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. 8,641,681

PETITION FOR INTER PARTES REVIEW

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

TABLE OF CONTENTS

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Pat. No. 8,641,681 ("the '681 patent").
1002	Declaration of Karl Leinsing.
1003	U.S. Pat. No. 8,617,482 ("Tryggvason").
1004	U.S. Published App. No. 2005/0147524 ("Bousquet").
1005	U.S. Published App. No. 2008/0132880 ("Buchman").
1006	U.S. Published App. No. 2006/0030827 ("Raulerson").
1007	U.S. Published App. No. 2011/0165020 ("Tryggvason Publication").
1008	U.S. Pat. No. 5,184,742 ("DeCaprio").
1009	U.S. Pat. No. 8,740,864 ("Hoang").
1010	International Standard ISO 594/1, CONICAL FITTINGS WITH A 6% (LUER) TAPER FOR SYRINGES, NEEDLES AND CERTAIN OTHER MEDICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS (1st ed. 1986).
1011	International Standard ISO 594/2, CONICAL FITTINGS WITH A 6% (LUER) TAPER FOR SYRINGES, NEEDLES AND CERTAIN OTHER MEDICAL EQUIPMENT – PART 2: LOCK FITTINGS (2nd ed. 1998).
1012	U.S. Pat. No. 3,987,930 ("Fuson").
1013	U.S. App. Ser. No. 13/736,166, Preliminary Amendment dated February 28, 2013.
1014	U.S. App. Ser. No. 13/736,166, Office Action dated August 8, 2013.
1015	U.S. App. Ser. No. 13/736,166, Amendment dated September 17, 2013.
1016	U.S. App. Ser. No. 13/736,166, Notice of Allowance.
1017	U.S. Pat. No. 5,954,957 ("Chin-Loy").
1018	U.S. Pat. No. 4,597,758 ("Aalto").

1019	U.S. Pat. No. 4,624,664 ("Peluso").
1020	U.S. Pat. No. 5,533,980 ("Sweeney").
1021	PCT/EP2009/057321 dated June 15, 2009.
1022	U.S. Provisional App. Ser. No. 61/073,051 dated June 17, 2008.
1023	Tryggvason claim charts.
1024	Buchman claim charts.
1025	U.S. App. Ser. No. 12/610,141, dated October 30, 2009.
1026	U.S. App. Ser. No. 13/736,166, Office Action dated May 16, 2013.
1027	Affidavit of Process Server Serving Ivera Medical Corporation with Summons, Complaint, and Motion for Preliminary Injunction, dated February 10, 2014.
1028	U.S. Provisional App. Ser. No. 60/774,708 dated February 17, 2006.
1029	U.S. App. Ser. No. 13/736,166, Amendment dated June 25, 2013.
1030	Decision, Institution of *Inter Partes* Review, 37 C.F.R. § 42.108 in IPR2014-01124.

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. 8,641,681 ("the '681 patent") has been asserted in the U.S. District Court, District of Utah in Case No. 2-14-cv-00070, in *Catheter Connections, Inc. v. Ivera Medical Corporation*, filed February 4, 2014. Petitioner has filed petitions for *inter partes* review of related U.S. Patent Nos. 8,647,326 (IPR2014-01124), and 8,647,308 (IPR2015-00665). The Board has instituted trial as to the petition in IPR2014-01124. (Ex. 1030).

NOTICE OF SERVICE INFORMATION

Please address all correspondence to the lead counsel at the addresses shown above. Petitioner also consents to service by email at: smith@turnerboyd.com, seraphine@turnerboyd.com, gu@turnerboyd.com, docketing@turnerboyd.com.

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 1-22 of U.S. Patent No. 8,641,681 ("the '681 patent")(Ex. 1001) be canceled based on the following grounds of unpatentability, explained in detail in the next section. Each claim has only one ground:

Ground 1. Claims 1, 2, 4, 9, 10, 11, 13, 14, 15, 17, 18, 21 and 22 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto.

Ground 2. Claims 3 and 16 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto, in further view of Sweeney.

Ground 3. Claims 5 and 12 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto, in further view of Buchman.

Ground 4. Claims 6, 7, 8, 19 and 20 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto, in further view of Hoang.

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).

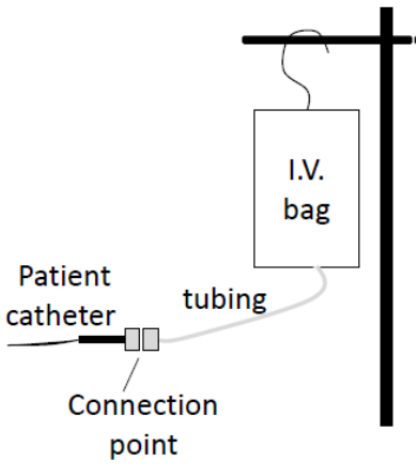
A. Technology Background

This *inter partes* review relates to connectors used with medical implements used to supply a patient's blood vessels with fluid or to withdraw fluid, for example, patient catheters, syringes, and intravenous (IV) tubing. (Ex. 1002, ¶ 22). More specifically, the technology at issue relates to *caps* used to cover standardized connectors, called "luer connectors", which are commonly used to attach two or more medical implements together. (*Id.*, ¶ 23).

1. Luer Connectors

Because many of the claimed elements of the '681 patent relate to the basic features of luer connectors, it is helpful to first provide a brief explanation these standardized medical connectors.

Luer connectors are widely used with medical implements. (Ex. 1002, ¶ 24). An example of a common use of luer connectors is at the connection point between a catheter inserted into a patient's vein, and intravenous (IV) tubing, through which fluid is supplied by an IV bag. In this diagram, for example, a luer connector is placed on the



end of the patient's catheter, and a second, corresponding luer connector, is placed on the end of the IV tubing. (*Id.*, ¶¶ 25, 26).

Luer connectors have been around since the late 1800s, when Hermann Wülfing Luer invented a way of putting a stopper tapered by 6% in a bottle and having it form a seal. (Ex. 1002, ¶ 27). The defining characteristic of "luer" connectors is the 6% taper. (*Id.*, ¶ 28). In 1986, the fundamental features of luer connectors were standardized and published by the International Organization for Standardization (ISO), as international standard ISO 594-1, *Conical Fittings With A* 6% (*Luer*) *Taper For Syringes, Needles And Certain Other Medical Equipment*. In 1998, an update, ISO 594-2, standardized locking mechanisms for luer connectors, discussed in more detail below. (Exs. 1010 and 1011)(Ex. 1002, ¶ 29).

So that they can be attached to each other, one luer connector is a "*male*" luer connector, and the other a "*female*" luer connector. A simplified example of a male and female luer connector is shown below, in a figure from the ISO 594-1:1986 Standards. (Ex. 1010, p. 4)(Ex. 1002, ¶ 30). To the left in the figure is a male luer connector ("male fitting") with a post that has a 6% taper on its sides. (Ex. 1002, ¶ 31). The post

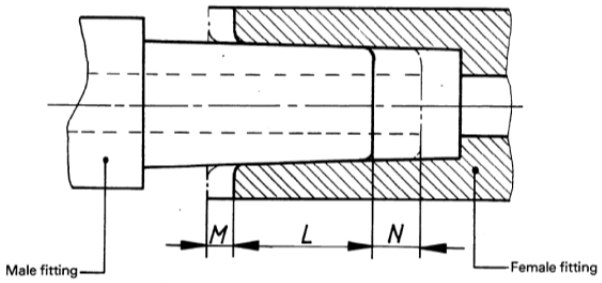


Figure 2 — Typical assembly of 6 % (Luer) conical fittings

may be a lumen, also sometimes referred to as a nozzle. A lumen or nozzle is a hollow post, through which fluid may flow. (*Id.*).

To the right in the above figure, shaded in the original, is a female luer connector ("female fitting"). (Ex. 1002, ¶ 32). The female luer connector has an open end, into which the male luer connector is received. The walls of the opening into the female luer connector have a 6% taper corresponding to the walls of the post of the male luer connector. (*Id.*). The female luer connector also has an opening through which fluid may flow. (*Id.*).

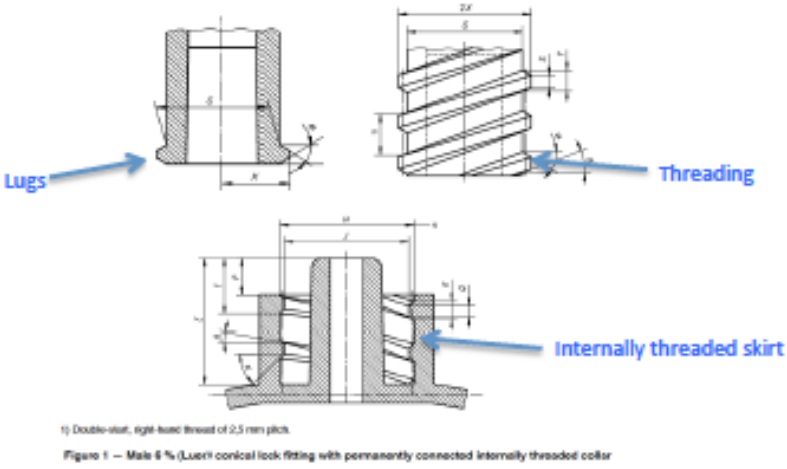
The use of standardized luer connectors allows for the interchangeability of different medical implements. (Ex. 1002, ¶ 33). In the above example, for instance, the catheter remains in place in the patient's vein to supply fluids or medications. The IV tubing may be disconnected to change to another fluid bag, with new tubing, or to administer medications with a syringe. One or both of the connectors may also be left unconnected, pending later use. (*Id.*, ¶¶ 34, 35).

The luer connectors shown above are "luer-slip" connectors: male and female luer-slip fittings that conform to luer taper dimensions, and are wedged together and held by friction (they have no threads). (Ex. 1002, ¶ 36). Other luer connectors are "luer-lock" connectors. Luer-lock connectors have the same features as described above for luer slip connectors, and are additionally joined securely to one another. (*Id.*, ¶ 37). Typically this is by means of threads

(alternatively "lugs") on the female luer connector, which connects to threads in a "skirt" or "collar" on the male luer connector. (*Id.*).

