoang in view of Lake.

Ground 6. Claims 2 and 3 are invalid under 35 U.S.C. § 103(a) over Hoang in view of Lake, in further view of Mayoral.

THRESHOLD REQUIREMENT FOR INTER PARTES REVIEW

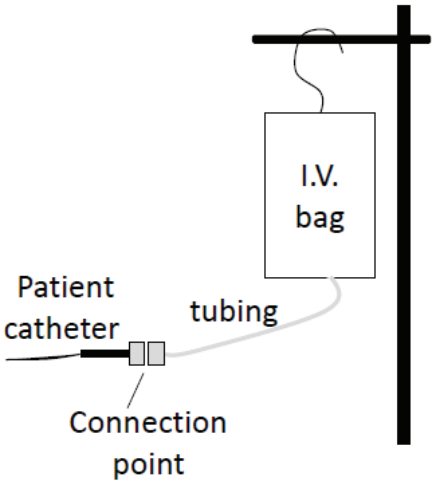
This petition presents "a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the petition". 35 USC § 314(a), as shown in the Grounds explained below.

I. Introduction

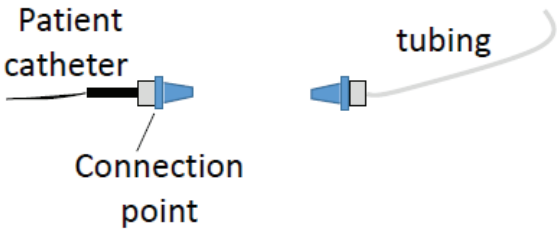
The petition is supported by the declaration of Karl R. Leinsing. (Ex. 1002).

A. Technology Background

This *inter partes* review relates to certain components for intravenous (IV) tubing. Such tubing is used in medical facilities to supply a patient's blood vessels with fluid or withdraw blood. The fluid is often supplied by an IV bag, shown right. The bag hangs from a rack, while the bottom of the bag has an opening connected to a tube. The tube runs downward toward a patient. Near the patient, the tube attaches to a patient catheter, via a port or valve. The catheter is inserted into a patient's vein. (Ex. 1002, ¶¶ 21-24).

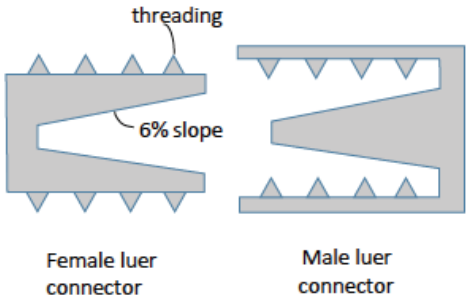


The subject matter of this proceeding focuses on the connection point between the IV tubing and the port on the patient's catheter. The connection point may have two interlocking ("male" and "female") connectors. (Ex. 1002, ¶ 26). When the system utilizes male and female connectors, those connectors sometimes have compatible threads to allow them to be securely fastened to one another, and later to be disconnected, as shown here. The ability to disconnect the connectors

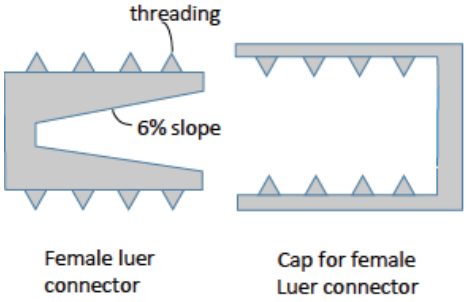


means that different IV fluids can be supplied through the same catheter, or that the IV tubing can be disconnected altogether when not needed, leaving the patient's catheter in place. (*Id.*, ¶ 27). When disconnected, the connectors can be covered with "caps", shown in blue in the above figure. (*Id.*, ¶ 28).

The connectors are sometimes "luer" connectors. The term "luer" will occur repeatedly throughout this proceeding. A luer connector is a specific type of connector that uses a conical fitting with a 6% taper to create a seal. (Ex. 1002, ¶¶ 30-31). The sealing surfaces of luer connectors are sometimes secured or "locked" in place by threading. (*Id.*, ¶ 32).



A simplified example of a male and a female luer connector with locking threads is shown left. (Ex. 1002, ¶ 33). If the luer connectors in the drawing had caps, each cap would have compatible threading to secure the cap in place. For example, as shown right, a cap intended to cover the female luer connector would have threading similar to the male luer connector. (*Id.*, ¶ 34).



B. The '326 Patent

The '326 patent relates to "caps that can be used to protect the sterility of the unconnected medical connectors, such as connectors that may be used for fluid flow or fluid delivery systems." (Ex. 1001, 1:28-31). As recognized by the applicants for the '326 patent, however, "[c]aps used for protecting sterility of medical connectors [were] well known in the medical art" at the time of the invention. (Ex. 1003, 1:54-55)(statement in related patent)(Ex. 1002, ¶ 40).

The '326 patent thus relates more specifically to *an assembly of two caps*, one cap for a male connector and one cap for a female connector *that are coupled together* in a sterile manner. (Ex. 1001, Abstract) (Ex. 1002, ¶ 41). These two caps can be coupled together because they have complementary threading. (Ex. 1002, ¶ 45). The assembly can then be separated to concurrently cap the respective ends of the medical connectors that they protect. (*Id.*). The patent specification alleges the benefits of the invention as follows:

> "Commonly, a fluid pathway is used to intermittently administer medications to a patient. For example, a fluid pathway, which communicates fluids with a patient's blood stream, may have one or more connectors associated therewith. Each of the fluid pathway connectors can be connected to other connectors, such as a connector associated with an IV bag. In such a situation, the medical connectors, such as luer lock connectors, are connected and disconnected at various times, and may remain disconnected for

> several minutes or hours. Medical connector caps are used to cover and protect the various medical connectors while the connectors are separated from one another. **When the medical connectors are separated from each other, there are two connectors that each can benefit from being covered by a cap. Therefore, in some cases, it can be advantageous to have a single connector set that can be used to provide protection for both ends of a separated connection.**" (Ex. 1001, 3:66-4:16 (emph. add.)).

Figure 1 of the '326 patent shows this assembly of a pair of separable caps. As stated in the patent specification: "Shown in FIGs 1-1B is a system, or unit, or assembly 100 of a pair of separable caps 102 and 104, which are securely, but releasably, affixed one to the other across a common interface 106." (Ex. 1001, 4:17-20).

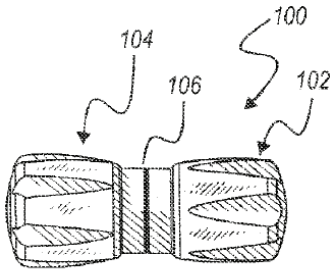


Figure 1

This allows that "caps 102 and 104 can be distributed in a coupled state, such as that shown in FIGS 1-1B, and may be decoupled by a user (e.g. a medical professional) and subsequently coupled with connectors." (Ex. 1001, 4:23-27).

For this configuration to work, it is necessary that one cap has male threads and the other cap has female threads. (Ex. 1002, ¶ 47). Figures 4 and 5, below, show how the male and female caps can be connected with respective medical connectors when separated from each other:

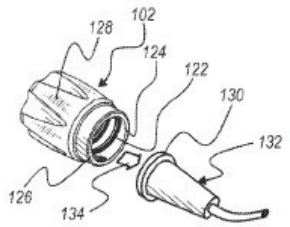


Figure 4

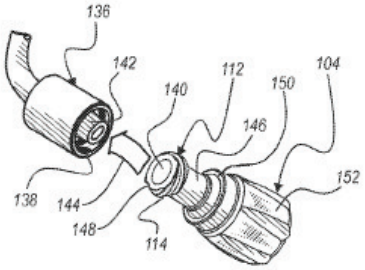


Figure 5

The caps in the '326 patent can be coupled with different types of medical connectors. (Ex. 1001, 3:64-67 ("An example of medical connectors for which caps disclosed herein may be used are intravascular connectors associated with a fluid pathway, such as a central line))(Ex. 1002, ¶ 43). In one embodiment, the caps are specifically shown to engage luer connectors. (Ex. 1001, 5:43-44 ("As seen in FIG. 5, threads 114 of cap 104 are of a size and pitch to engage threads 138 of a male luer-lock connector 136.")) (Ex. 1002, ¶ 44).

The caps described in the '326 patent are also "disinfecting caps". This means that the caps may include features for disinfecting the connectors when in place. As shown in the '326 patent, these features may include, for example, an absorbent pad and cleaning agent within the caps to contact the connectors when fitted with the cap. (Ex. 1001, 7:53-9:26) (Ex. 1002, ¶ 42).

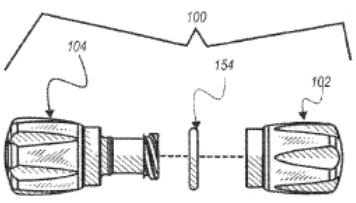


Figure 7

One aspect of the paired disinfecting caps of the '326 patent is that the two caps, when threaded together opening-to-opening, seal each other. Figure 7 of the

patent, above, shows an o-ring that is used to maintain the seal between the two caps. The seal between the caps is designed to "limit or prevent evaporation or loss of an antiseptic agent disposed within caps 102 and 104 when caps 102 and 104 are coupled together." (Ex. 1001, 7:5-7). The antiseptic agent disposed inside the caps can be in liquid or solid form, and can be included on an absorbent pad inserted into the sterilization cavity or chamber. (*Id.*, 7:53-8:2) (Ex. 1002, ¶ 50).

The specification further discloses that tape or a foil seal can be wrapped around the interface between the two caps and the o-ring, as shown in Figure 8A [158]. As described in the patent, "[f]urther safety in sealing against internal surface contamination may be provided by a sealing tape, or a planar or foil seal, such as tape 158 seen in FIG. 8A." (Ex. 1001, 7:31-33). "Thus tape 158 provides both a seal to prevent microbial ingress and a mechanism for maintaining the secure connection between caps 102 and 104 prior to use." (*Id.*, 7:41-43).

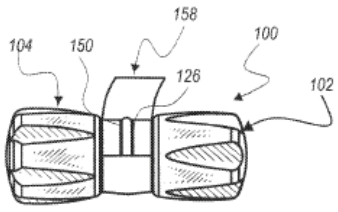


Figure 8A

The '326 patent shows various embodiments of the invention, but each includes an "assembly" of one male and one female connector cap. Figure 18, left, for example, shows a pair of caps, one male and one female, connected in a side-by-side fashion. The '326 patent explains Figure 18: "the *assembly* 1500 can include a cap 1502 and cap 1504 that are coupled with each other when in pre-use

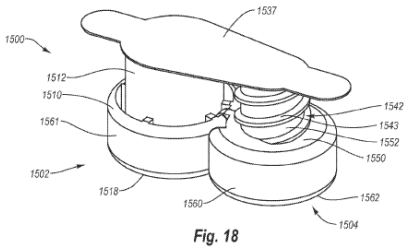


Fig. 18

state and that can be removed from each other. The cap 1502 can be *configured to couple with a female connector,* and the cap 1504 can be *configured to couple with a male connector.*" (Ex. 1001, 20:9-15 (emph. add.)). The caps in Figure 18 are connected to each other in a "pre-use configuration via a *common cover* 1537." (Ex. 1001, 20:19) (emph. add).

C. History of the '326 Patent

The '326 patent issued from a chain of applications, including one provisional application and three CIPs. Through the course of these applications, both the specification and claims changed in significant ways. These changes are relevant to the effective filing date for the claims as issued. Of particular relevance are the changes made from "medical connectors" to "luer connectors," and the addition of new matter relating to "a cover extending over … at least two disinfecting caps".