These locking features are shown here, in figures from the (prior art) ISO 594-2:1998 Standards (with added identifiers). (Ex. 1011, pp. 6-8) (Ex. 1002, ¶ 37).

The two female luer-lock connectors are shown with lugs (left) and helical threads (right). (Ex. 1002, ¶ 38). The fitting on the bottom in the above figure is a corresponding male luer-lock connector with a threaded skirt. The skirt, or collar, extends around the post of the male luer-lock connector. (*Id.*). When connected, the lugs or threads on the female luer-lock connector interlock with the threading on the skirt of the male luer-lock connector. (*Id.*).

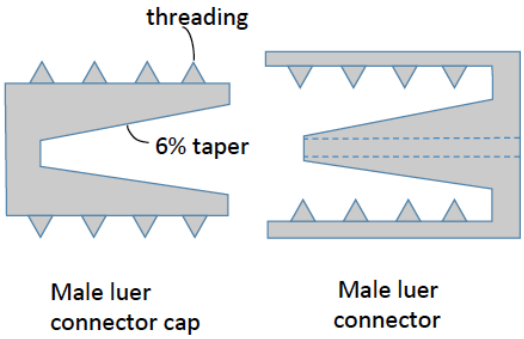


2. Caps for Luer Connectors

At times there is no need to have medical implements connected, but at the same time it is desired to reserve one or both for future use. (Ex. 1002, ¶ 39). For example, IV tubing can be

disconnected when not needed, leaving a patient's catheter in place for later use. (*Id.*). When disconnected, the luer connectors can be covered with "caps", shown in blue in the above diagram. (*Id.*, ¶ 40).

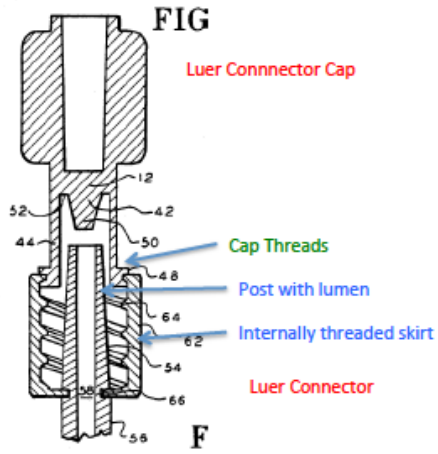
Similarly to the fit between a male luer connector and a female luer connector, luer connector caps correspond in shape to the luer connectors that they are intended to cap. (Ex. 1002, ¶ 41). For example, in the simplified example shown here, a male luer connector *cap* (left) connects to a male luer connector (right). (*Id.*). The male luer connector has an internally threaded skirt, which corresponds to the external threading on the male luer connector cap. The dotted blue lines indicate the lumen (or nozzle) that allows fluid to pass through the post of the male luer connector. (*Id.*,¶ 42).



(i) Sterile Protective and Disinfecting Luer Connector Caps

Caps for luer connectors have been known for decades, an early example being U.S. Patent 3,987,930 ("Fuson")(Ex. 1012), which issued in 1976. (Ex. 1012)(Ex. 1002, ¶ 43). Fuson disclosed a "dual purpose intravenous tubing cap [] provided for sealing both male and female Luer-tapered intravenous tubing end fittings". (Ex. 1012, 2:34-36)(Ex. 1002, ¶ 43).

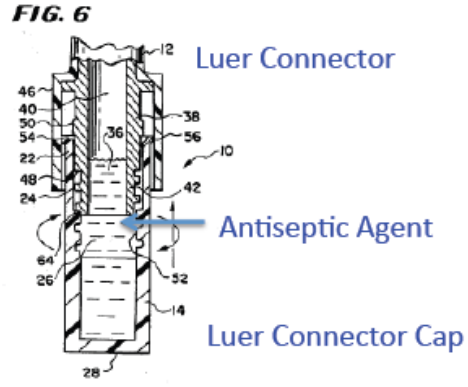
Protective caps for luer connectors were oftentimes referred to as "deadender" caps. (Ex. 1002, ¶ 44). U.S. Patent No. 5,184,742 ("DeCaprio"), "Deadender Cap for Luer Fitting", issued in 1993. (Ex. 1008). DeCaprio disclosed a "cap that is designed to be screwed into a standard medical Luer male thread connection to dead end that connection". (Ex. 1008, Abstract)(Ex. 1002, ¶ 44). Figure 3 of DeCaprio is shown here, with external threads [48], designed to connect with the internal threads [64] on the skirt [62] of the male luer connector. (Ex. 1008, 4:24-27)(Ex. 1002, ¶45).



Early caps for luer connectors, like Fuson and DeCaprio, protected the sterility of the connector against touch contamination. These are often called "sterile protective caps". (Ex. 1002, ¶ 46). While sterile protective caps served an important function, in some applications it was required that medical personnel disinfect the luer connector prior to use. This was typically done with an isopropyl alcohol or betadine swab. (*Id.*, ¶ 47).

As luer connector caps evolved, the disinfecting feature was added to the caps themselves, generally by including an antiseptic within the cap body. (Ex. 1002, ¶ 48). An early example of a disinfecting cap is U.S. Patent No. 4,624,664

("Peluso"), which included an antiseptic in the cap, and which issued in 1986.



(Ex. 1019)(Ex. 1002, ¶ 49). As shown in Figure 6 of Peluso here, an antiseptic fluid [36] is contained in the cap for disinfecting the luer connector when inserted into the cap. (Ex. 1019)(Ex. 1002, ¶ 49).

U.S. Patent No. 8,617,482 ("Tryggvason"), the principal reference of Ground 1, is another early example of a disinfecting luer connector cap. (Ex. 1003).

B. The '681 Patent

The specification of '681 patent relates generally to caps for both male and female luer-lock connectors. (Ex. 1001)(Ex. 1002, ¶ 51). The claims of the '681 patent are directed to a disinfecting cap for "a medical male luer-lock connector, of the type including a post having a lumen through which fluid flows and an internally helically threaded skirt surrounding the post", like the male connectors shown in the 1998 ISO 594-2 Standards discussed above. (Ex. 1001, cl. 1, 18)(Ex. 1002, ¶ 52)(Ex. 1011).

1. Independent Claims 1 and 18

The *cap* claimed in both independent claims includes limitations that relate to the basic features of luer connectors discussed above. Those features were, of course, not new at the time of the invention of the '681 patent. Consequently, the

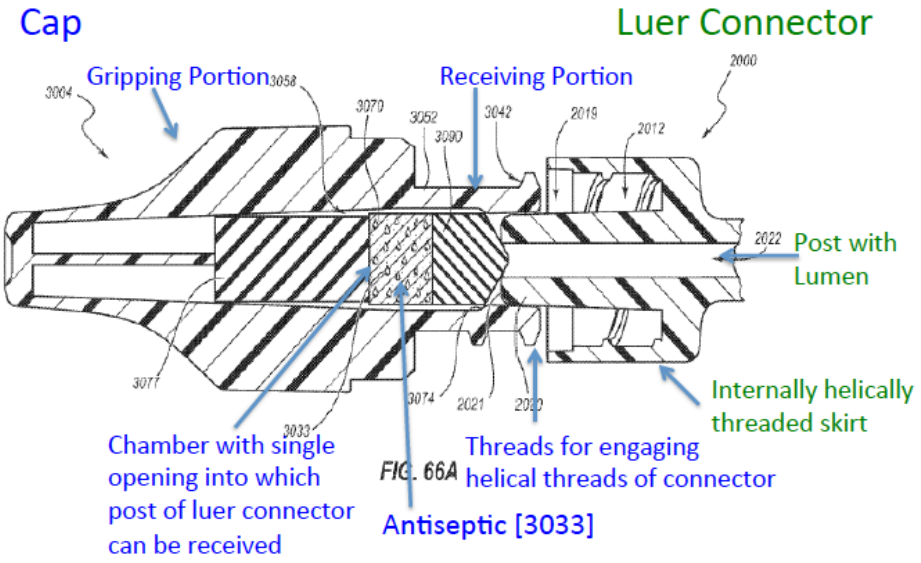
Applicants added specific disinfecting limitations to both claims 1 and 18, indicated in bold below:

> "a. a receiving portion defining a chamber into which the post of the male luer-lock connector can be received, the chamber having only a single opening, the receiving portion defining an external surface having means for engaging helical threads of the internally helically threaded skirt, wherein the receiving portion is configured to fit within the skirt of the male luer-lock connector when the post is received into the receiving portion;
>
> b. an antiseptic agent disposed in the chamber;
>
> c. **a member movably disposed within the chamber, the member shaped to enter the lumen so as to engage against an interior edge of an opening of the lumen when the post is received into the receiving portion to diminish flow of the antiseptic agent into the lumen while permitting flow of the antiseptic agent past the member to the post of the male luer-lock connector**"

(Ex. 1001, claims 1 and 18). Claim 1 adds one more claim element: "d. *a gripping portion*." (E. 1001, cl. 1)(emph. add.).

It is helpful to first discuss the basic features of the cap and luer connector that are described in the independent claims, many of which are shown in Figure 66A of the '681 patent, annotated below. (Ex. 1001, Fig. 66A)(Ex. 1002, ¶ 54). First, the male luer-lock connector is shown on the right, with an internally, helically

threaded skirt and a post with a lumen. (Ex. 1002, ¶ 55). To the left, the *cap* for the male luer-lock connector is shown. The cap has a gripping portion and a receiving portion, a chamber with a single opening into which the post of the male luer-lock connector can be received, and a means for engaging the helical threads of the connector (in this figure the means are threads). (Ex. 1002, ¶ 56).



The next element in both independent claims 1 and 18 is "an antiseptic agent disposed in the chamber." This is also seen in the above Figure 66A of the '681 patent, at 3033. (Ex. 1001)(Ex. 1002, ¶¶ 57, 58).

2. Disinfecting Limitations in the '681 Patent

The '681 patent's "member enter[s] the lumen so as to engage against an interior edge of an opening of the lumen … to diminish flow of the antiseptic agent into the lumen while permitting flow of the antiseptic agent past the member to the post of the male luer connector". (Ex. 1001, cl. 1, 18).

The '681 patent specification calls the "member" a "sealing member", and explains that in Figure 66A, "the luer 2020 has been advanced sufficiently far into the disinfection chamber 3058 to contact the sealing member 3090 and to form a seal therewith." (Ex. 1001, 52:29-32)(Ex. 1002, ¶ 59). Figure 38 of the patent, annotated here, shows the antiseptic (here in a sponge) [3070], the sealing member, and the corresponding male connector with a post and lumen. (Ex. 1001). The specification explains:

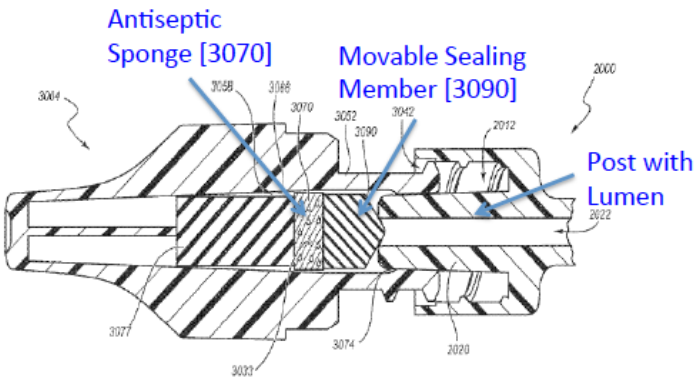


FIG. 66B

> "In FIG. 66B, the luer 2020 has been **advanced slightly further into the disinfection chamber 3058, thereby compressing the pad 3070 somewhat and forcing antiseptic 3033 out of the pad 3070**. The sealing member can define an outer diameter than [sic] is smaller than an inner diameter of this portion of the disinfection chamber 3058 such that **a fluid path is present about an exterior of the sealing member 3090**. "

(Ex. 1001, 52:38-44)(emph. add.)(Ex. 1002, ¶ 60). In other words, as the member is pushed into the chamber by the post of the male luer connector, the pad is compressed and antiseptic flows past the sides of the sealing member, to coat the post of the male luer connector. (Ex. 1002, ¶ 61).

3. Dependent claims of the '681 patent

The dependent claims of the '681 patent add limitations relating to the specific shape of the part of the member that enter into the lumen (claims 2-4, 15-17); a biasing structure (claims 5, 12); a cover for the cap (claims 6-8, 19-20); a taper in the cap's chamber (claims 9-10); threading to engage with the connector (claim 11); a chamber having a fixed volume (claims 13, 21); and a member configured to retain antiseptic in the chamber prior to use (claims 14, 22). (Ex. 1001).

4. Prosecution of the '681 Patent

The application for the '681 patent was filed January 8, 2013, and the patent issued February 4, 2014. (Ex. 1001). Applicants filed a preliminary amendment on February 28, 2013. (Ex. 1013). Claim element [c] was amended as follows:

> "c. a ~~sealing~~ member movably disposed within the chamber and configured to ~~sealingly~~ engage with the lumen when the post is received into the receiving portion to ~~prevent~~ <u>diminish</u> flow of the antiseptic agent into the lumen while permitting the flow of the antiseptic agent past the sealing member to the post of the male luer-lock connector"

(Ex. 1013, p. 4).

The Examiner rejected the claims as amended, under § 103(a) based on U.S. Appl. Publication 2011/0165020 ("Tryggvason Publication")(Ex. 1007), in view of Chin-Loy. (Ex. 1014). The Examiner explained:

> Re claim 1, Tryggvason et al. disclose a male-disinfecting cap 5 (Fig 4) for applying an antiseptic agent (Para 58) to a medical male connector 4 (Fig 4) of the type including a post 10 (Fig 4) having a lumen 9 (Fig 4) through which fluid flows and an internally helically threaded skirt (as seen in Fig 4; Para 54) surrounding the post, the cap comprising: a receiving portion (the portion of the body 11 surrounding chamber 12+ 14, as seen in Fig 4) defining a chamber 12+ 14 (Fig 4) into which the post of the male connector can be received (as seen in Fig 4), the chamber having only a single opening (seen to the right in Fig 4), the receiving portion defining an external surface having means 13 (Fig 4) for engaging helical threads of the internally helically threaded skirt (Para 54), wherein the receiving portion is configured to fit within the skirt of the male connector when the post is received into the receiving portion (as seen in Fig 4); an antiseptic agent disposed in the chamber (Para 58); **a member 15 (Fig 4) movably disposed within the chamber and configured to engage with the lumen when the post is received into the receiving portion to diminish flow of the antiseptic agent into the lumen while permitting flow of the antiseptic agent past the member to the post of the male connector (Para 58);** and a gripping portion (the portion of body 11 that does not surround chamber 12+14, as seen in Fig 4).

(Ex. 1014, p. 5)(emph. add). The only claim element missing from the Tryggvason Publication, according to the Examiner, was that the cap was not for use with a luer connector. (Ex. 1014, pp. 5-6). The Examiner overlooked, however, the express

disclosure in Tryggvason Publication that the cap's "engagement means 6, 7 could be … **luer** connections" and also that the "external surface of the [post] projection 10 may … form a **luer fitting** with the distal end of the lumen". (Ex. 1007, ¶ 54)(emph. add.)(*see also* Ex. 1002, ¶ 76).

To overcome the Examiner's rejection based on the Tryggvason Publication, Applicants amended the portion of the claims relating to the disinfecting features, and specifically the shape of the member:

> "a member movably disposed within the chamber ~~and~~, the member shaped ~~configured~~ to enter the lumen so as to engage ~~with~~ against an interior edge of an opening of the lumen when the post is received into the receiving portion to diminish flow of the antiseptic agent into the lumen while permitting flow of the antiseptic agent past the member to the post of the male luer-lock connector"

(Ex. 1015, p. 5). By making this amendment Applicants acquiesced to the Examiner's finding that the other limitations of the independent claims were disclosed in the prior art. *See Litton Systems, Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1438 (Fed. Cir. 1984)(filing CIP application in response to a new matter rejection estops patentee from arguing that the PTO's rejection was erroneous).

The patent claims were allowed based on Applicants' amendment. (Ex. 1016 , p. 9).

C. Tryggvason Prior Art

The Tryggvason Publication cited by the Examiner during prosecution later issued as U.S. Patent No. 8,617,482 ("Tryggvason")(Ex. 1003). The Tryggvason patent makes the same disclosures as the Tryggvason Publication. (*Compare* Ex. 1003 and 1007)(Ex. 1002, ¶ 128).

As discussed herein, and set forth in the claim charts in Ground 1 below, Tryggvason discloses all of the claim elements of the independent claims of the '681 patent, except a "member shaped to enter the lumen so as to engage against an interior edge of an opening of the lumen". (Ex. 1002, ¶ 62). The minor modification to the shape of Tryggvason's member, however, would have been obvious to one of skill in the art at the time of the invention of the '681 patent. *See* Ground 1.

Briefly, Tryggvason discloses disinfecting caps for both male and female medical luer connectors. (Ex. 1003)(Ex. 1002, ¶¶ 64-67). Tryggvason shows a cap for a male connector in Figure 4, annotated here. (Ex. 1003)(Ex. 1002, ¶ 68). In this figure the cap [5] is shown on the left, and the male connector [4] on the right. (Ex. 1002, ¶ 69). Tryggvason's cap is for use with a male connector

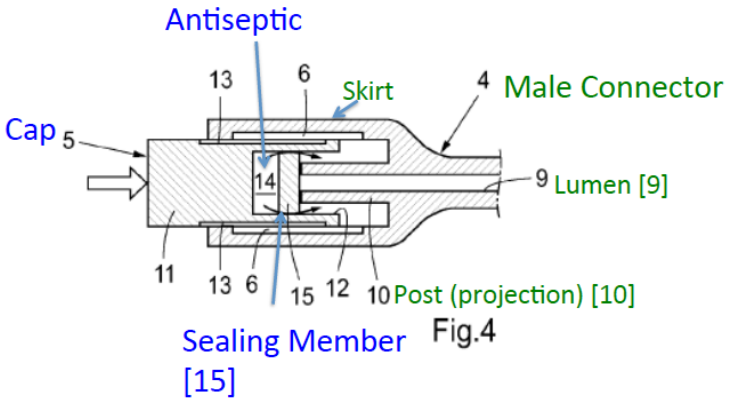


Fig.4

with skirt surrounding a post (called a projection in Tryggvason) [10], with a lumen [9]. (Ex. 1003, 6:54-63)(Ex. 1002, ¶ 69). Tryggvason mistakenly refers to the connector [4] shown in Figure 4 as a female connector; however, as evidenced by the post with lumen and surrounding skirt, the connector 4 shown is actually a male connector. (Ex. 1002, ¶¶ 70-71).

As also seen in the above figure, Tryggvason's cap also has a "member" [15] that is movable within the chamber. (Ex. 1003). Tryggvason calls its member a "seal" [15], and it is seen between the sealed cavity [14] containing antiseptic (called disinfectant in Tryggvason), and the receiving portion of the cap. (Ex. 1003, 7:36-39)(Ex. 1002, ¶ 75).

Tryggvason's cap works in the same way as the cap in the '681 patent. As the connector advances into the chamber, it moves the seal (member) into the chamber, and antiseptic (disinfectant) is pressed out of the sealed cavity, around the member, to the post of the male connector.