1. The Howlett '541 Provisional

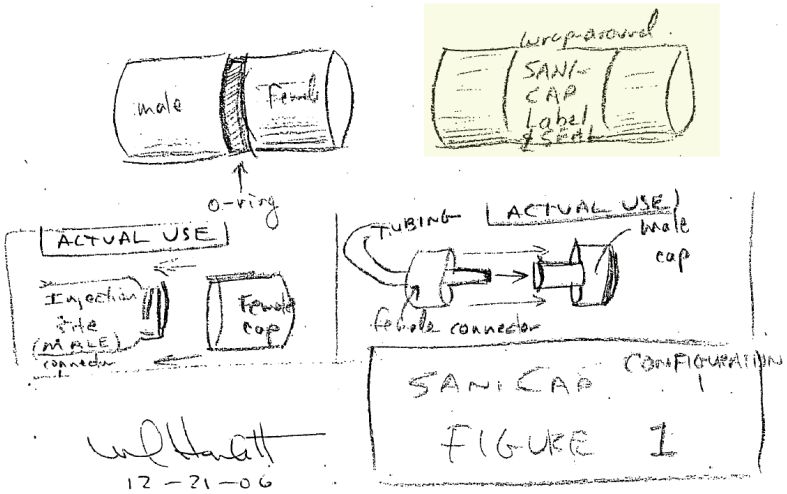
The first application in the '326 patent chain is provisional application No. 60/880,541, filed January 16, 2007 (the "Howlett '541 provisional"). The Howlett '541 provisional describes the invention as a:

> "unique screw-on protective cap for connectors commonly used in a variety of medical apparatus (e.g. IV tubing sets and needleless injection sites/connectors attached to vascular access devices)." (Ex. 1005, p. 7).

The Howlett '541 provisional does not specify "*luer* connectors" as a type of

connector with which the system can be used. (Ex. 1005) (Ex. 1002, ¶ 82).

The Howlett '541 provisional further states that, "[t]he device is *uniquely designed to 'nest' both a male and female cap in a single unit* in which the male and female caps connector or screw into each other forming a seal." (Ex. 1006, p. 7). Figure 1 includes a drawing of the "nested" male and female caps, shown coupled together (top) and also relative to a male and female medical connector (bottom).

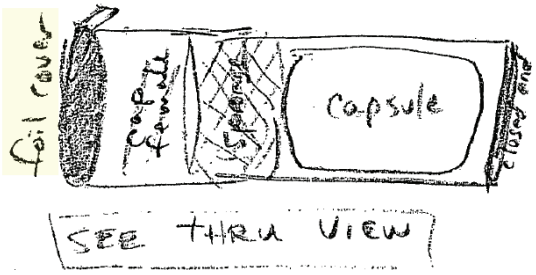


When coupled together, the caps can have "*wrap-around*" seal (highlighted yellow in the portion of Figure 1 above). The specification states:

> "[a]s the two caps are tightened, a seal is formed between the two (e.g. o-ring) that prevents the evaporative loss of the antiseptic and maintains the sterility of the two caps within. **A second wrap-around, adhesive seal** (e.g. foil leaf) may be added to maintain the integrity of this seal during transport and storage." (Ex. 1005, p. 7) (emph. add.).

In contrast to this seal, the Howlett '541 provisional separately discloses a "cover" that can be used with a single female-cap embodiment of the invention. The specification explains, "[c]onfiguration 4 (figure 4) employs the same

antiseptic delivery methods described in configurations 2 and 3. However, the male cap is eliminated and replaced by a discardable *cover* or seal (e.g. foil seal)."



(Ex. 1005, p. 8). This "cover" is highlighted in yellow in the relevant portion of Figure 4, shown here. While the Howlett '541 provisional sometimes refers to the "cover" as a "cover or seal", the wrap-around seal of Figure 1 is consistently referred to only as a "seal." (*Id.*) (Ex. 1002, ¶ 91).

2. Examination History of the '326 Patent

Following the Howlett '541 provisional and three CIP applications, application No. 12/610,033 (the "Solomon '033 application"), which led to the '326 patent, was filed on October 30, 2009. Four inventors (Solomon, Ferguson, Hitchcock, and Bandis) were added in the Solomon '033 application.

The original claims of the Solomon '033 application described "a system configured for use with a *pair of separated medical connectors,*" "wherein the male cap and the female cap *are attached to each other and are in a sealed condition* when in pre-use configuration." (Ex. 1004, p. 93).

In mid-2011, the Petitioner released a new product called the "Curos Strip®". The Curos Strip® packaged a number of female connector caps on a strip of foil. (Ex. 1007). This allowed medical professionals to hang a strip of caps from an IV rack, and tear off a new cap whenever needed. An image of the Curos Strip® product is shown right (the caps are green).

Shortly after the Curos Strip® product was first sold, the applicants canceled the pending claims, and added new claims. (Ex. 1013). The new claims were no longer limited to a "*pair*" of male and female caps, but instead claimed a system with "***at least two*** *disinfecting caps*." (Ex. 1013, pp. 5-6 (emph. add.)). The new claims also replaced the "*sealed connection*" with claimed a "***cover extending over*** *the exterior surface of the* ***at least two disinfecting caps***." (*Id.*, (emph. add.)).

In making the amendment, the applicants stated that the "*cover*" element could be found in Figures 18 and 19 of the specification, paragraph 130 and claims 16, 21, 22 and 24. (Ex. 1013, p. 7). Figure 18 is shown again, right. Figures 18 and 19, and the associated disclosure, were first added via CIP filing in October 2009, (Ex. 1004, pp. 113-114), and were not present in the Howlett '541 provisional, or the three intervening CIP applications. (Ex. 1002, ¶ 85).

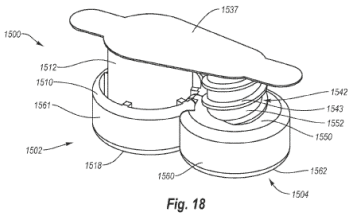


Fig. 18

The Examiner rejected the amended claims as unpatentable over U.S. Patent No. 7,780,794 to Rogers ("Rogers '794"). One inventor of this patent is the CEO of Ivera Medical Corporation, the maker of the Curos Strip®. (Ex. 1008).

In rejecting the new claims, the Examiner found that Rogers '794 disclosed disinfecting caps, each including (i) a receiving portion having a chamber defining a single opening in which a luer connector can be received, (ii) an exterior surface extending around the opening for receiving a cover, (iii) an absorbent pad having an antiseptic agent disposed in the chamber, and (iv) a means for engaging threads of luer connectors. (Ex. 1009, p. 4). The Examiner also found that "*Rogers teaches that multiple caps may be attached to a single cover … so as to seal the chamber of each disinfecting cap*". (*Id.*) (emph. add.).

The applicants did not dispute that Rogers '794 taught the subject matter of the pending claims, but instead argued that Rogers '794 was not eligible prior art because it was not entitled to the priority dates of its provisional applications "with respect to the disclosure of the seal." (Ex. 1010, p. 6). Therefore, the applicants argued, Rogers '889's effective filing date was February 12, 2007 (the date the utility application was filed), for subject matter directed to the seal (or "cover"). (*Id.*).

This argument alone, however, could not remove Rogers '794 as prior art. To pre-date the February 12, 2007 filing date of Rogers '794, the applicants also had to

be entitled to the benefit of the filing date of the Howlett '541 provisional. The applicants argued:

> "In contrast, applicants are entitled to their provisional filing date of January 16, 2007 (USSN 60/880,541) as it discloses an embodiment of the claims, **that is two caps with a 'cover extending over the exterior surface of the at least two disinfecting caps, so as to seal the chamber of each disinfecting cap**.'" (Ex. 1010, p. 6) (emph. add.).

The applicants cited Figure 1 of the Howlett '541 provisional to support this argument. (*Id.*) However, Figure 1 shows only a wrap-around "seal" around exactly two caps coupled opening-to-opening, with complementary male and female threads. It does not disclose a "cover extending over … at least two caps", as claimed in the '326 patent. (*Compare* Ex. 1005, Fig. 1 to Ex. 1001, claim 1). The applicants' argument to the Examiner also contradicted the applicants' prior assertion that support for the "cover" element was found in Figures 18 and 19 and the associated disclosure, which were added much later in the October 2009 Solomon '033 application. (Ex. 1013, p. 7).

In response to applicants' argument, the Examiner identified another reason the '326 patent was not entitled to the effective date of the Howlett '541 provisional: "because the applicant's provisional application 60/880,541 does not teach the claimed feature of 'a chamber defining a single opening in which a *luer connector* can be received'. … *the effective filing date of the present application is the filing*

date of the 12/014,388 application which is January 15, 2008. Rogers remains as *eligible prior art* …." (Ex. 1011, p. 3) (emph. add.).

Following this action, the Examiner and applicants conducted an interview. The Examiner's interview summary states:

> "The proposed amendment does not provide the claims with the filing date of the provisional application 60/880,541 **since the provisional does not explicitly teach luer connectors. Therefore, Rogers is still eligible as prior art.**" (Ex. 1012, p. 2 (emph. add.)).

The Examiner suggested amending the independent claims to replace "luer connector" with terms consistent with the provisional, and specifically the limitation "medical tubing connector". (*Id.*). Following the Interview, applicants amended one portion of the claim – "a chamber defining ~~a single~~ an opening in which a ~~luer~~ medical tubing connector can be received" (Ex. 1020, p. 5) – but did *not* remove other references to "luer connectors" in the independent claims. (*See* Ex. 1001, claims 1 and 16 , "A system of medical *luer connector* caps comprising: … a means for engaging threads of *luer connectors*") (emph. add.).

D. Rogers '889

The application leading to Rogers '794 was filed February 12, 2007, and first published on January 24, 2008 as U.S. Pub. No. 2008/0019889 ("Rogers '889") (Ex. 1006). The disclosure in Rogers '794 that the Examiner relied on during the prosecution of the '326 patent is also found in Rogers '889. *See* Ground 1, claim

charts.

Rogers '889 claims the benefit of provisional application No. 60/850,438, filed October 10, 2006 (the "Rogers '438 provisional"). The Rogers '438 provisional is incorporated by reference into U.S. Application Ser. No. 11/705805 ("the Rogers '805 application"), the utility application that led to Rogers '889 and Rogers '794. The Rogers '438 provisional supports the claims of Rogers '889. (Ex 1002, ¶ 95) (Ex. 1016).

Rogers '889 discloses a cleaning device for a medical implement much like that claimed in the '326 patent. (Ex. 1002, ¶ 96). The specification states:

> "The cleaning device includes a **cap** having an opening to an inner cavity, the opening being adapted to receive a site of the medical implement. The cleaning device further includes a compressible cleaning material that contains a cleaning agent prior to receipt of the site of the medical implement, i.e., the cleaning material is pre-loaded with the cleaning agent. The compressible cleaning material is at least partially secured in the inner cavity and adapted to swab and clean the site with the cleaning agent." (Ex. 1006, Abstract) (emph. add.).

Rogers '889 shows a disinfecting cap for a "luer connector," including a housing with internal threads "sized and arranged to accommodate luer threads, i.e., standardized male threads designed to mate with the female threads on a medical implement". (Ex. 1006, ¶ 33) (Ex. 1002, ¶ 95).

Rogers '889 also shows a cover extending over the opening of the disinfecting cap. Rogers calls its "cover" a "seal." This is different, though, from the "wrap-around seal" in the '326 patent and the applications leading to that patent. (Ex. 1002, ¶ 97). The Rogers '889 cover can be seen in Figure 2 [1], left, wherein "a foil seal [cover] 1 is configured to attach to a sealing surface 2 of the housing 4." (Ex. 1006, ¶ 33).

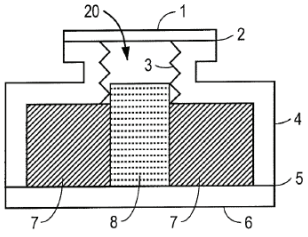


FIG. 2

The above disclosures are also found in the Rogers '438 provisional, as shown in the claim charts below in Ground 1. Rogers '889 further discloses that the cover can extend over more than one disinfecting cap:

> "In still yet another aspect, a cleaning system for a medical environment includes a **plurality of caps**. … The system further includes a **seal [cover]** that **covers** the opening of each of the **plurality of caps**, **and from which individual ones of the plurality of caps can be selectively removed** to be used for cleaning the site of the medical implement." (Ex. 1006, ¶ 9) (emph. add.) (*see also* claim 24).