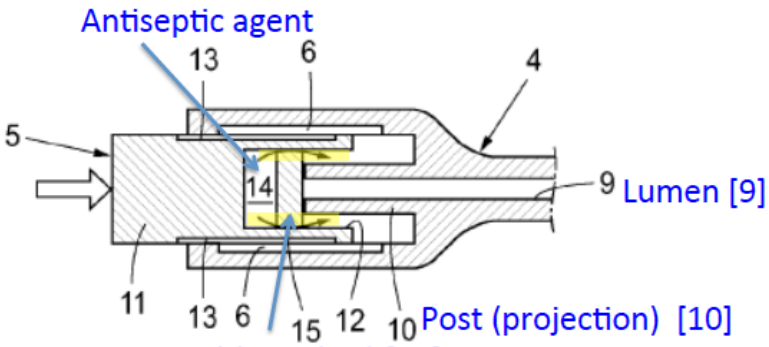


Fig.4

(Ex. 1002, ¶ 77). Tryggvason's specification explains:

> "FIG. 4 illustrates a capping device 5 which is mounted onto the exposed end of the second [male] connector 4 in FIG. 2. … As the

> capping device 5 is advanced onto the second connector 4, **the front end of the projection [post] 10 engages the seal 15 and actively presses disinfectant out of the sealed cavity 14 and onto the external surface of the projection 10 (<u>as indicated by arrows in FIG. 4</u>)**."

(Ex. 1003, 7:31-40)(emph. add)(Ex. 1002, ¶ 78).

Thus, the "seal" of Tryggvason performs the same function as the "member" or "movable member" discussed in the '681 patent, releasing the antiseptic agent onto the post of male luer connector. (Ex. 1002, ¶ 79).

Because Tryggvason's member [15] is positioned over the opening of the lumen of the male luer connector, as explained in the quoted portion of the specification above, the antiseptic agent flows *around the sides of the seal (member)* [15] to the post [10] of the male luer connector, as described in the '681 patent ("while permitting the flow of the antiseptic agent past the member to the post of the male luer-lock connector"). (Ex. 1001, cl. 1, 18). The member thus diminishes the flow of antiseptic fluid into the lumen of the male luer connector, as described in the '681 patent. (Ex. 1003, 7:31-40)(Ex. 1002, ¶ 80). This is shown annotated in Figure 4 above (arrows in the original figure). (Ex. 1003)(Ex. 1002, ¶ 81).

D. Prior Art "Members" Shaped to Enter Into and Engage Against an Interior Edge of an Opening of the Lumen

While the member in Tryggvason diminishes the flow of the antiseptic agent

into the chamber, the independent claims of the '681 patent specify that the member is "shaped to enter the lumen so as to engage against an interior edge of an opening of the lumen". (Ex. 1001, cl. 1, 18). As discussed above, this claim limitation was added during prosecution to overcome the Tryggvason Publication, as the one patentable feature of the '681 patent. *See* Section I.B.4.

It was not new, however, at the relevant timeframe for obviousness, for disinfecting luer caps to include members shaped to enter into the lumen of the connector to diminish the flow of antiseptic fluid into the lumen. (Ex. 1002, ¶ 82). It was also not new for a male luer connector caps to include a member shaped to "engage against an interior edge of an opening of the lumen" to form a fluid-tight seal. (*Id.*, ¶ 83). Examples of such prior art caps are discussed next, after a brief explanation of the member described in the '681 patent.

1. Member of the '681 patent

A cap having a member that is shaped to enter into the lumen of the male luer connector is shown in Figure 38 of the '681 patent, shown here. (Ex. 1001).

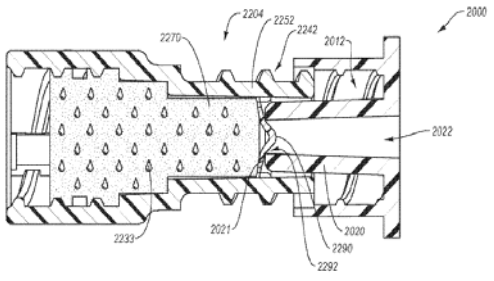


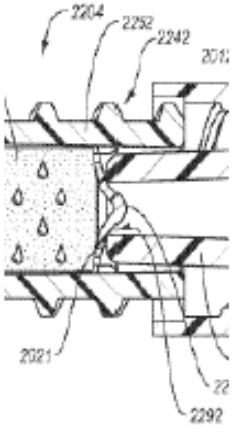
FIG. 38

Here, the cap is on the left, the male luer connector [2020] on the right, and the sealing member at 2090. (Ex. 1001)(Ex. 1002, ¶ 86).

The term "interior edge of an opening of the lumen" does not appear in the

specification of the '681 patent. The closest relevant description appears to be as follows:

> "A tip 2021 of a male luer 2020 contacts the seal region 2292 of the sealing member 2290. In the illustrated embodiment, a portion of the sealing member 2290 extends into a lumen 2022 of the connector 2000 **such that the contact is primarily between an inner edge of the tip 2021 and a thin band of the sealing member 2290.**"



(Ex. 1001, 32:34-39)(emph. add.)(Ex. 1002, ¶¶ 84, 87). The contact is seen in the expanded portion of Figure 38 of the '681 patent, here. (Ex. 1002, 121). The specification further explains the purpose of the shape of the member:

> "Such an arrangement **can assist in forming a fluid-tight seal** due to a relatively higher pressure that results between the tip 2021 and the sealing member 2290 when forces (e.g., an insertion force on the tip 2021 and an oppositely directed biasing force on the sealing member 2290) are distributed over relatively smaller areas. Such an arrangement **likewise can allow antiseptic to contact much or all of an external surface of the luer 2020, including a distal surface of the tip** 2021."

(Ex. 1001, 32:40-48)(emph. add.)(Ex. 1002, ¶ 88).

2. Members Shaped to Enter The Lumen to Diminish the Flow of Antiseptic Agent into the Lumen in the Prior Art

One example of a prior art disinfecting cap with a member shaped to enter into the lumen is U.S. Appl. Publication 2005/0147524 ("Bousquet"), filed January 6, **2004** and published July 7, **2005**. (Ex. 1004) (Ex. 1002, ¶ 89). Bousquet discloses a luer connector cleaner with an "end cap". (Ex. 1004, ¶ 23)(Ex. 1002, ¶ 89). The assembly "is secured to the exposed end of a catheter or length of tubing implanted in a patient". (Ex. 1004, ¶ 21).

Bousquet calls its "member" an "axial post" (highlighted in the figure to the left) and explains:

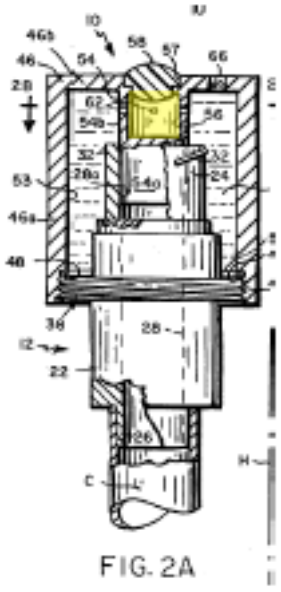


FIG. 2A

> "an axial post 54 extends down from the end wall 46*b* of the end cap 14 at the center of that wall. Post 54 has a slight external taper so that when the end cap 14 is screwed into connector 12, a segment 54*a* of **the post projects into stem 24** and wedges against the wall of lumen segment 28*a* **providing a fluid-tight seal between the post and stem 24**".

(Ex. 1004, ¶ 40)(emph. add.)(Ex. 1002, ¶¶ 94, 95).

Once the cap is in place, liquid sterilizing agent is injected into the cap, surrounding the connector but blocked from entering into the lumen by the axial post. (Ex. 1004, ¶ 42-45)(Ex. 1002, ¶¶ 92-93, 96). Bousquet explains:

> "Therefore**, in order to prevent the sterilizing agent from entering**

> **the lumen of the connector body, the end wall of end cap is formed with an integral post which extends into the end of the connector stem and blocks the opening to that lumen when the cap is coupled to the connector.**"

(Ex. 1004, ¶ 25)(emph. add) (Ex. 1002, ¶ 97).

U.S. Published Application No. 2006/0030827 ("Raulerson") also discloses a member shaped to enter into the lumen of the luer connector. (Ex. 1006)(Ex. 1002, ¶ 100). Raulerson was published February 9, **2006**, and discloses a cleaning device for applying a disinfectant to a luer connector. (Ex. 1006)(Ex. 1002, ¶¶ 99-100). Raulerson calls its member a "guide member" and it can be seen here in Figure 3 of the patent. (Ex. 1006)(Ex. 1002, ¶ 102). When attached to the connector, the Raulerson's guide member enters into the bore (lumen) of the corresponding luer connector. (Ex. 1002, ¶ 102).

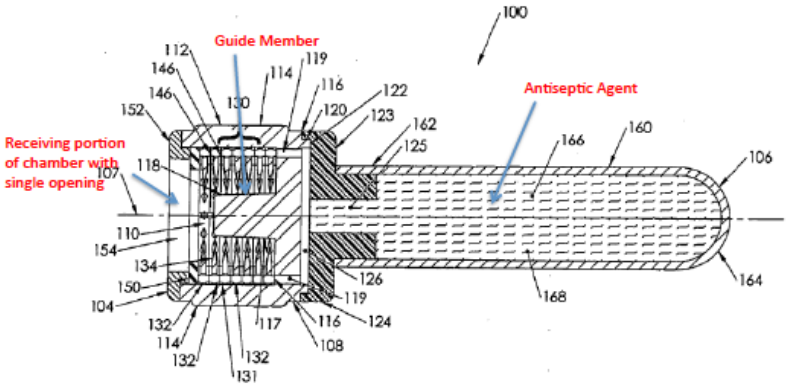


FIG. 3

Raulerson applies antiseptic agent to a corresponding luer connector. (Ex. 1006)(Ex. 1002, ¶ 99). Raulerson's specification explains that when "the fluid is transmitted from the reservoir toward the first end through passageways to wet the luer proximal end":

> "The guide member 117 **prevents fluid from entering the catheter 194 through the interior of the luer 190 after the fluid has been forced into the longitudinal passage 110 from the reservoir**."

(Ex. 1006, Abstract, ¶ 16)(emph. add.)(Ex. 1002, ¶ 105).

3. Members Shaped to Engage Against an Interior Edge of an Opening of the Lumen in the Prior Art

Luer caps with members shaped to engage against an interior edge of an opening of the lumen were also well known in the relevant timeframe for obviousness. (Ex. 1002, ¶ 106). One example is DeCaprio, discussed above. (Ex. 1008) (Ex. 1002, ¶ 107). As explained, DeCaprio discloses a male luer cap for a male luer connector having a post with a lumen and an internally threaded skirt. *See* Section I.A.

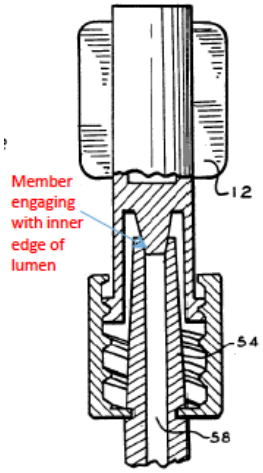
DeCaprio calls its member a "projection" [50], and explains:

> "Within the cylindrical hub 44 is a **tapered projection** 50 that extends outwardly from separation wall 42 toward open end 46 and tapers inwardly a predetermined amount. An annular surface 52 is formed on separator wall 42 surrounding the tapered projection 50."

(Ex. 1008, 3:65-4:2)(emph. add.)(Ex. 1002, ¶ 108).

Figure 4 of DeCaprio, below, shows the cap fully engaged with the male luer connector. (Ex. 1008)(Ex. 1002, ¶ 109). The member (projection) is engaged against an interior edge of an opening of the lumen of the male luer connector. (Ex. 1002, ¶ 110). DeCaprio's specification explains:

FIG. 4



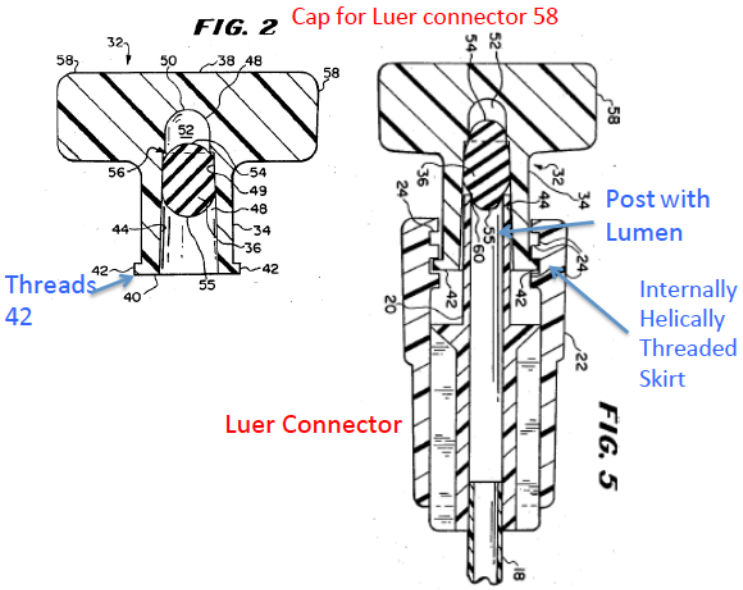
> "Due to the specific predetermined dimensions of deadender cap 12, it can be seen that when the deadender cap 12 is **fully tightened on to male Luer fitting 54, the tapered projection 50 fits within and closes passageway 58**."

(Ex. 1008, 4:39-43)(emph. add.)(Ex. 1002, ¶ 111). The fit between the tapered member of the cap and the lumen stops fluid from flowing, in the case of DeCaprio keeping the fluid inside of the luer connector: "In carrying out such tightening, **the liquid passing out of passageway 58** through flat opening 60 **is halted**…". (Ex. 1008, 4:56-57)(Ex. 1002, ¶ 112).

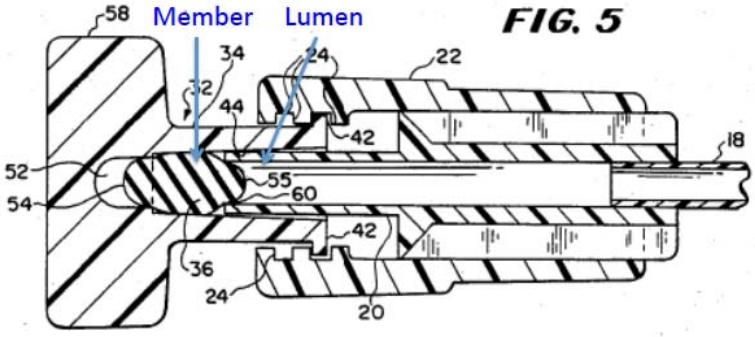
U.S. Patent No. 4,597,758 ("Aalto"), filed September 21, 1982, and issued July 1, 1986, also discloses a member shaped to engage against an interior edge of an opening of the lumen. (Ex. 1018) (Ex. 1002, ¶ 113). Aalto discloses a "sealing closure for a luer fitting in open communication with a pressurized liquid supply". (Ex. 1018)(Ex. 1002, ¶ 114). The specification explains that the "device of the present invention provides **a leak-proof sealing closure for a male Luer fitting**". (Ex. 1018, 2:12-13)(emph. add). (Ex. 1002, ¶ 115).

Aalto discloses a number of the '681 patent's claim limitations that relate generally to luer connectors. As can be seen in Figures 1 (cap) and 5 (cap and connector), annotated below, Aalto discloses a cap ("sealing closure") [32] for a

male luer connector ("luer fitting") [20], having a skirt with internal helical threading [24] that can connect with threading ("ridges") [42] on the cap [32]. (Ex. 1018, 4:2-6, "The sealing closure 32 is mounted about the Luer fitting 20 with a twisting motion, thereby threading the ridges 42 into the internal threads 24 …")(Ex. 1002, ¶ 116).



Aalto calls the opening in the end of the lumen an "outlet" [60]. (Ex. 1018)(Ex. 1002, ¶ 117). The "outlet" [60] is shown in Figure 5 (annotated here) adjacent to Aalto's member, which is an "elastomeric insert" [36]. (Ex. 1018)(Ex. 1002, ¶ 118). The '681 patent contemplates that a member may be made of an elastomeric material, like that in Aalto. (Ex. 1001, 31:18-22)("The sealing member 2290 can be formed of any suitable material, **such as an elastomer**…")(emph. add.)(Ex. 1002, ¶ 115).



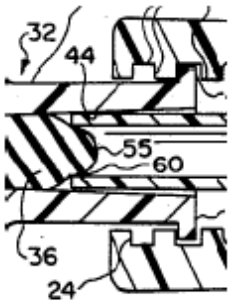
Aalto's member (elastomeric insert) is moveable and deformable, and enters into the lumen (outlet) of the male connector when the cap and connecter are attached to one another. (Ex. 1018)(Ex. 1002, ¶ 119). Aalto's specification explains:

> "As the sealing closure is brought into mating contact with the Luer fitting 20, **the elastomeric insert is compressed further**. The locking ring 22 on the Luer fitting 20 and the ridges 42 on the sealing closure 32 create a pressure lock. Stated differently, the Luer fitting 20 is forcefully held in mating contact with the tapered inner surface 44. **The elastomeric insert 36 creates a liquid-tight seal with the outlet 60 of the Luer fitting 20. The second-end side 55 of the insert will be partially displaced into the outlet 60.**"

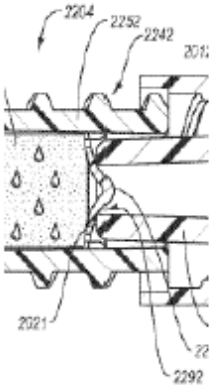
(Ex. 1018, 4:11-20)(emph. add.)(Ex. 1002, ¶ 120).

As can be seen in the expanded portion of Figure 5 of Aalto, shown to the left here, the member (elastomeric insert) [55] engages with the "interior edge of an opening of the lumen" (outlet) [60] when the cap and connector are attached, just as in the expanded portion of Figure 38 of the '681 patent, shown right. (Ex. 1002, ¶ 121).

Aalto



'681 Patent



II. CLAIM CONSTRUCTION

A. Overview of the challenged claims

Claims 1 and 18 are independent claims, claims 2-17 depend from claim 1, and claims 19-22 depend from claim 18.

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. [citations omitted]. 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 used in district courts differs from that 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. Claims 1 and 18 –"means for engaging helical threads"

The term "means for engaging helical threads" is used in independent claims 1 and 18. The '681 patent specification discloses that "threads or other suitable attachment features" may be used to connect the claimed cap to a corresponding

connector, including a connector with helical threads. (Ex. 1001, 39:53-55). During prosecution of the '681 patent, the Examiner found, and Applicants did not argue otherwise, that the "means" could be "threading disposed on the receiving portion", (Ex. 1014, p. 8), or "an external surface having lugs 58, 60 (Fig 1) for engaging helical threads of an internally threaded skirt of the male luer-lock connector". (Ex. 1026, p. 5). The proper construction of "means for engaging helical threads" is thus "threads, lugs or other suitable attachment features that can engage with helical threads, and equivalents thereof".

D. Claims 2 and 3 – "bulge"

The term "bulge" is used in claims 2 and 3 of the patent, in relation to the shape of the member. The term "bulge" does not appear in the patent specification, nor was it discussed during prosecution of the patent. (Ex. 1001)(Ex. 1002, ¶ 123). The proper construction of the term "bulge", consistent with the understanding of one of ordinary skill in the art, is "a protuberance". (Ex. 1002, ¶ 123).

E. Claims 4 and 17 – "dome shaped"

The term "dome shaped" is used in claims 4 and 17, also in relation to the shape of the member. In claim 4 the member is described as a "dome shaped" bulge, and in claim 17 a "dome shaped" convex surface. The term "dome" or "dome shaped" does not appear in the patent's specification, nor was it discussed during prosecution of the patent. (Ex. 1001)(Ex. 1002, ¶). This term is used in contrast

to claims 3 and 16, which describe a "conically shaped" member. (Ex. 1001). The proper construction of the term "dome shaped", consistent with the understanding of one of skill in the art, is "a rounded or spherical convex shape". (Ex. 1002, ¶ 123).