As stated, during prosecution of the application for the '326 patent, the Examiner found this same language in Rogers '794 disclosed "that multiple caps may be attached to a single cover so as to seal the chamber of each disinfecting cap". (Ex. 1009, p. 4).

E. Rogers '889 is Prior Art to the '326 Patent.

The Examiner's analysis concerning the status of Rogers as prior art incorporated several errors, described below. It is helpful to compare the timeline of the chain of applications for the '326 patent with the chain for Rogers:

Date	'326 patent chain	Rogers chain
October 10, 2006		Rogers '438 provisional filed
January 16, 2007	Howlett '541 provisional filed	
February 12, 2007		Rogers '805 app. for Rogers '889 publication/'794 patent filed
January 15, 2008	Howlett '388 app. filed	
January 24, 2008		Rogers '889 publication published
June 30, 2008	Howlett '761 CIP app. filed	
July 11, 2008	Howlett '749 CIP app. filed	
October 30, 2009	Solomon '033 CIP app. filed	
August 24, 2010		Rogers '794 patent issued
February 11, 2014	Solomon '326 patent issued	

Based on these dates, Rogers '889 qualifies as prior art to the '326 patent because: (i) the '326 patent is not entitled the effective filing date of the Howlett '541 provisional, and therefore Rogers '889 is prior art under § 102(e)(1) based on the filing date of the Rogers '805 application; and (ii) Rogers '889 is entitled to the

effective filing date of the Rogers '438 provisional, which was before the Howlett '541 provisional.

1. Legal Standards

To qualify for the benefit of the filing date of a prior provisional application, the provisional (and any intervening) application must provide written description support for the claims as issued. 35 U.S.C. §§ 120 and 119(e). Proper written description support must demonstrate that the inventors had ***possession*** of the invention. A specification that merely renders the claims ***obvious*** does not meet the written description requirement. *See Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010)(*en banc)*.

2. The Howlett '541 provisional does not support the "luer connectors" claimed in the '326 patent.

Independent clams 1 and 16 claim, "A system for medical *luer connector* caps comprising: … a means for engaging the threads of *luer connectors*." (Ex. 1001). The term "luer connector", however, appears nowhere in the Howlett '541 provisional. (Ex. 1002, ¶ 82).

Instead, the Howlett '541 provisional disclosed only: "[a] unique screw-on protective cap *for connectors commonly used in a variety of medical apparatus* (e.g. IV tubing sets and needless injection sites/connectors attached to vascular access devices)". (Ex. 1005, p. 1) (emph. add). This does not demonstrate to a

person skilled in the art that the named inventors of the Howlett '541 provisional had possession of an invention *specifically limited to* "luer connectors". (Ex. 1002, ¶ 82).

During prosecution, the Examiner found that the Howlett '541 provisional "*does not explicitly teach luer connectors. Therefore, Rogers is still eligible as prior art*." (Ex. 1012, p. 2)(emph. add.). In response, the applicants amended one part of the claim language: "a chamber defining ~~a single~~ an opening in which a ~~luer~~ medical tubing connector can be received." (Ex. 1020, p. 5). By making this amendment, the applicants acquiesced to the Examiner's position that the Howlett '541 provisional did not adequately teach "luer connectors". *See Litton v. Whirlpool*, 728 F.2d 1423, 1438 (Fed. Cir. 1984) (explaining that filing a CIP application in response to a new matter rejection estops patentee from arguing that the PTO's rejection was erroneous).

The applicants, however, left the term "luer connectors" elsewhere in the claims of the patent. (Ex. 1001, claims 1 and 16). A person of ordinary skill in the art would not have understood the "medical connectors" described in the Howlett '541 provisional to mean "luer connectors". As explained above and in the Leinsing declaration, a "luer connector" is a particular and standardized system for mating a male-taper and female-taper fittings. Key features of the luer connector include its 6% taper, and the specifications of the ISO 594 standards. (Ex. 1002, ¶ 31). There

are types of "medical connectors" other than luer connectors that fall within the broad description of the Howlett '541 provisional, including connectors used in blunt needle systems and blunt cannula systems. (*Id.*, ¶ 83) (Exs. 1022 and 1023). The '326 patent itself recognizes that there are medical connectors *other than* "luer connectors," showing "luer connectors" as only one embodiment of the patented invention. (Ex. 1001, 5:43-44). *See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989) ("Under [defendant's] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless . . . .").

It is also not enough for Patent Owner to argue that it would have been obvious to use the system described in the Howlett '541 provisional with "luer connectors". A description that merely renders the invention obvious does not satisfy the written description requirement. *See Ariad*, 598 F.3d at 1352. One skilled in the art would not have known that the inventors of the Howlett '541 provisional placed any inventive emphasis on "luer connectors" as opposed to the much broader category actually disclosed. The independent claims of the '326 patent, which claim "luer connectors", are therefore not entitled to the filing date of the Howlett '541 provisional. This failure extends to the narrower dependent claims as well.

3. The Howlett '541 provisional does not support a "cover extending over" "at least two disinfecting caps".

Claim 1 of the '326 patent claims: "a cover extending over … *the at least two disinfecting caps*", and claim 16: "a cover extending over … *the first and second exterior surfaces*" of two disinfecting caps. (Ex. 1001). The Howlett '541 provisional does not, however, describe "a cover" over two or more caps.

Instead, the Howlett '541 provisional describes only: (1) a nested pair of male and female caps with a "wrap-around seal"; or (2) a "cover" over a single female-cap embodiment (the same as in the Rogers '438 provisional). (Ex. 1005)(Ex. 1002, ¶ 86). There is no description of any system using more than two disinfecting caps, let alone how such a system would work. (*Id.*, ¶ 87).

The Patent Owner cannot point to the "seal" in the Howlett '541 provisional to support the claimed "cover". A "seal" as shown in the Howlett '541 provisional could not be used with anything other than a pair of exactly two – and not "at least two" – disinfecting caps, and does not support this claim limitation. (Ex. 1002, ¶¶ 87-88, 90). Further, during prosecution applicants pointed to Figures 18 and 19 – added in the October 2009 Solomon '033 application – to support the addition of the "cover" element to the claims. (Ex. 1013, p. 7). This conclusion is also supported by the inventorship change, which indicates that there was new matter added to the Solomon '033 CIP application.

Moreover, the Howlett '541 provisional explicitly distinguishes between the "wrap-around" seal described in Fig. 1, and the "cover" that is shown as replacing the male disinfecting cap in Fig. 4. (Ex. 1005, p. 7). One of ordinary skill in the art would *not* have understood from the disclosure of a cover over a *single, female-cap* embodiment in the Howlett '541 provisional that Howlett had invented "a cover extending over" "at least two disinfecting caps". (Ex. 1002, ¶ 89). The '326 patent is therefore not entitled to the effective filing date of the Howlett '541 provisional for this additional reason. Again, this failure extends to the narrower dependent claims.

4. Rogers '889 is entitled to the effective filing date of the Rogers '438 provisional.

The § 102(e) date of Rogers can extend to the filing date of the Rogers '438 provisional. *See In re Giacomini*, 612 F.3d 1380 (Fed. Cir. 2010). The disclosure of the Rogers '438 provisional is shown in tandem with that of Rogers '889 in the claim charts set forth below in Ground 1.

The Rogers '438 provisional makes the same relevant disclosure as the Rogers '889 provisional, except that – like the Howlett '541 provisional – the Rogers '438 provisional shows the "cover" element only in relation to a single disinfecting cap. (Ex. 1017, Fig. 2) (Ex. 1002, ¶ 173). Accordingly, if the '326 patent may claim the effective date of the Howlett '541 provisional (Jan. 16, 2007), based on a

finding that the description of a cover over a single cap is sufficient, then Rogers '889 should likewise be prior art as of date of the Rogers '438 provisional for this concept, which is still earlier (Oct. 10, 2006). In this case, Rogers '889 would anticipate the '326 patent as in Ground 1.

Conversely, if disclosure of a cover over a single cap is found not to be a sufficient written description such that Rogers '889 is not entitled to the filing date of the Rogers '438 provisional for that claim element, then the '326 patent should also not be entitled to the filing date of the Howlett '541 provisional. Rogers '889 is therefore still prior art under § 102(e)(1), based on the February 12, 2007 filing date of the Rogers '805 utility application, which was before the first utility application in the '326 patent chain (Jan. 24, 2008). In this case, Rogers would also anticipate the '326 patent as in Ground 1.

If, however, it is somehow determined that the '326 patent is entitled to the filing date of the Howlett '541 provisional, but Rogers '889 is not entitled to the filing date of the Rogers '438 provisional for the "cover" element, then Rogers '889 is still entitled to the earlier date *for the disclosures therein,* and the '326 patent is invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Lake as in Ground 3.

II. CLAIM CONSTRUCTION

A. Overview of the challenged claims

Claims 1 and 16 are independent claims, and claims 2-9, 12 and 14-15 all

depend from claim 1.

B. Applicable legal standard for claim construction

A claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." See 37 C.F.R. § 42.100(b). As stated by the Federal Circuit in *In re ICON Health and Fitness, Inc.*:

> "[T]he PTO must give claims their broadest reasonable construction consistent with the specification. Therefore, we look to the specification to see if it provides a definition for claim terms, but otherwise apply a broad interpretation."

496 F.3d 1374, 1379 (Fed. Cir. 2007).

The standard of claim construction used in district courts differs from the standard applied before the USPTO. Claim constructions herein are directed to the USPTO standard, and are not necessarily the constructions that the Petitioner believes would be adopted in court. The Petitioner does not acquiesce or admit to the constructions reflected herein for any purpose outside of this proceeding.

C. Claim 1 — "means for engaging threads of luer connectors"

The term "means for engaging threads of luer connectors" is used in independent claims 1 and 16. During prosecution of the Solomon '033 application for the '326 patent, the Examiner found that the corresponding structure described in the specification as "threads that mate with the threads of luer connectors." (Ex. 1025). This construction is supported in the patent specification, and was not

opposed by the applicants. (Ex. 1001, 5:16-18, 43-44). The proper construction of "means for engaging threads of luer connectors" is thus "threads that mate with the threads of luer connectors, and equivalents thereof".

D. Claim 2 — "means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a female luer connector"

The term "means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a female luer connector" is used in claim 2. The '326 patent provides no clear corresponding structure for this claim term. As best as Petitioner can ascertain, the disinfecting caps have threads disposed in the chamber of the cap to securely connect the cap to the connector. (Ex. 1001, 5:5-25). The proper construction of this claim term is "threads on the interior of the opening of the cap, that mate with the threads of a female luer connector, to securely connect the cap to the connector, and equivalents thereof".

E. Claim 4 — "means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a male luer connector"

The term "means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a male luer connector," used in claim 4, is the same language as used in Claim 2 except regarding a male luer connector. For the same reasons as above, the proper construction of this term is "threads on the interior of the opening of the cap, that mate with the threads of

male luer connector, to securely connect the cap to the connector, and equivalents thereof".

F. Claim 9 — "connection interface"

The term "connection interface" is used in dependent claim 9. The term "connection interface" as used throughout the specification refers to the part of the cap that connects with either a second cap or a medical connector. The patent states that: "[t]he threaded *connection interface* 1030 thus can allow for selective coupling of the cap 1002 to be coupled with a medical connector in a secure yet selectively removable fashion." (Ex. 1001, 10:22-24) (emph. add.). The specification does not limit a "connection interface" to a threaded connection. (*Id.*, 10:25-28). The proper construction of "connection interface" is thus "the part of a connector cap that connects with another medical implement or connector cap".

III. DETAILED EXPLAINATION OF REASONS FOR UNPATENTABILITY

Ground 1. Claims 1, 4-9, 12, and 14-16 are invalid under 35 U.S.C. § 102 over Rogers '889.