F. Claims 5 and 12 – "biasing structure"

The term "biasing structure" is used in dependent claims 5 and 12; in claim 5, "biasing structure disposed in the chamber on a side of the member facing an interior of the chamber", and in claim 12 "biasing structure disposed in the chamber to impose a thrust on the member". (Ex. 1001). The '681 patent specification refers to a "biasing member" or "biasing element" as:

> "The sealing member 2290 can be coupled with a **biasing element** 2276, which can be configured to resist or oppose movement of the sealing member 2290. Stated otherwise, the **biasing element** 2276 can provide a bias to the sealing member in a direction of an initial position of the sealing member 2290 … once the sealing member 2290 has been disposed from that initial position."

(Ex. 1001, 31:25-31 (emph. add.); *see also* 54:47-49). The specification further explains that the biasing member of the '681 patent provides an "oppositely directed biasing force on the sealing member". (Ex. 1001, 32:43-44). The proper construction of "biasing structure" is thus "a structure that applies a returning force to an object in a particular direction".

G. Claim 12 – "thrust"

The term "thrust" is used in dependent claim 12, which claims a cap with a "biasing structure disposed in the chamber to impose a thrust on the member". (Ex. 1001, cl. 12). The term thrust is not used in the patent's specification, nor was the meaning of the term addressed during the prosecution of the patent. (Ex. 1001). The proper construction of this term, consistent with the understanding of one of ordinary skill in the art, is "propulsive force in a particular direction". (Ex. 1002, ¶ 123).

III. DETAILED EXPLAINATION OF REASONS FOR UNPATENTABILITY

Ground 1. Claims 1, 2, 4, 9, 10, 11, 13, 14, 15, 17, 18, 21 and 22 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto.

Claims 1, 2, 4, 9, 10, 11, 13, 14, 15, 17, 18, 21 and 22 are invalid under 35 U.S.C. § 103(a) over U.S. Patent No. ("Tryggvason")(Ex. 1003) in view of U.S. Patent No. 4,597,758 ("Aalto")(Ex. 1018)(Ex. 1002, ¶ 124). The level of skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 20-21, 130).

A. Tryggvason and Aalto are Prior Art to the '681 patent

The '681 patent was filed January 8, 2013, but claims priority to a series of patent applications that date back to January 2007. (Ex. 1001, p.1 (63)). However, the earliest priority date that the patent might be entitled to is October 30, 2009, the

filing date of Application No. 12/610,141 ("the '141 Application"). It was for the first time in this application that any of the disclosures cited to by Applicants to support their claim amendment adding the limitation "a member shaped to enter into and engage against an interior edge of an opening of the lumen" (made to overcome the Tryggvason Publication) were disclosed. (Ex. 1025) (*See* Ex. 1015, p. 10, identifying Figs. 37-39 (item 2290), 42-49 (items 2390, 2490, 2590, 2690), 52, 64 and 66A-D (item 3090) and corresponding paragraphs 206, 212-214, 227, and 316)(Ex. 1002, ¶ 126). Further, the disclosures in the applications prior to the '141 Application do not otherwise support the claimed inventions of the '681 patent. (Ex. 1002, ¶ 127). Accordingly, the priority date of the '681 patent is no earlier than October 30, 2009.

Applicants correctly did not contest that the Tryggvason Publication was prior art to the '681 patent application during prosecution of the patent. (Ex. 1015).

Tryggvason is prior art to the '681 patent under 35 U.S.C. § 102(e), because it issued from PCT application PCT/EP2009/057321, filed on June 15, 2009, which designated the United States and was published in English as WO/20090153224. (Ex. 1021). 35 U.S.C. § 102(e)("[A]n international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection [102(e)] of an application filed in the United States only if the international application designated the United States and was published under

Article 21(2) of such treaty in the English language."). The PCT application also properly relied on its provisional application under 35 U.S.C. § 119(e). (Ex. 1022). The § 102(e) effective date for Tryggvason should be the provisional date, June 17, 2008, because the disclosures therein support the claims of the issued patent. (*Id.*). (Ex. 1023)(Ex. 1002, ¶ 128). Both dates are before the October 30, 2009 priority date of the '681 patent.

Aalto is prior art under § 102(b) as it issued in 1986. (Ex. 1018)(Ex. 1002, ¶ 129).

B. Summary of Tryggvason and Aalto

An explanation of Tryggvason is provided in the Technical Introduction, above, and the claim charts below. In summary, Tryggvason discloses: (a) a disinfecting cap for a male luer connector with a post and an internally helically threaded skirt; (b) a chamber with a receiving portion, and a single opening; (c) the chamber having a member that seals an antiseptic agent within the cap prior to use; (d) a member that is movable and can be "displaced" by pressure from the male luer connector being inserted in the chamber; and (e) the member diminishing the flow of antiseptic fluid into the lumen of the male luer connector. *See* Section I.C. (Ex. 1002, ¶ 131).

Tryggvason thus discloses all of the elements of the independent claims of the '681 patent, except that its member is not shaped to enter into and to engage against

an interior edge of an opening of the lumen of the male luer connector. This claim limitation is, however, disclosed in Aalto. (Ex. 1002, ¶ 132).

An explanation of Aalto is also provided in the Technical Introduction, above. In summary, Aalto discloses: (a) a cap for use with a male luer connector having an internally helically threaded skirt surrounding a post; (b) a tapered chamber with a single opening, that opening being the receiving portion of the cap; (c) a movable member for sealing the lumen of the male luer connector; (d) the member shaped to enter into the lumen; (e) and the member shaped to engage against an interior edge of an opening into the lumen of the male luer connector to reduce or stop fluid flow. *See* Section I.D.3. (Ex. 1002, ¶¶ 133, 136).

C. Motivation to Combine Tryggvason and Aalto

It would have been obvious to one of skill in the art to use the shape of the member of Aalto in Tryggvason's disinfecting cap. (Ex. 1002, ¶ 134). Disinfecting caps for luer connectors that included a member that entered into the lumen to diminish the flow of antiseptic into the lumen were not new at the time of the invention of the '681 patent (see Bousquet and Raulerson). (*Id.*, ¶ 135). Nor was it new to include a member that engaged against an interior edge of an opening in a lumen to reduce or stop fluid flow in luer connector caps (see DeCaprio and Aalto). (*Id.*, 136). One of skill in the art would have been familiar with these known prior art luer connector caps, and would have understood the change to the

member of Tryggvason to be a minor modification. (*Id.*).

One of skill in the art would have been motivated to use the shape of the member from Aalto on the cap of Tryggvason to create a more consistently reliable seal between the cap and connector. (Ex. 1002, ¶ 137). One of skill in the art would have also been motivated to use the shape of the member from Aalto on the cap of Tryggvason to allow the antiseptic agent to reach the tip of the lumen (the most likely area needing disinfecting) during the disinfecting process. (Ex. 1002, ¶ 138). The '681 patent acknowledges this as a motivating factor: "Such an arrangement likewise can allow antiseptic to contact much or all of an external surface of the luer 2020, including a distal surface of the tip 2021." (Ex. 1001, 32:45-48)(Ex. 1002, ¶ 139).

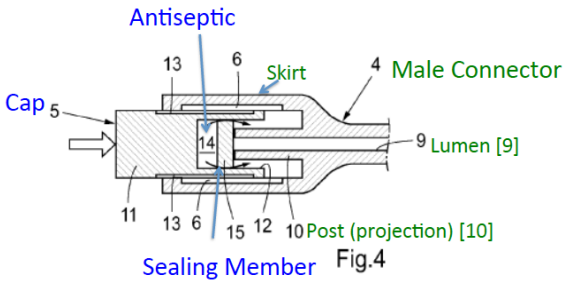
The combination of Tryggvason with Aalto represents the use of a known disinfecting cap for a male luer connector with a movable member (Tryggvason), with the known male luer connector cap having a member shaped to enter into and engage against an interior edge of an opening into the lumen (Aalto), each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 140). *See KSR Int'l Co. v. Teleflex, Inc*., 127 S. Ct. 1727, 1739-42 (2007). There do not appear to be any secondary indicia of non-obviousness present. (Ex. 1002, ¶ 141). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

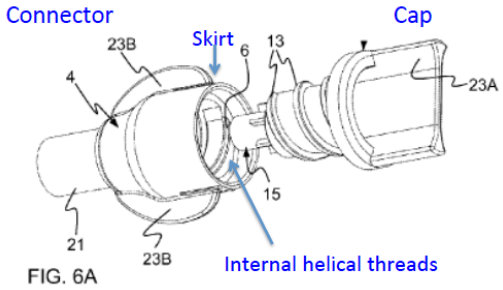
Tryggvason in view of Aalto teaches claims 1, 2, 4, 9, 10, 11, 13, 14, 15, 17, 18,

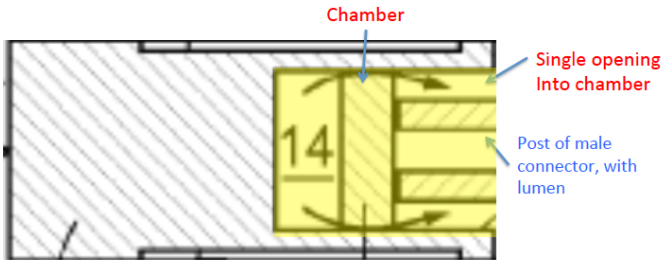
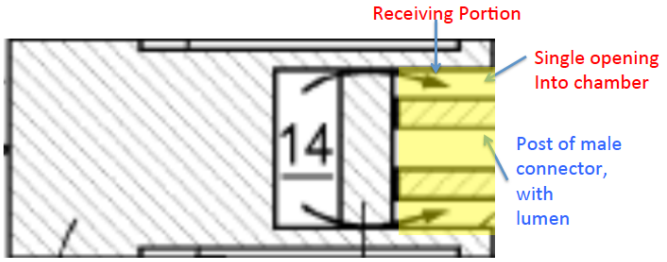
21 and 22 of the '681 patent, as shown in the following claim charts.

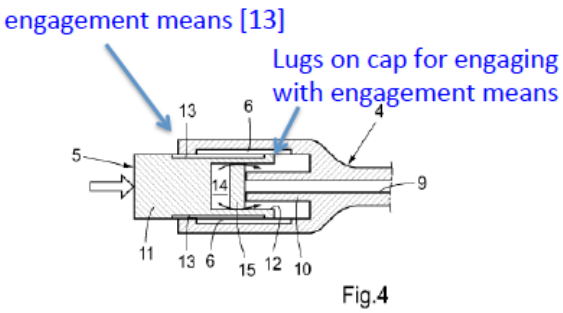
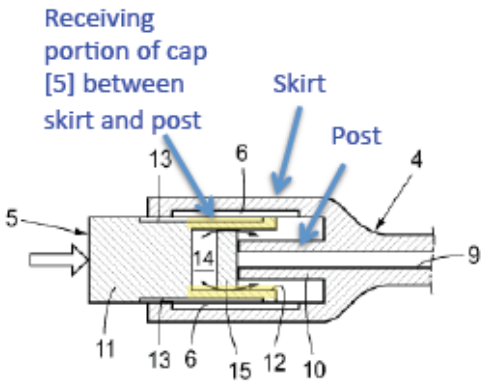
Claims 1 and 18 share the same elements, addressed in the following chart, except that claim element 1j is only in claim 1.

1a/18a. A male-disinfecting cap for applying an antiseptic agent to a medical male luer-lock connector, of the type including a post having a lumen through which fluid flows and an internally helically threaded skirt surrounding the post, the cap comprising:	Tryggvason discloses a male disinfecting cap: "[a] capping device is configured to terminate a connector while disconnected from another connector in a fluid transportation system …" (Ex. 1003, Abstract)(Ex. 1002, ¶¶ 142-143). The cap in Tryggvason is a "disinfecting cap" for "applying an antiseptic agent to a medical male luer-lock connector". The cap has an antiseptic disposed inside, whereby the cap disinfects the connector. (Ex. 1002, ¶ 144). The antiseptic agent is called a **"disinfectant"**, and is seen at [14] in Figure 4 below. (*Id.*). The specification describes the cap containing a "disinfectant", and then identifies the disinfectant as substances that are antiseptic agents. "The capping device comprises a body defining a chamber with an opening, **a liquid-containing disinfectant in the chamber**, …" (Ex. 1003, 3:23-25)(emph. add.)(Ex. 1002, ¶ 145). "In one embodiment, the **disinfectant** comprises at least one of: **povidone iodine, iodine-containing antimicrobials, and betadine**." (Ex. 1003, 4:15-18)(emph. add). (Ex. 1002, ¶ 145). Povidone iodine, iodine-containing antimicrobials, and betadine are all **antiseptic agents**. (Ex. 1002, ¶ 146). The cap in Tryggvason is for use on "medical" connectors. The specification explains "the disclosed embodiments as well as underlying inventive concepts are **generally applicable in applications that require sterile conditions, in particular applications that insert a medical fluid into the body of a patient**. Examples of other applications

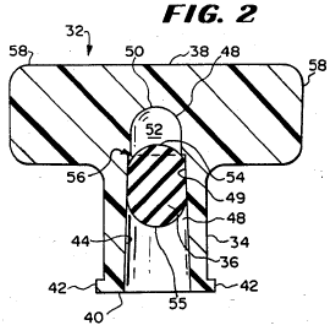
	where sterile connectors are desirably made include the processing of blood and its fractions, the mixing of sterile solutions, connecting catheters with urinary drainage bags, and hemodialysis or blood oxygenation procedures especially with patients who have diminished immunological capability." (Ex. 1003, 5:53-63)(emph. add.)(Ex. 1002, ¶ 147). These are medical applications. (Ex. 1002, ¶ 147). Tryggvason discloses a "male" cap, for use with a male connector with a skirt, a post with a lumen, and an internal helical threading. (Ex. 1002, ¶ 148). This is shown in Figure 4 of the patent, annotated here. Figure 4 shows the cap [5], right, connecting with **a male connector** [4] with **a skirt, a post ("projection")** [10] and **lumen** [9], right. (Ex. 1003, 6:57-58, "The first and second connectors 2, 4 define a respective lumen 8, 9")(Ex. 1002, ¶ 148).  Fig.4 The "**lumen**" of the male connector is a "**lumen through which fluid flows**". Tryggvason's specification explains that when the male connector is attached to a female connector prior to use with the cap: "**The first and second connectors 2, 4 define a respective lumen 8, 9.** When the first connector 2 is brought into engagement with the second connector 4, an internal projection of the second connector 4 enters the lumen 8 of the first connector 2 **to establish a fluid path** through the connectors." (Ex. 1003, 6:57-62)(emph. add.)(Ex. 1002, ¶ 148). The connector in Tryggvason is a "***luer*-lock" connector. The specification explains: "The engagement means 6, 7 could be any of a variety of

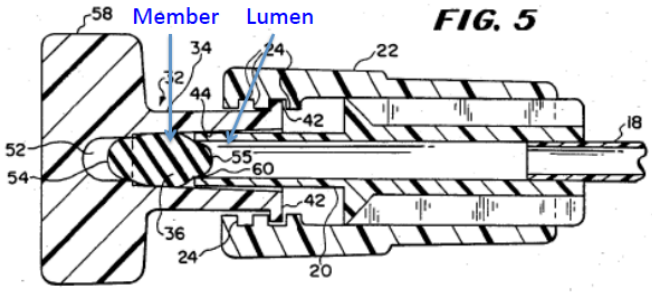
	mutually engaging constructions such as, for example, threaded fitments, **luer connections**, friction fits, and snap fittings. … The external surface of the projection **may** or may not **form a luer fitting with the distal end of lumen 8**." (Ex. 1003, 6:54-63)(emph. add.)(Ex. 1002, ¶ 149). The male connector [4] is a "**luer-*lock***" connector, as it has engaging means [6] that "lock" with the lugs [13] on the skirt of the connector. (Ex. 1002, ¶ 150). Tryggvason also discloses a cap [5] for use with a connector [4] having **helical threads**, including internal threads on the skirt of the connector. This is shown in Figures 6A-6C of the patent, annotated above, which show a female connector and corresponding cap. (Ex. 1003)(Ex. 1002, ¶ 151). The female connector shown in annotated Figure 6A has **a skirt with internal helical threads**, identified in the above figure. (Ex. 1002, ¶ 151). The patent specification further states that the helical threads disclosed in Figure 6 could be used on either the female connector and corresponding cap, or on a male connector and corresponding cap. (Ex. 1003, 7:50-52, "It should also be understood that, in all embodiments discussed herein, either one of the connectors 2, 4 could be used as patient connector")(Ex. 1002, ¶ 152). On a male cap, the internally helically threaded skirt would surround the **post with a lumen of the male connector**. (Ex. 1002, ¶ 153).  FIG. 6A
1b/18b. a receiving portion defining a chamber into which the post of the male	Tryggvason discloses a receiving portion defining a chamber into which the post of the male luer-lock connector can be received. (Ex. 1002, ¶ 154). Tryggvason's **chamber** is discussed in claim limitation 1c/18c. below, and seen highlighted in Figure 4 below. (Ex. 1002, ¶ 155). The chamber extends into the cap, with the receiving portion at

luer-lock connector can be received,	one end, and the sealing cavity at the other end, and the seal (member) in between. (*Id.*).  The **receiving portion** is the opening in the cap that receives the male luer connector, to the right of the sealing member, as shown in Figure 4 here, where the post [10] of the male luer-lock connector is being received into the cap [5]. The male connector is a "luer-lock" connector as described in [1a.] above. (Ex. 1002, ¶¶ 156). The  **receiving portion** is shown highlighted in yellow in the cap portion of Figure 4 here. (Ex. 1002, ¶ 157). The receiving portion defines a **chamber**, which is shown above, and further in claim limitation [1c/18c.] below. (Ex. 1002, ¶¶ 155, 158).
1c/18c. the chamber having only a single opening,	The chamber of Tryggvason is seen highlighted in yellow in Figure 4 in claim limitation [1b/18b.] above, where it is seen there that the chamber has only a single opening. (Ex. 1002, ¶ 158). The specification of Tryggvason further explains that, "The capping device comprises a body defining a chamber with **an** opening …" (Ex. 1003, Abstract, 3:23-24)(emph. add.)(Ex. 1002, ¶ 159).
1d/18d. the receiving portion defining an external surface having means for engaging	The receiving portion of Tryggvason defines an external surface having means for engaging helical threads of the internally helically threaded skirt. As explained above, the proper construction of "means for engaging helical threads" is "threads, lugs or other suitable attachment features that can engage with helical threads, and equivalents thereof". (Ex. 1002, ¶¶ 160, 161). Tryggvason calls its means for engaging the skirt of the

helical threads of the internally helically threaded skirt,	connector "engagement means", and its engagement means are seen in Figure 4 below at [6]. (Ex. 1002, ¶ 162). Tryggvason explains that these engagement means could be any of a number of different constructions: "The engagement means 6, 7 could be any of a variety of mutually engaging constructions such as, for example, threaded fitments, luer connections, friction fits, and snap fittings."(Ex. 1003, 6:54-57)(Ex. 1002, ¶ 163). The means shown in Figure 4, annotated here, are lugs that would engage helical threads of the internally helically threaded skirt of a corresponding connector. (Ex. 1002, ¶ 164).  Fig.4
1e/18e. wherein the receiving portion is configured to fit within the skirt of the male luer-lock connector when the post is received into the receiving portion;	Tryggvason discloses the **receiving portion** "configured to fit within the skirt of the male luer-lock connector when the post is received into the receiving portion". In Figure 4 annotated here, the receiving portion of the cap [5] is seen, highlighted, between the post and skirt of the connector [4]. (Ex. 1002, ¶¶ 165, 166).  Fig.4
1f/18f. an antiseptic agent disposed in the chamber;	Tryggvason discloses an antiseptic agent disposed in the chamber. The antiseptic agent is called a "disinfectant", and is seen at [14] in Figure 4 above, **"disposed in the chamber"** of the cap. (Ex. 1002, ¶ 167). The specification describes the cap containing a "disinfectant", and then identifies the disinfectant as