Claims 1, 4-9, 12, and 14-16 are unpatentable under 35 U.S.C. § 102 over Rogers '889. (Ex. 1019). Rogers '889 is prior art under § 102(e)(1) for the reasons set forth in Section I.E. above.

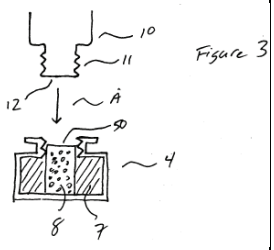
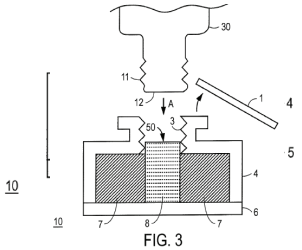
Rogers '889 discloses a system of disinfecting caps, threaded for use with luer connectors, wherein the disinfecting caps include an opening to receive a medical

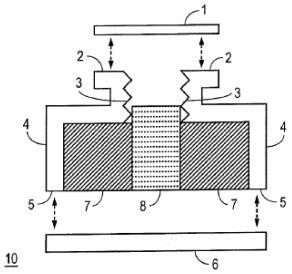
implement, such as an IV tube. Rogers '889 further discloses a system wherein a cover extends over the opening in the disinfecting cap or a plurality of disinfecting caps. A basic explanation of Rogers '889 is provided in the technical introduction, above.

Rogers '889, and the Rogers '438 provisional, teach claims 1-9, 12, and 14-16 of the '326 patent as shown in the following claim chart. Note that the Rogers '438 provisional is incorporated by reference into Rogers '889. (Ex. 1002, ¶ 93)

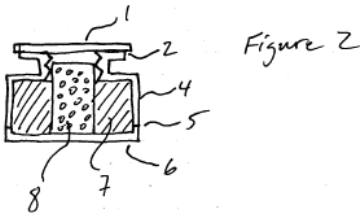
[1a]. A system for medical luer connector caps comprising:	**Rogers '889** discloses a system for medical luer connector caps. Rogers '889 first discloses a "cap" for a "medical implement". Rogers '889 states: "In one aspect, the cleaning device incudes a **cap** having an inner cavity, the opening being adapted to receive a site of the **medical implement.**" (Ex. 1006, ¶ 5) (emph. add.) (Ex. 1002, ¶ 100). Rogers '889 discloses that a "medical implement" can be a "luer connector", explaining that: "The term **'medical implement'** is used to denote any tool or object that can be used in a medical setting and that can connect to a site cleaning device as described herein according to a number of embodiments. Examples of **medical implements include,** but are not limited to … **luer connectors….**" (Ex. 1006, ¶ 28) (emph. add.) (Ex. 1002, ¶ 101). The **Rogers '438 provisional** also discloses a system for medical luer connector caps, stating: "In Figure 1, the disinfecting **cap** is shown … Internal threads 3 are **luer threads** designed to mate with the female threads of another **medical implement**." (Ex. 1017, p. 6) (emph. add.) (Ex. 1002, ¶ 102).

	The presence of "luer threads" indicates a "luer connector". (Ex. 1002, ¶ 103).
[1b]. at least two disinfecting caps, each including a receiving portion having	**Rogers '889** discloses at least two disinfecting caps each including a receiving portion. Rogers '889 describes the "receiving portion" as "an inner cavity and opening" that receives the medical implement, and also that this "inner cavity" is in a "plurality of caps". (Ex. 1002, ¶ 104). Per claim limitation [1e] below, the receiving portion includes threads as well. (*Id.*) The specification and the claims teach these elements: "In still yet another aspect, a cleaning system for a medical environment incudes **a plurality of caps. Each cap includes an inner cavity and an opening to receive** a site of the medical implement into the inner cavity." (Ex. 1006, ¶ 9) (emph. add.) (Ex. 1002, ¶ 104). *See also* Ex. 1006, claim 24. Note that the published claims of Rogers '889 are supported by the application as filed and the Rogers '438 Provisional. (Ex. 1002, ¶ 92). The caps in Rogers '889 are "disinfecting caps". (Ex. 1002, ¶ 105). The "cleaning device" (cap) includes "a compressible cleaning material" that is "pre-loaded with the cleaning agent," and is "adapted to swab and clean the site with the cleaning agent." (*Id.*). The specification describes: "The **cleaning device** further includes a **compressible cleaning material** that **contains a cleaning agent** prior to the receipt of the site of the medical implement, i.e. the cleaning material is pre-loaded with the cleaning agent. The compressible cleaning material is at least partially secured in the inner cavity and **adapted to swab and clean the site with the cleaning agent**." (Ex. 1006, ¶ 5) (emph. add.). (Ex. 1002, ¶ 105). The cap "disinfects" the medical implement because the cleaning agent "cleans the site of bacterial or even viral microorganisms", used in order to prevent the transmission of pathogens into or onto a patient from a potentially contaminated surface of a medical implement, or "site". As explained in the specification, such pathogens include microorganisms such as bacteria and viruses.

	(Ex. 1006, ¶¶ 5, 27)(Ex. 1002, ¶ 105). The **Rogers '438 provisional** shows a single cap having a receiving portion, which is described as the "internal chamber", which "receives" the medical implement. (Ex. 1002, ¶ 106). The specification states: "With the foil seal 1 and the bottom 6 attached to housing 4 they create a hermetically sealed **internal chamber**." (Ex. 1017, p. 7) (emph. add.) (Ex. 1002, ¶ 106). The cap in the **Rogers '438 provisional**, titled "Disinfecting Cap," is a disinfecting cap. (Ex. 1002, ¶ 108). The specification explains how the system disinfects the medical implement, shown also in Fig. 3, right:  Figure 3 "As medical implement 10 threads 11 are rotationally inserted into housing 4 surface 50 which is soaked with the **disinfecting agent scrubs surface 12.** As medical implement 10 continues in direction A it axially compresses material 8 **continuing to clean** surface 12 with surface 50. This movement A also begins to allow material 7 to begin to allow material 7 to begin **scrubbing threads** 11. Material 7 is also soaked with the disinfecting material **so as to perform a thorough cleaning** of the threaded area." (Ex. 1017, pp. 8-9) (emph. add.) (Ex. 1002, ¶ 108).
[1c]. (i) a chamber defining an opening in which a medical tubing connector can be received,	**Rogers '889** discloses a "chamber" defining an opening in which a "medical tubing connector" can be received. This is described in claim limitation [1b] above, with the "chamber" defining the opening to the "inner cavity" described there. This is also shown in Fig. 2, right, where the opening to the inner cavity is shown [20]. (Ex. 1002, ¶ 109).  FIG. 3 It is shown in Figure 3 that a "medical implement" can be received into the chamber. (Ex. 1002, ¶ 110). "FIG. 3 illustrates a medical implement 30 moving toward housing 4, in a direction A

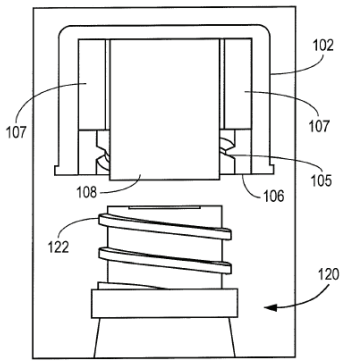
	…"). (Ex. 1006, ¶ 37). Rogers '889 then discloses that a "medical implement" can be a medical tubing connector, such as the "access port on a tubing set": "Examples of medical implements include, but are not limited to, **access ports on tubing sets (extension sets, T-connectors and IV sets).**" (Ex. 1006, ¶ 28) (emph. add.) (Ex. 1002, ¶ 111). The **Rogers '438 provisional** also discloses a chamber defining an opening in which a medical tubing connector can be received. The "chamber" is described in the Rogers '438 provisional as the "internal chamber", as explained in claim limitation [1b] above and in reference to Fig. 3. Fig. 3 shows the chamber as containing cleaning materials 7 and 8. (Ex. 1002, ¶ 113). The "medical implement" can be a medical tubing connector, specifically a "luer connector," in the Rogers '438 provisional. *See* claim limitation [1a] above. A "luer connector" is specific type of medical tubing connector. (Ex. 1002, ¶ 114).
[1d]. (ii) an exterior surface extending around the opening for receiving a cover	**Rogers '889** discloses an exterior surface extending around the opening for receiving a cover. Rogers '889 refers to this as a "sealing surface". The "sealing surface" is seen in Fig. 1, right [2]. The threads [3] are axisymmetric, so it can be seen that the "seal" is placed "around the opening". (Ex. 1002, ¶ 116). The specification explains that the "sealing surface" can receive a "cover" (referred to as a "foil seal"):  FIG. 1 "A foil seal 1 is configured to attach to a **sealing surface** 2 of the housing 4." (Ex. 1006, ¶ 33) (emph. add.) (Ex. 1002, ¶ 117). The **Rogers '438 provisional** also discloses an exterior surface extending around the opening for receiving a cover, also referring to the "cover" as a "foil seal," and the surface as a "sealing surface". (Ex 1002, ¶ 118). The specification explains: "Figure 2 illustrates the fully assembled disinfecting cap.

	The **foil seal 1 is attached** to housing 4 at **sealing surface** 2." (Ex. 1017, p. 7) (emph. add.).
[1e]. (iii) a means for engaging threads of luer connectors; and	**Rogers '889** discloses that the "receiving portion" has a means for engaging threads of luer connectors, as that term is construed above. The means described in Rogers '889 are "threads sized and arranged to accommodate luer threads ". (Ex. 1002, ¶ 119). Rogers '889 states: "The housing 4 further includes internal threads 3. In a preferred exemplary embodiment, the **internal threads 3 are sized and arranged to accommodate luer threads**, i.e. standardized male threads designed to mate with the female threads on a medical implement..." (Ex. 1006, ¶ 33) (emph. add.) (Ex. 1002, ¶ 119). Rogers '889 further discloses that a "medical implement" can be a "luer connector." *See* claim limitation[1a] above. (*Id.*, ¶ 120). The **Rogers '438 provisional** also discloses a means for engaging threads of luer connectors. The specification states: "Internal threads 3 are **luer threads designed to mate with the female threads** of another medical implement." (Ex. 1017, p. 6) (emph. add.) (Ex. 1002, ¶ 121). The presence of "luer threads" indicates a "luer connector". (Ex. 1002, ¶ 122).
[1f]. a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of	**Rogers '889** discloses "a cover extending over" "a plurality of" disinfecting caps, so as to seal the chambers of the caps. The "cover" in Rogers '889 is described in claim limitation [1d] above. (*See also* Ex. 1002 ¶¶ 123-124). Rogers '889 then discloses that this cover (seal) can "extend over" the "at least two disinfecting caps" (a "plurality of caps"): "The system further includes a **seal that covers the opening of each of the plurality of caps**, and from which individual ones of the plurality of the caps can be selectively removed to be used for cleaning the site of the medical implement." (Ex. 1006, ¶ 9) (emph. add.) (*see also* Ex. 1006, cl. 24) (Ex. 1002, ¶¶ 125-126).

the at least two disinfecting caps.	With the cover (seal) in place in Rogers '889, the chamber (inner cavity) of the cap is "sealed". (Ex. 1002, ¶ 127). Rogers '889 states: "… prior to **sealing** of the opening 132 **with a seal** and **closure of the inner cavity**." (Ex. 1006, ¶ 47) (emph. add.). The **Rogers '438 provisional** discloses a cover (referred to as a "seal") extending over the exterior surface of one cap, so as to seal the chamber of that cap. The "cover" is seen in Fig. 2, right. (Ex. 1002, ¶ 128).  Figure 2 The specification explains: "The housing 4 has a sealing surface **2 for attachment of foil seal 1** …" (Ex. 1017, p. 6) (emph. add.) (Ex. 1002, ¶ 128). The specification explains that the cover "seals" the chamber: "With **the foil seal** 1 and the bottom 6 attached to housing 4 they **create a hermetically sealed internal chamber.**" (Ex. 1017, p. 7) (emph. add.) (Ex. 1002, ¶ 128).

[4]. A system according to claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to	**Rogers '889** discloses a means for engaging threads disposed in the chamber of the cap as set forth in claim limitation [1e] above ("internal threads 3") (Ex. 1006, ¶ 33, Fig. 1) (Ex. 1002, ¶ 130). Rogers '889 further discloses that the threads are disposed in the chamber so as to "secure" a "female luer connector". (*See* Section III, claim construction) (Ex. 1002, ¶ 131). The specification describes these threads as "mating with" the corresponding threads on the medical implement that can be a luer connector: "The housing 4 further includes **internal threads 3**. In a preferred exemplary embodiment, the internal threads 3 **are sized and arranged to accommodate luer threads, i.e. standardized male threads designed to mate with the female threads on a medical implement** to which the cap 10 attaches." (Ex. 1006, ¶

engage a female luer connector.	33)(emph. add.). Rogers '889 discloses that a "medical implement" can be a "luer connector." See [1a] above. (Ex. 1002, ¶ 132). The **Rogers '438 provisional** also discloses a means for engaging threads of at least one disinfecting cap is disposed in the chamber of the cap so as to engage a female luer connector, as set forth in claim limitation [1e] above. (Ex. 1002, ¶ 133). The specification also describes "securing" the threads with the corresponding threads of a medical implement, which can be a luer connector: "Internal threads 3 are **luer threads designed to mate with the female threads of another medical implement**." (Ex. 1017, p. 6) (emph. add.) (Ex. 1002, ¶ 133). The presence of "luer threads" indicates a "luer connector". (Ex. 1002, ¶ 134).

[5]. A system according to claim 4, wherein the means for engaging threads includes a helical thread.	**Rogers '889** discloses a system wherein the means for engaging threads includes a helical thread. **(**Ex. 1002, ¶ 135). Fig. 9 of Rogers '889 shows the thread [105] on the inner walls of the cavity (or chamber), coupling with threads that are wrapped around the medical implement in a helix. (Ex. 1002, ¶ 136).  FIG. 9 The **Rogers '438 provisional** also discloses a means for engaging threads (the "internal threads") that includes luer threads. See claim 4 above. Luer threads are helical. (Ex. 1002, ¶ 137).

[6]. A system according to claim 1	**Rogers '889** discloses a system wherein the cover (the "foil seal," *see* 1[f] above) comprises an adhesive, and in particular "glue". (Ex. 1002, ¶ 138). "Glue" is an adhesive. (*Id.*, ¶ 61). Rogers '889 states:

wherein the cover comprises an adhesive	"The **foil seal 1 is then attached** to housing 4 at sealing surface 2 **by glue**, solvent, thermal bonding, etc." (Ex. 1006, ¶ 36) (emph. add.) (Ex. 1002, ¶ 133). The **Rogers '438 provisional** also discloses a system wherein the cover comprises an adhesive, again "glue". The specification states: "The foil seal 1 is attached to housing 4 at sealing surface 2. **The attachment means is a bonding by glue,** solvent, etc." (Ex. 1017, p. 7) (emph. add.) (Ex. 1002, ¶ 139).

[7]. A system according to claim 1 wherein the cover comprises an impervious pliable material.	**Rogers '889** discloses a system wherein the cover comprises an "impervious pliable material." Rogers '889 discloses a cover ("seal") that is "foil". (Ex. 1002, ¶ 140). The '326 patent considers foil to be an impervious pliable material. (Ex. 1001, claim 8). Rogers '889 states: "the opening of the cap is sealed with **a foil-based seal or other material suitable for retaining a cleaning agent in the cleaning material and preventing evaporation of the cleaning agent**." (Ex. 1006, ¶ 30) (emph. add.) (Ex. 1002, ¶ 140). The **Rogers '438 provisional** also discloses a system wherein the cover comprises an "impervious pliable material," again "foil". (Ex. 1002, ¶ 141). The specification states: "Figure 2 illustrates the fully assembled disinfecting cap. **The foil seal** 1 is attached to housing 4 at sealing surface 2." (Ex. 1017, p. 7) (emph. add.) (Ex. 1002, ¶ 141).

[8]. A system according to claim 7 wherein the material is a	See claim 7 above. As explained, the cover (seal) can be foil.

foil or a plastic.	

[9]. A system according to claim 1 wherein each of the at least two caps further comprises a connection interface	**Rogers '889** discloses a system wherein each of the at least two caps further comprises a "connection interface". Regarding plural caps, see the discussion in [1b] and 1[f] regarding Rogers '889's disclosure of a system that includes a plurality of caps. (Ex. 1002, ¶ 144). A "connection interface" is the part of the disinfecting cap and the medical implement that connect. (*See* section III, claim construction). Rogers '889 discloses this connection as the "threads" that "mate with" threads on a medical implement. (Ex. 1002, ¶ 145). "The housing 4 further includes **internal threads 3**. In a preferred exemplary embodiment, the internal threads 3 are sized and arranged to accommodate luer threads, i.e. standardized male threads designed **to mate with the female threads on a medical implement to which the cap 10 attaches.**" (Ex. 1006, ¶ 33) (emph. add.) (Ex. 1002, ¶ 145). The **Rogers '438 provisional** also discloses a means for engaging threads of luer connectors, also "threads" that "mate with" a medical implement. (Ex. 1002, ¶ 146). The specification explains: "Internal threads 3 are **luer threads designed to mate with the female threads of another medical implement**." (Ex. 1017, p. 6) (emph. add.) (Ex. 1002, ¶ 146).

[12]. A system according to claim 1 wherein each of the	**Rogers '889** discloses a system wherein each of the caps further comprise a gripping portion. (Ex. 1002, ¶ 147). Rogers '889 states: "a cleaning device includes **a cap having a shape** and/or external features **to promote easy gripping** …" (Ex. 1006, ¶ 26) (emph. add.) (Ex. 1002, ¶ 147).

caps further comprise a gripping portion.	The **Rogers '438 provisional** also discloses a cap with a gripping portion, as shown in Figure 1 above. A medical professional can grip the vertical sides shown in the Figure, as is necessary to screw the cap on. (Ex. 1002, ¶ 148).

[14]. A system according to claim 1 wherein the system further comprise an antiseptic agent.	**Rogers '889** discloses a system that further comprises an antiseptic agent. The antiseptic agent in Rogers '889 is "isopropyl alcohol". Isopropyl alcohol is an antiseptic agent. (Ex. 1002, ¶ 149). "The first and second cleaning materials 7 and 8 in the inner cavity 20 are at least partially saturated with a cleaning agent, such as **isopropyl alcohol**..." (Ex. 1006, ¶ 36)(emph. add.) (*see also* claim 8) (Ex. 1002, ¶ 149). The **Rogers '438 provisional** also discloses a system that further comprises an "antiseptic agent", also "alcohol". (Ex. 1002, ¶ 150). The specification states: "This internal chamber contains materials 7 and 8 and the chamber is filled or partially filled with **isopropanol alcohol** ..." (Ex. 1017, p. 7) (emph. add.) (Ex. 1002, ¶ 150).

[15]. A system according to claim 14 wherein the system further comprise an absorbent pad.	**Rogers '889** discloses a system that includes an absorbent pad. The absorbent pad in Rogers '889 is the "cleaning material". The "cleaning material" can be "gauze, foam or similar cleaning material". "Gauze" and "foam" are both absorbent materials. (Ex. 1002, ¶ 151). Rogers '889 states: "The cleaning material in the cap that can be an alcohol-**soaked piece of gauze, foam** or similar cleaning material." (Ex. 1006, ¶ 31) (emph. add.) (Ex. 1002, ¶ 151). Rogers '889 further discloses that the "cleaning material" can be "at least partially saturated." Material that can be saturated is absorbent. (Ex. 1002, ¶ 152). "The first and second cleaning materials 7 and 8 in the

	inner cavity 20 are **at least partially saturated** with a cleaning agent …" (Ex. 1006, ¶ 36) (emph. add.) (*see also* Ex. 1006, ¶ 43 ("a second cleaning material 108 that also holds or is **at least partially saturated** by the cleaning agent.")) (Ex. 1002, ¶ 152). The **Rogers '438 provisional** also discloses a system that further comprises an "absorbent pad," describing a "foam" material that can be "soaked" with, and therefore must absorb, the disinfecting agent. (Ex. 1002, ¶ 153). "The material 7 may be cotton, **foam** or other suitable material. Material 8 is a second compressible material of cotton, **foam** or other suitable material." (Ex. 1017, p. 6) (emph. add.) (Ex. 1002, ¶ 153). "… the upper surface 50 of compressible **material 8**. As medical implement 10 threads 11 are rotationally inserted into housing 4 surface 50 **which is soaked with the disinfecting agent** …" (Ex. 1017, p. 8) (emph. add.) (Ex. 1002, ¶ 153).

[16a]. A system for medical luer connector caps comprising:	**Rogers '889** and the **Rogers '438 provisional** disclose a system for medical luer connector caps, as explained in claim limitation [1a] above. (Ex. 1002, ¶ 154).
[16b]. a first disinfecting cap, including a first receiving portion having:	**Rogers '889** and the **Rogers '438 provisional** disclose a disinfecting cap including a receiving portion, as explained in claim limitation [1b] above. (Ex. 1002, ¶ 155).
[16c]. (i) a first chamber in which a medical tubing connector can be received,	**Rogers '889** and the **Rogers '438 provisional** disclose a chamber in which a medical tubing connector can be received, as explained in claim limitation [1c] above. (Ex. 1002, ¶ 156).
[16d]. (ii) a first exterior	**Rogers '889** and the **Rogers '438**

surface extending around the opening for receiving a cover,	**provisional** disclose an exterior surface extending around the opening for receiving a cover as explained in claim limitation 1[d] above. (Ex. 1002, ¶ 157).
[16e]. (iii) a first means for engaging threads of luer connectors; and	**Rogers '889** and the **Rogers '438 provisional** disclose a means for engaging threads of luer connectors as explained in claim limitation [1e] above. (Ex. 1002, ¶ 158).
[16f]. a second disinfecting cap, including a first receiving portion having:	**Rogers '889** discloses that the disinfecting cap including a receiving portion is found in a "plurality of caps". See limitations [1b] and [16b] above. (Ex. 1002, ¶ 159).
[16g]. (i) a second chamber in which a medical tubing connector can be received,	**Rogers '889** discloses that the disinfecting cap including a receiving portion is found in a "plurality of caps". See claim limitations [1b] and [16c] above. (Ex. 1002, ¶ 160).
[16h]. (ii) a second exterior surface extending around the opening for receiving a cover,	**Rogers '889** discloses that the disinfecting cap including a receiving portion is found in a "plurality of caps". *See* limitations [1b] and [16d] above. (Ex. 1002, ¶ 161).
[16i]. (iii) a second means for engaging threads of luer connectors; and	**Rogers '889** discloses that the disinfecting cap including a receiving portion is found in a "plurality of caps". See limitations [1b] and [16e] above. (Ex. 1002, ¶ 162).
[16j]. a cover extending over and solely in contact with the first and second exterior surfaces, so as to seal the chambers of the at least two disinfecting caps.	**Rogers '889** discloses "a cover extending over … the first and second exterior surfaces" ("a plurality of") that seals the chambers of the caps as explained in claim limitation [1f] above. (Ex. 1002, ¶ 163).

Ground 2. Claims 2 and 3 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Mayoral.

Claims 2 and 3 are invalid under 35 U.S.C. § 103(a) over Rogers '889 as in Ground 1 (incorporated by reference), in further view of U.S. Patent No. 6,394,983 ("Mayoral"). (Ex. 1021) (Ex. 1002, ¶ 164). Mayoral is prior art under § 102(b) as the patent issued in 2002. (Ex. 1002, ¶ 165). The level of skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 54-65).

Claim 2 of the '326 patent states, "[a] system according to claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed on an exterior wall of the cap so as to engage a *male* luer connector." Claim 3 depends from claim 2, and describes a system wherein the means for engaging threads includes a "helical thread". (Ex. 1001).

Rogers '889 discloses the disinfecting cap of the '326 patent where the cap engages a female luer connector. (Ex. 1006, ¶ 33). Mayoral describes a cap having threads for connecting with a male luer connector. (Ex. 1002, ¶ 166). As stated Mayoral:

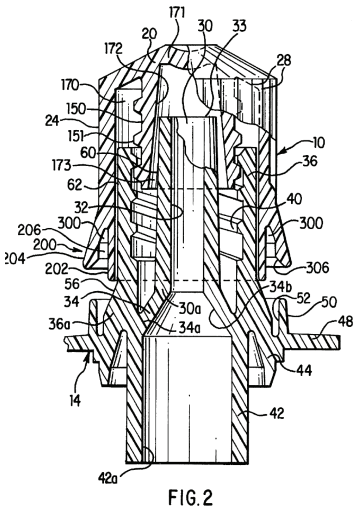
> "The present invention relates to a system for covering a portion of a fitting or connector on a medical device or other apparatus through which fluid is transferred. The present invention is especially suitable **as a cap and male Luer lock connector combination for a Luer lock type of fluid transfer device** such as a hypodermic needle." (Ex. 1021, 1:5-10) (emph. add.).

It would have been obvious to combine the teachings of Mayoral with Rogers '889. (Ex. 1002, ¶ 168). Specifically, it would have been clear to a person of ordinary skill in the art that male threads complement female threads, and that a male connector needs a cap with female threads, and a female connector needs a cap with male threads. (*Id.*). *See, e.g., Ex parte Heinz*, 2006 Pat. App. LEXIS 3428, *20 (BPAI 2006) ("If a person of ordinary skill in the art is presented with a female connector on an automotive wiring harness, they will instantly recognize that a male connector must connect with the female connector and vice-versa."); MPEP § 2144.04.IV.A (mere reversal of parts is obvious).

Explaining that "courts have held that shifting the location of parts is within the general skill of a worker in the art", during prosecution of the '326 patent, the Examiner further found that, "*[t]herefore, it would have been obvious to one of skill in the art at the time the invention to shift the location of the helical threads to an external surface of the housing to yield ... predictable result[s*]." (Ex. 1011, pp. 6-7)(emph. add.).

The combination of Rogers '889 and Mayoral represents the incorporation of a of the known cap for a male luer connector (Mayoral) with the known disinfecting luer connector cap (described in Rogers '889), each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 172). *See KSR Int'l Co. v. Teleflex, Inc*., 127 S.Ct. 1727, 1739-42 (2007). Rogers '889 in view of Mayoral

teaches claims 2 and 3 of the '326 patent, as follows:

[2]. A system according to claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed on an exterior wall of the cap so as to engage a male luer connector.	**Mayoral** discloses a system wherein the means for engaging threads of at least one of the disinfecting caps is disposed on an exterior wall of the cap so as to engage a male luer connector. (Ex. 1002, ¶ 173). The male threads are shown in Figure 2 [151] of the patent (below right). (Ex. 1002, ¶ 174). Mayoral states: "The cap 10 includes an end wall 20 and an annular, inner sleeve 150 extending from the end wall 20…. The inner sleeve 150 has **male threads** 151 for engaging the connector collar internal thread form 40. (Ex. 1021, 5:59-65) (Ex. 1002, ¶ 174).  FIG.2 As also explained, the male threads are male luer threads. (Ex. 1002, ¶ 175). The patent states: "The cap is **especially suitable for a 6% Luer tapered conical nozzle** with a surrounding annular collar … that has a double-start, right–hand, internal thread." (Ex. 1021, 2:63-67) (emph. add.) (Ex. 1002, ¶ 175).

[3]. A system according to claim 2, wherein the means for engaging threads includes a helical thread.	See claim 5 above. **Mayoral** also discloses helical threads, in Figure 2 above. (Ex. 1002, ¶ 177).

Ground 3. Claims 1, 4-9, 12, and 14-16 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Lake.

If it is determined that the '326 patent is entitled to an effective date of January 17, 2006 based on the filing date of the Howlett '541 provisional, and Rogers '889

is not entitled to the earlier filing date of the Rogers '438 provisional, then claims 1, 4-9, 12 and 14-16 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of U.S. Pat. No. 7,282,186 ("Lake").

As shown in Ground 1 above, the Rogers '438 provisional makes the same disclosures as the Rogers '889 provisional, except for claim limitations [1f] and [16j] relating to a cover extending over more than a single disinfectant cap. (Ex. 1002, ¶ 179). This subject matter was obvious in view of Lake.

Lake is prior art under § 102(b) because it was published in 2004. (Ex. 1002, ¶ 181). Lake is relevant because it describes a method of packaging wherein multiple disinfecting caps are connected to one other under a single cover. (Ex. 1019, Fig. 4, 3:59-65) (Ex. 1002, ¶ 183). This is shown in Figure 4 of Lake, right. As explained in Lake, "[t]he invention can be packaged in many different ways. There is shown in FIG. 4 an embodiment in which several decontamination devices 10 are joined at edges 58. The edges 58 are perforated, scored, or otherwise construed to permit the detachment of the decontamination devices from one other. Covers 62 can then be removed by peeling or otherwise removing the covers 62 from housings 64." (Ex. 1019, 3:59-65) (Ex. 1002, ¶ 183).

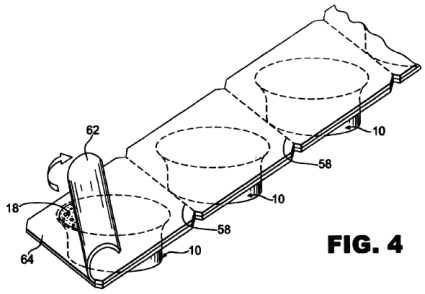
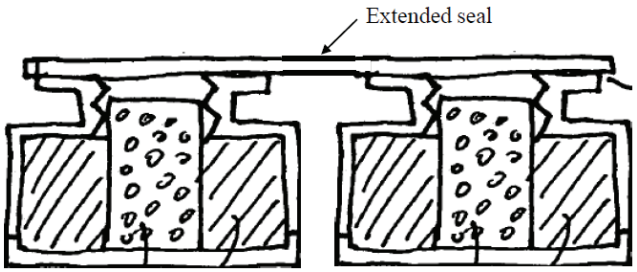


FIG. 4

Reasons for Combining Rogers '889 and Lake

It would have been obvious to use the packaging system of Lake with the system for disinfecting caps described in Rogers '889. (Ex. 1002, ¶ 155). Like Rogers '889, Lake is a system directed to preventing against contamination in medical devices, and is directed to use with various medical apparatus. (Ex. 1019, 4:25-31 ("The invention is suitable for many different medical apparatus. … It is only necessary that the housing of the decontamination device be adapted to receive the portion of the medical apparatus that is to be decontaminated") (Ex. 1002 ¶ 186). Lake, like Rogers '889, does so by placing an absorbent material with an antiseptic agent in contact with the medical apparatus. (Ex. 1019, 3: 5-23) (Ex. 1002, ¶ 186). Lake is analogous art, at least because it is reasonably pertinent to the problems faced by the alleged inventors of the '326 patent. (Ex. 1002, ¶ 193).

Both the Rogers '438 provisional and Lake describe a cover that can maintain the pre-use sterility of the disinfecting cap (or decontamination device), and Lake discloses the use of such a cover with a plurality of devices. (Ex. 1019, Fig. 4)(Ex. 1002, ¶ 188). This would involve modifying the cover shown in the Rogers '438 provisional so that the seal extends across multiple caps as provided in Lake. (Ex. 1002, ¶ 188). This is shown here:

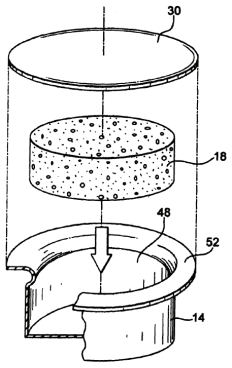
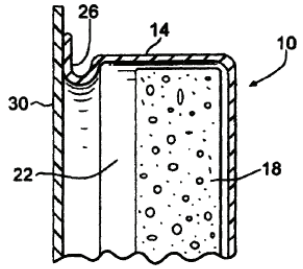


Both the Rogers '794 patent, which issued from Rogers '889, and Lake were cited during the prosecution of the '326 patent. A person of skill in the art would have understood that the teachings of the publications were related and should be considered together. (Ex. 1002, ¶ 190).

Incorporating the teachings from Lake into the system described in '889 Rogers (as supported by the Rogers '438 provisional) would have been well within the ordinary skill in the art. (Ex. 1002, ¶ 191). The combination represents the incorporation of a known method for packaging a decontamination device (Lake) with a known disinfecting luer connector cap (described in Rogers '889), each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 192). *See KSR Int'l Co. v. Teleflex, Inc*., 127 S.Ct. 1727, 1739-42 (2007).

Lake teaches the limitations not present in the Rogers '438 provisional as follows:

[1f]. a cover extending over and solely in contact with the exterior surface of each	**Lake** discloses "a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps". Lake discloses a cover that fits over the housing of the

of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps;	decontamination device. (Ex. 1002, ¶ 194). As shown in Fig. 3 and explained in the patent: "In FIG. 3 there is shown an exploded view in which the dispenser 18 is a pad and is placed in an interior 48 of the housing 14. The cover 30 is then secured to the flange 52 by a suitable adhesive so as to be removable." (Ex. 1019, 3:54-58) (Ex. 1002, ¶ 194).  **FIG. 3** Lake's caps are "disinfecting" because Lake discloses that the decontamination device has a housing [14] and a dispenser [18], that "can be of any suitable design for contacting the desired portion of the medical apparatus" with a "decontaminating compound." (Ex. 1019, 3:5-23) (emph. added) (Ex. 1002, ¶ 195). The patent then explains:  **FIG. 1** "the dispenser 18 comprises an absorbent pad which absorbs the decontaminating compound and dispenses the compound when contacted by the medical apparatus." (Ex. 1019, 3: 23-26) (Ex. 1002, ¶ 195). The decontaminating compound "can be any suitable compound or mixture of compounds. Such compounds include glutaraldeydes, such as 2% alkaline glutaraldeyde, glutaraldehyde-phenate; chlorine compounds, such as sodium hypchlorite and calcium hypochlorite; alcohols, such as 70-99% isopropyl or ethyl alcohol; iodophors, such as providone-iodine; peroxgen compounds, such as 3% stabilized hydrogen peroxide; phenolics, such as derivatives of phenol; and quarternary ammonium compounds, such as benzalkonium chloride." (Ex. 1019, 3:42-52) (Ex. 1002, ¶ 196). These compounds are disinfecting compounds. (Ex. 1002, ¶ 196). Lake further discloses "*at least two* disinfecting caps" with this "receiving portion". (Ex 1002, ¶ 197). The specification states:

	"Packaging for the decontamination device can be provided. A removable cover can be provided for the housing. **At least two of the decontamination devices can be detachably engaged**." (Ex. 1019, 2:1-4) (emph. add.) (Ex. 1002, ¶ 197) *See also* claim 6: "The decontamination device of claim 1, wherein **at least two of said housings are detachably engaged.**" (Ex. 1019, Claim 6) (emph. add.) (Ex. 1002, ¶ 198). Figure 4 of Lake, shown above, shows a connected strip of three (and possible additional) disinfecting caps ("decontamination devices") that are joined at their edges. (Ex. 1002, ¶ 199). A cover extends over the caps. (*Id.*). As explained in the patent: "The invention can be packaged in many different ways. There is shown in Fig. 4 an embodiment in which **several decontamination devices 10 are joined at edges 58**. The edges 58 are perforated, scored, or otherwise construed to permit the detachment of the decontamination devices from one other. **Covers 62 can then be removed by peeling or otherwise removing the covers 62 from housings 64.**" (Ex. 1019, 3:59-65) (emph. add.) (Ex. 1002, ¶ 199). As seen in Figure 4, Lake discloses a cover that extends over the housing of multiple disinfecting caps. (Ex. 1002, ¶ 200). The fact that the portion of the seal between the devices needs to be "scored" or "perforated" further indicates that a single seal over multiple devices is present. (*Id.*).

[16j]. a cover extending over and solely in contact with the first and second exterior surfaces, so as to seal the chambers of the at least two disinfecting caps.	**Lake** discloses a cover extending over a first and second disinfecting cap ("decontamination device") as explained in claim limitation [1f] above. (Ex. 1002, ¶ 201).

Ground 4. Claims 2-3 are invalid under 35 U.S.C. § 103(a) over Rogers '889 in view of Lake, in further view of Mayoral.

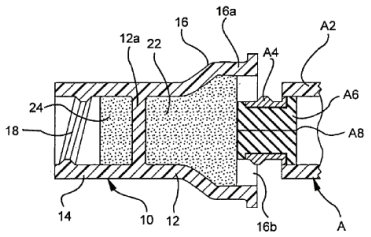
Claims 2 and 3 are invalid under 35 U.S.C. 103(a) over Rogers '889 and Lake as applied to the claims in Ground 3 (incorporated by reference), in further view of Mayoral. (Ex. 1021) (Ex. 1002, ¶ 202). The same reasons as explained in Ground 2 above apply here. Rogers '889 discloses the disinfecting cap of the '326 patent where the cap fits a female luer connector. (Ex. 1018, Fig. 3). Lake shows multiple caps sharing a single cover. (Ex. 1019, 3:59-65, Fig. 4). Caps with threads on an exterior wall to engage a *male luer connector* are disclosed in Mayoral. (Ex. 1002, ¶ 204). It would have been obvious to combine the teachings of Mayoral with Hoang and Lake for the same reasons that it would have been obvious to combine the teachings of Mayoral with Rogers '889 and Lake. (*Id.*, ¶ 205). The same claim charts as set forth in Ground 2 apply here.

Ground 5. Claims 1, 4-9, 12, and 14-16 are invalid under 35 U.S.C. § 103(a) over Hoang in view of Lake.

Claims 1, 4-9, 12, and 14-16 are unpatentable under 35 U.S.C. § 103(a) over U.S. Publication No. 2007/0112333 ("Hoang") (Ex. 1018) in view of Lake. (Ex. 1002, ¶ 207). Hoang is prior art under § 102(b) if the '326 patent is not entitled to an effective date of the Howlett '541 provisional, because Hoang was published in 2007. (Ex. 1002, ¶ 208). Hoang is also prior art under § 102(e)(1) because its

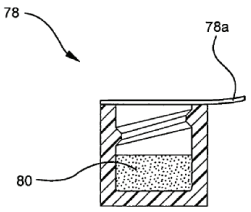
application was filed in 2005. (*Id.*, ¶ 209). Lake is prior art under § 102(b) because it was published in 2004. (*Id.*, ¶ 181). The level of ordinary skill is explained in the Leinsing declaration. (Ex. 1002, ¶¶ 54-65).

Much like the '326 patent, Hoang teaches caps for fluid line access valves. (Ex. 1018) (Ex. 1002, ¶ 210). The device in Hoang is a "cap/cleaner," with the cap [10] at one end and cleaning end [16] at the other, as shown in Figure 4, left. (Ex. 1002, ¶ 211). Both "[c]ap and cleaning devices antiseptically maintain patient fluid line access valves to minimize the risk of infection via catheters." (*Id.*, Abstract) (Ex. 1002, ¶ 211).



Hoang also shows a "stand-alone" cap, in Figure 10B, right, that contains a pad [80] with antimicrobial agent that comes into contact with the line when inserted therein. (Ex. 1018, ¶¶ 17, 22) (Ex. 1002, ¶ 212). The cap shown in Hoang has threads that can be attached to a medical connector, including a "luer" connector. (Ex. 1018, ¶ 22) (Ex. 1002, ¶ 215). Hoang discloses a cover that extends over an open end of the cap, called a "lid" in Hoang and shown in Figure 10B, 78a. (Ex. 1018, ¶ 43) (Ex. 1002, ¶ 213).

FIG. 10B



As explained above, Lake teaches a method of packaging multiple disinfecting caps so that the caps are connected to one other under a single cover. (Ex. 1019,

Fig. 4, 3:59-65) (Ex. 1002, ¶ 214). Also, while Hoang does not expressly disclose that the cover ("lid") is attached with an adhesive, as in claim 6 of the '326 patent, Lake does so. (Ex. 1019, 3:56-58) (Ex. 1002, ¶ 218).

Reasons for Combining Hoang with Lake

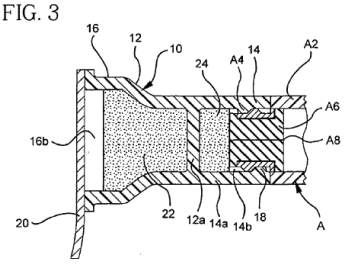
For similar reasons as those set forth above with respect to combining Rogers '889, as disclosed in the Rogers '438 provisional, with Lake as in Ground 3 above (incorporated by reference), it would have been obvious to one of ordinary skill in the art to use the packaging system of Lake with the system for disinfecting caps described in Hoang. (Ex. 1002, ¶¶ 219-220). This would involve the extension of the Hoang cover across two or more caps, for the same reasons provided for Rogers '889 and Lake. (*Id.*).

Notably, in the prosecution of a related Rogers patent, the Examiner rejected the claims as unpatentable over Hoang in view of Lake, finding that there was motivation to combine these references, and forcing the applicants there to amend the claims. (Ex. 1027 and 1028). As stated by the Examiner there:

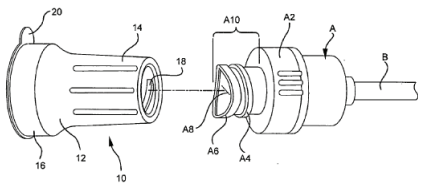
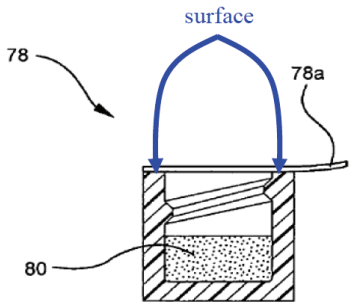
> "Hoang does not expressly disclose that the plurality of cleaning devices are attached to a strip of the flexible material, wherein the strip includes at least one hole. However, Lake teaches a plurality of cleaning cup devices (Fig. 4, element 10) for medical implements, the cleaning devices being attached to a strip of flexible material (element 62) … such that the cups are selectively removable from the strip of

> flexible material, the cups having an inner cavity that is sealed by the flexible strip of material when the cleaning device is attached to the strip of flexible material and configured to be unsealed upon removal of the cleaning device from the strip of flexible material (see Fig. 4). **One of ordinary skill in the art at the time of the invention would have been motivated to modify the system of Hoang by providing the plurality of cleaning devices attached to a strip of the flexible material, as in Lake, in order to maintain an orderly arrangement of multiple cleaning caps which are readily accessible for use.**" (Ex. 1027, p. 8-9) (emph. add.).

Hoang in combination with Lake teaches claims 1-9, 12, and 14-16 of the '326 patent, as follows:

[1a]. A system for medical luer connector caps comprising:	**Hoang** discloses a system for medical luer connector caps. Hoang first describes a "cap" for a "fluid line access valve". (Ex. 1002, ¶ 221). The specification describes: "a patient **fluid line access valve cap**/cleaner device…" (Ex. 1018, ¶ 17) (emph. add.) (Ex. 1002, ¶ 221). Hoang shows in reference to Fig. 3 that the "fluid line access valve" may be a "male luer taper". (Ex. 1002, ¶ 222). The specification states: FIG. 3  "FIG. 3 illustrates cap/cleaner 10 covering access portion A10 of access valve A. Septum A6 provides an accessible seal for either a needle or a **male luer taper**. In the case of a needleless access device, such as that shown in FIG. 3, slit A8 extends through septum A6 to provide a port for insertion of the **male luer taper**." (Ex. 1018, ¶ 22) (emph. add.)

	(Ex. 1002, ¶ 222). Where the valve can accept a male luer taper, the threads of the cap would also accept luer threads, or in other words be compatible with a luer connector. (Ex. 1002, ¶ 223).
[1b]. at least two disinfecting caps, each including a receiving portion having	**Hoang** discloses a disinfecting cap that has a receiving portion. The cap in Hoang, referred to as a "cap/cleaner," has a "receiving portion" called a "cavity". (Ex. 1002, ¶ 224). The specification states: "As shown, cap end 14 includes **cap 14a with cavity** 14b…." (Ex. 1018, ¶¶ 23, 24) (emph. add.) (Ex. 1002, ¶ 224). The "cavity" "receives" the access portion such that it is "within [the] cavity" of the cap. (Ex. 1002, ¶ 225). As stated in Hoang: "In use, cap end 14 of cap/cleaner 10 is placed over access portion A10 **such that A10 is within cavity 14b of cap end 14**." (Ex. 1018, ¶ 24) (emph. add.) (Ex. 1002, ¶ 225). Hoang's caps are "disinfecting" because the cavity contains a pad that is "impregnated with an antimicrobial **agent to aid in maintaining antiseptic conditions of access portion A10 of valve** A." (Ex. 1018, ¶ 23)(emph. add.)(Ex. 1002, ¶ 226). As explained in Hoang, "[a]ny of a number of antimicrobial agents may be used", including for example "chlorhexidine diacetate, chloroxylenol, povidone-iodine, Triclosan, benethonium chloride, benzalkonium chloride, octendine, antibiotic, etc. (Ex. 1018, ¶ 23). These are disinfecting agents. (Ex. 1002, ¶ 226). Hoang discloses "at least two disinfecting caps" by discussing "a new, second cap/cleaner". (*Id.*, ¶ 227). The specification states: "If immediately capped, a **new, second cap/cleaner** 10a is obtained and removed from its package." (Ex. 1018, ¶ 35)(emph. add.)(Ex. 1002, ¶ 227).
[1c]. (i) a	**Hoang** discloses chamber defining an opening in which a

chamber defining an opening in which a medical tubing connector can be received,	medical tubing connector can be received. As stated in [1b] above, Hoang first discloses a housing with a "cavity" (chamber) for covering the access portion. (Ex. 1002, ¶ 228). The chamber is the opening into that chamber, shown in Fig. 1 below. Hoang further discloses that the chamber can receive "any number of" types of lines, including medical tubing such as intravenous (IV) lines. (*Id.*, ¶ 229). IV lines are one type of medical tubing. (*Id.*). FIG. 1  "FIG. 1 shows an exploded view of patient fluid line access valve cap/cleaner device 10 with patient fluid line access valve A and patient fluid line B. …. **Line B may be** any of a number of types that include, for example, **intravenous (IV) lines** and catheters, saline wells, arterial lines and hemodialysis lines." (Ex. 1018, ¶ 17) (Ex. 1002, ¶ 229) (emph. add.).
[1d]. (ii) an exterior surface extending around the opening for receiving a cover	**Hoang** discloses an exterior surface extending around the opening for receiving a cover. Hoang first discloses a cover, which it calls a "lid": FIG. 10B  "Figure 10B shows a representative embodiment of a cap device 78 with **lid** 78a … " (Ex. 1018, ¶ 43) (emph. add.)(Ex. 1002, ¶ 230). In the figure, the surface has been shown with added blue arrows pointing to the surface. The surface is shown around housing in Figure 10B. (Ex. 1002, ¶ 231). The housing is in the shape of a cylinder in three dimensions, and thus the "surface" is "around" the opening. (*Id.*).
[1e]. (iii) a means for	**Hoang** also discloses a means for engaging threads of luer connectors. As stated above, this term is properly construed as

engaging threads of luer connectors; and	"threads that mate with the threads of luer connectors." (*See* section III, claim construction). In reference to Figure 3 above, Hoang discusses rotating the cap/cleaner and valve relative to one other to interlock the threads. (Ex. 1002, ¶ 232). Hoang states: "In use, cap end 14 of cap/cleaner 10 is placed over access portion A10 such that access portion A10 is within cavity 14b of cap end. … As shown in FIG. 3, valve A **includes thread A4**. By rotating cap/cleaner 10 or valve A relative to one another, threads A4 and 18 (of cap/cleaner 10) **interlock to provide a secured attachment**." (Ex. 1018, ¶ 24) (emph. add.)(Ex. 1002, ¶ 232). As explained in claim limitation [1a] above, it is further disclosed that Figure 3 (above) can include a "luer taper". Where the valve can accept a male luer taper, the threads of the cap would also accept luer threads, or in other words be compatible with the threads for a female connector. (Ex. 1002, ¶¶ 217, 234).
[1f]. a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps;	See claim element [1d] above regarding the cover extending over the surface of a single cap as disclosed in **Hoang**. (Ex. 1002, ¶ 235). **Lake** discloses "a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps", as explained in Rogers '889 claim element [1f] above. (Ex. 1002, ¶ 236).

[4]. A system according to	**Hoang** also discloses the means for engaging threads of at least one of the disinfecting caps is disposed on an interior wall

claim 1, wherein the means for engaging threads of at least one of the disinfecting caps is disposed in the chamber of the cap so as to engage a female luer connector.	of the cap so as to engage a female luer connector. (Ex. 1002, ¶ 237). **Hoang** discloses a means for engaging threads disposed in the chamber of the cap as set forth in claim limitation [1e] above. (*Id.*, ¶ 238). In Hoang, "threads" [18] are shown "disposed on the intertior wall of the cap" in Figure 3, also shown above. (*Id.*, ¶ 239). The specification explains that the threads are threads that can engage a luer connector. See claim limitation [1e] above. (*Id.*, ¶ 240). The threads in **Hoang** maintain the connection between the cap and the connector. (Ex. 1002, ¶ 241). The threads "interlock" to "secure" the connection. (*See* section III, claim construction). "By rotating cap/cleaner 10 or valve A relative to one another, **threads A4 and 18** (of cap/cleaner 10) **interlock to provide a secured attachment**." (Ex. 1018, ¶ 24)(emph. add.) (Ex. 1002, ¶ 241).

[5]. A system according to claim 4, wherein the means for engaging threads includes a helical thread.	**Hoang** discloses a means for engaging threads that includes helical threads. Fig. 1 in Hoang, shown in claim limtation [1c] above, shows that the threads include helical threads. (Ex. 1002, ¶ 242). As also stated in Hoang, the threads are connected by a "twisting" motion. The twisting motion both cleans and connects the cap to the connector. Such rotational force also indicates helical threads. (Ex. 1002, ¶ 243). "The **twisting motion** involved in removing and placing the cap device 78 with respect to access potion A10 provies friction for cleaning. Additional cleaning can be accomplished by **twisting cap device** 78 in one direction and then in the reverse direction for a desired amount of time." (Ex. 1018, ¶ 44)(emph. add.)(Ex. 1002, ¶ 243).

[6]. A system according to claim 1 wherein the cover comprises an adhesive.	**Lake** discloses a cover that comprises an "adhesive". (Ex. 1002, ¶ 244). The specification states: "The **cover** 30 is then secured to flange 52 by a suitable **adhesive** so as to be removable." (Ex. 1019, 3:56-58)(emph. add.)(Ex. 1002, ¶ 244).

[7]. A system according to claim 1 wherein the cover comprises an impervious pliable material.	**Hoang** discloses a system wherein the cover comprises an impervious pliable material. (Ex. 1002, ¶ 245). Hoang discloses a cover, as explained in claim limitation [1d] above. (*Id.*, ¶ 246). Hoang further discloses that the "lid" is made of "foil," which is impervious, or a material that "completely seals the opening" and creates a "moisture barrier," and is therefore "impervious". (Ex. 1002, ¶ 247.) The '326 patent recognizes foil as an impervious pliable material. (Ex. 1001, claim 8)(Ex. 1002, ¶ 247). Hoang states: "Lid 20 is typically made of foil or similar type material and **completely seals the opening** (not shown) of cleaning end 16. **Any type of material or seal may be used as long as a moisture barrier is provided**." (Ex. 1018, ¶ 19)(emph. add.)(Ex. 1002, ¶ 247). Figure 10(b) also shows the "lid" is to be pulled from the cap, in bent fashion, for removal. Accordingly, the lid must also be pliable. (Ex. 1002, ¶ 248).

[8]. A system according to claim 7 wherein the material is a foil or a plastic.	**Hoang** discloses a system where the cover is a foil. (Ex. 1002, ¶ 249). "Lid 20 is typically made of **foil** or similar type material and completely seals the opening (not shown) of cleaning end 16." (Ex. 1018, ¶ 19)(emph. add.)(Ex. 1002, ¶ 249).

[9]. A system	Hoang discloses a system wherein a cap comprises a

according to claim 1 wherein each of the at least two caps further comprises a connection interface	**connection interface**. As stated above, a "connection interface" is where one disinfecting cap or medical implement connects with another disinfecting cap or medical implement. (*See* section III, claim construction). Hoang discloses that connection is made when the cap (cap/cleaner) is "threaded to" and "interlocks" with the access valve. (Ex. 1002, ¶ 250). Hoang explains: " By rotating cap/cleaner 10 or valve A relative to one another, **threads A4 and 18 (of cap/cleaner 10) interlock to provide a secured attachment**." (Ex. 1018, ¶ 24) (emph. add.)(Ex. 1002, ¶ 250).

[12]. A system according to claim 1 wherein each of the caps further comprise a gripping portion.	**Hoang** discloses a system wherein the system further comprise a gripping portion. (Ex. 1002, ¶ 251). The specification explains: "With either cleaning device 74 or cap device 78, **additional gripping surface may be added by extending the length of the housing**. The increased gripping surface would provide easier handling of devices 74 and 78." (Ex. 1018, ¶ 45) (emph. add.)(Ex. 1002, ¶ 251).

[14]. A system according to claim 1 wherein the system further comprise an antiseptic agent	**Hoang** discloses a system that further comprises an antiseptic agent. Hoang refers to the antiseptic agent as an "antimicrobial agent." An anti-microbial agent is an antiseptic agent. (Ex. 1002, ¶ 252). "The device of claim 2, where the pad is impregnated with an **antimicrobial agent**." (Ex. 1018, claim 3) (emph. add.) (Ex. 1002, ¶ 252). Hoang further discloses specific examples of antiseptic or antimicrobial agents used in a dry pad in the cap. (Ex. 1002, ¶ 253). Hoang states: "Dry pad 24 is impregnated with an antimicrobial agent to aid in **maintaining antiseptic conditions** of access portion A10 of valve A..... Any of a number of **antimicrobial agents** may be used to impregnate

	dry pad 24. Some examples include chlorhexidine gluconate, chlorheidine diaceiate, chloroxylenol, povidone iodine, Triclosan, benzethonium chloride, benzalkonium chloride, octenidine, antibiotic, etc." (Ex. 1018, ¶ 23) (emph. add.) (Ex. 1002, ¶ 253). There is also disclosed in some embodiments of Hoang a wet pad. That wet pad is also used with an antiseptic agent, specifically alcohol. (Ex. 1002, ¶ 254). Hoang states: "Wet pad 22 is impregnated with a **cleaning agent** and optionally a **antimicrobial agent**. … The cleaning solution is typically an **alcohol- or water-based solution**. …" (Ex. 1018, ¶¶ 27-28)(emph. add.)(Ex. 1002, ¶ 254).

[15]. A system according to claim 14 wherein the system further comprise an absorbent pad.	**Hoang** discloses a system that further comprises an absorbent pad. Hoang describes both a dry pad and a wet pad. Both can be a "foam sponge pad". ((Ex. 1018, ¶¶ 23, 27). "Foam" is an absorbent material. (Ex. 1002, ¶ 255). "Suitable material … includes non-woven material or a **foam sponge pad** may be made of polyurethane, polyester, cotton or any bioengineered plastic material such as silicone." (Ex. 1018, ¶ 23) (emph. add.) (Ex. 1002, ¶ 255).

[16a]. A system for medical luer connector caps comprising:	**Hoang** discloses a system for medical luer connector caps as explained in claim limitation [1a] above. (Ex. 1002, ¶ 256).
[16b]. a first disinfecting cap, including a first receiving portion having:	**Hoang** discloses a disinfecting cap that has a receiving portion as explained in claim limitation [1b] above. (Ex. 1002, ¶ 257).
[16c]. (i) a first chamber in which a medical tubing connector can be received,	**Hoang** discloses chamber defining an opening in which a medical tubing connector can be received as explained in claim limitation [1c] above. (Ex. 1002, ¶ 258).

[16d]. (ii) a first exterior surface extending around the opening for receiving a cover,	**Hoang** discloses an exterior surface extending around the opening for receiving a cover as explained in claim limitation [1c] above. (Ex. 1002, ¶ 259).
[16e]. (iii) a first means for engaging threads of luer connectors; and	**Hoang** also discloses a means for engaging threads of luer connectors as explained in claim limitation [1d] above]. (Ex. 1002, ¶ 260).
[16f]. a second disinfecting cap, including a first receiving portion having:	**Hoang** discloses a second disinfecting cap having a first receiving portion. See claim limitation [1b] above. (Ex. 1002, ¶ 261). See limitation [16b] above regarding a first receiving portion. (*Id.*, ¶ 262).
[16g]. (i) a second chamber in which a medical tubing connector can be received,	See claim limitations [1b] and [16c] above. (Ex. 1002, ¶ 263).
[16h]. (ii) a second exterior surface extending around the opening for receiving a cover,	See claim limitations [1b] and [16d] above. (Ex. 1002, ¶ 264).
[16i]. (iii) a second means for engaging threads of luer connectors; and	See claim limitations [1b] and [16e] above. (Ex. 1002, ¶ 265).
[16j]. a cover extending over and solely in contact with the first and second exterior surfaces, so as to seal the chambers of the at least two disinfecting caps.	**Lake** discloses "a cover extending over and solely in contact with the exterior surface of each of the at least two disinfecting caps, so as to seal the chambers of the at least two disinfecting caps" as set forth in claim limitation [1f] above. (Ex. 1002, ¶ 266).

Ground 6. Claims 2 and 3 are invalid under 35 U.S.C. § 103(a) as obvious over Hoang in view of Lake, in further view of Mayoral.

Claims 2 and 3 are invalid under 35 U.S.C. 103(a) over Hoang and Lake as applied to the claims in Ground 5 (incorporated by reference), in further view of Mayoral. (Ex. 1021)(Ex. 1002, ¶ 267). The same reasons as explained in Ground 2 and Ground 4 above apply here. Hoang, like the '889 Rogers publication, discloses the disinfecting cap of the '326 patent where the cap fits a female luer connector. (Ex. 1018, Fig. 3). Lake shows multiple caps sharing a single cover. (Ex. 1019, 3:59-65, Fig. 4). Disinfecting caps with threads on an exterior wall to engage a *male luer connector* are disclosed in Mayoral. (Ex. 1002, ¶ 198). It would have been obvious to combine the teachings of Mayoral with Hoang and Lake for the same reasons that it would have been obvious to combine the teachings of Mayoral with Rogers '889 and Lake. (Ex. 1002, ¶ 268).

IV. CONCLUSION

The Petitioner therefore requests institution of trial and cancellation of claims 1-9, 12, and 14-16 of the '326 patent.

Date: July 8, 2014 Signed: /Matthew A. Smith/ RN 49,003

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing petition for inter partes review, together with all exhibits and other documents filed therewith, was served by Federal Express on this day, July 8, 2014, on the Patent Owner's counsel of record at the United States Patent & Trademark Office having the following address:

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