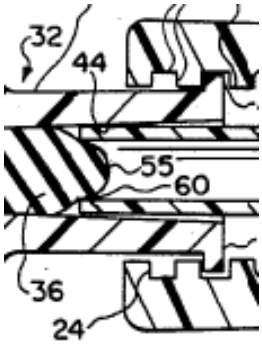
	substances that are antiseptic agents. (Ex. 1002, ¶¶ 167, 168). "The capping device comprises a body defining a chamber with an opening, **a liquid-containing disinfectant in the chamber**, …" (Ex. 1003, 3:23-25)(emph. add.)(Ex. 1002, ¶ 168). "In one embodiment, the disinfectant comprises at least one of: povidone iodine, iodine-containing antimicrobials, and betadine." (Ex. 1003, 4:15-18) (Ex. 1002, ¶ 168). Povidone iodine, iodine-containing antimicrobials, and betadine are all **antiseptic** agents. (Ex. 1002, ¶ 169)(emph. add.).
1g/18g. a member movably disposed within the chamber,	Tryggvason discloses a chamber as discussed in limitations [1b/18b] and [1c/18c] above. Tryggvason also discloses a "member movably disposed within the chamber". Tryggvason calls its sealing member a "sealing element". (Ex. 1003, Abstract)(Ex. 1002, ¶ 171). The specification explains that the sealing element is disposed within the chamber, and specifically "arranged in the opening of the chamber": "The capping device comprises a body defining a chamber with an opening, … [and] **a sealing element arranged in the opening**". (Ex. 1003, 3:23-25)(emph. add.)(Ex. 1002, ¶ 172). Tryggvason next discloses that the sealing element is a "movable member". (Ex. 1002, ¶ 173). The specification explains that the sealing element is "displaced", and thus movable, when the connector is inserted into the cap: "The capping device comprises … a structure for engaging and guiding the first connector towards the body such that **a portion of the first connector displaces the sealing element into the chamber**". (Ex. 1003, 3:23-29)(emph. add.)(Ex. 1002, ¶ 173). Tryggvason's sealing member [15] is in the chamber of the

	cap, as shown in Figure 4 and as explained in claim limitations [1b/18b] and [1c/18c] above. (Ex. 1002, ¶ 174). Aalto also discloses a movable sealing member. Aalto's member is an "elastomeric insert" that is contained in the chamber of the male luer connector cap, as seen at [36] in Figure 2 of the patent here. (Ex. 1002, ¶ 175). The specification explains, "As seen in FIG. 2, the elastomeric insert 36 is compressively retained in the cavity by the cylindrical surface 49". (Ex. 1018, 3:54-56)(Ex. 1002, ¶ 176). The member (elastomeric insert) moves into the lumen of the male connector when the cap and connecter are attached to one another. (Ex. 1018)(Ex. 1002, ¶ 177). The specification explains that the member moves in relation to the insertion of the post of the male luer connector into the chamber of the cap: "As the sealing closure is brought into mating contact with the Luer fitting 20, **the elastomeric insert 36 is compressed further**." (Ex. 1018, 4:11-13)(emph. add.)(Ex. 1002, ¶ 178). FIG. 2 
1h/18h. the member shaped to enter the lumen so as to engage against an interior edge of an opening of the lumen when the post is received into the receiving portion	Aalto discloses a member shaped to enter the lumen so as to engage against an interior edge of an opening of the lumen when the post is received into the receiving portion. (Ex. 1002, ¶ 179). Aalto's member is an "elastomeric insert", as described in claim limitation [1g/18g] above, which enters into the lumen of the male connector when the cap and connecter are attached to one another. Ex. 1002, ¶ 180). Aalto calls the lumen an "outlet", and the cap's member and lumen are identified here in Figure 5, where the cap and connector are shown attached to one another:



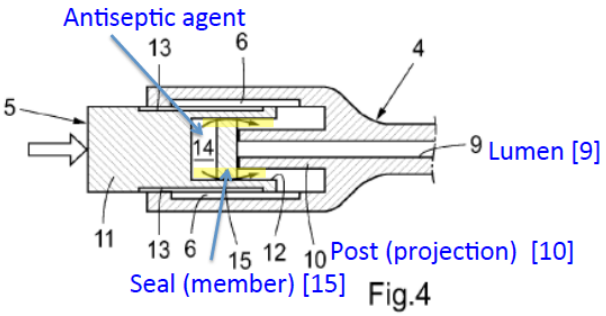
(Ex. 1018)(Ex. 1002, ¶ 181). Aalto's specification explains that when the cap and connector are attached, the member "enters" into the lumen:

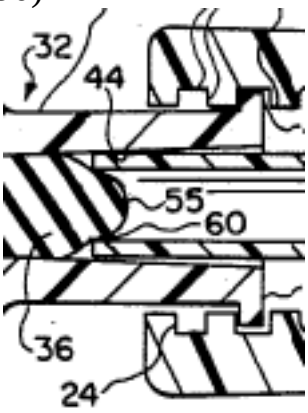
> "As the sealing closure is brought into mating contact with the Luer fitting 20, the elastomeric insert 36 is compressed further. The locking ring 22 on the Luer fitting 20 and the ridges 42 on the sealing closure 32 create a pressure lock. Stated differently, the Luer fitting 20 is forcefully held in mating contact with the tapered inner surface 44. The elastomeric insert 36 creates a liquid-tight seal with the outlet 60 of the Luer fitting 20. **The second-end side 55 of the insert 36 will be partially displaced into the outlet 60**." (Ex. 1018, 4:11-20)(emph. add.)(Ex. 1002, ¶ 182).



As can be seen in the expanded portion of Figure 5 of Aalto, shown right, the member (elastomeric insert) [55] engages with the "interior edge of the lumen" (outlet) [60] when the cap and connector are attached. (Ex. 1002, ¶ 183). The specification also explains the **engagement** of the member to the connector as the cap and connector are attached to one another, calling the engagement **"mating contact":**

> "As the sealing closure is brought into **mating contact** with the Luer fitting 20, the elastomeric insert 36 is compressed further." (Ex. 1018, 4:11-13)(Ex. 1002, ¶ 184).

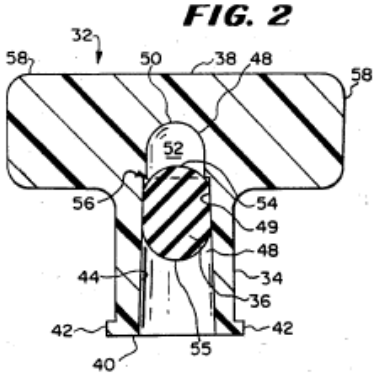
1i/18i. to diminish flow of the antiseptic agent into the lumen while permitting flow of the antiseptic agent past the member to the post of the male luer-lock connector; and	The member disclosed in Tryggvason diminishes the flow of the antiseptic agent into the lumen. (Ex. 1002, ¶ 188) Because Tryggvason's member [15] is positioned over the opening of the lumen of the male luer connector, the antiseptic agent flows around the sides of the sealing element (member) [15], to the post [10] of the male luer connector, shown highlighted in Figure 4 here. (Ex. 1003)(Ex. 1002, ¶ 186).  Fig.4 Aalto also discloses a member that diminishes the flow of fluid. Aalto's specification explains that when the cap and connector are attached a "liquid-tight" seal is formed: "As the sealing closure is brought into mating contact with the Luer fitting 20, the elastomeric insert 36 is compressed further. The locking ring 22 on the Luer fitting 20 and the ridges 42 on the sealing closure 32 create a pressure lock. Stated differently, the Luer fitting 20 is forcefully held in mating contact with the tapered inner surface 44. **The elastomeric insert 36 creates a liquid-tight seal with the outlet 60 of the Luer fitting 20.** The second-end side 55 of the insert will be partially displaced into the outlet 60." (Ex. 1018, 4:11-20)(emph. add.)(Ex. 1002, ¶ 188).
1j. a gripping portion.	Tryggvason discloses a gripping portion, most clearly seen in Figure 6A above. (Ex. 1002, ¶ 189). The specification explains: "Returning to FIG. 6, the capping device 5 further comprises a **grip portion 23A** in the form of a flange that can be gripped by a user in order to screw the capping device 5 in and out of the connector 4." (Ex. 1003, 10:40-43)(emph. add.)(Ex. 1002, ¶ 189).

2. A cap according to claim 1, wherein the member has a centrally disposed bulge shaped to enter the lumen.	The member of Aalto has a centrally disposed "bulge", as that term is properly construed, shaped to enter the lumen. As established above, the proper construction of the term "bulge" is "a protuberance". (Ex. 1002, ¶ 190) Aalto's member is described in claim limitations [1g/18g.] and [1h/18h.] above. (Ex. 1002, ¶ 191) As best seen in the expanded portion of Figure 5 of Aalto, shown right, the member (elastomeric insert) 55 has "a protuberance" that enters into the lumen (outlet) [60] when the cap and connector are attached, (Ex. 1002, ¶ 192). 

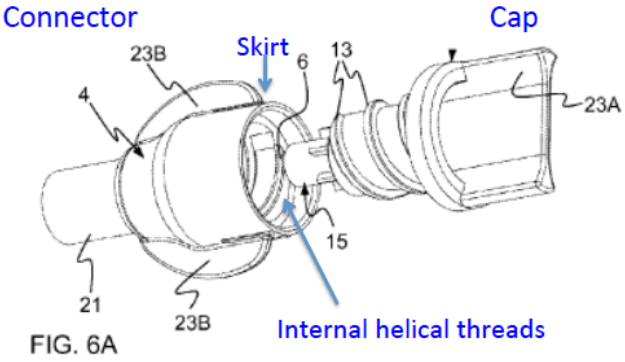
4. A cap according to claim 2, wherein the bulge is dome shaped.	Aalto's member, described in claim limitation [1h]/[18h] and claim 3 above, is "dome shaped", as that term is properly construed ("rounded or spherical convex shape"). As explained above, the proper construction of the term "dome shaped" is "rounded". As best seen in the expanded portion of Figure 5 of Aalto, shown in claim 3 above, the bulge in the member is "rounded" and thus "dome shaped". (Ex. 1002, ¶ 194).

Claims 9 and 10 relate to a taper in the wall of the cap's chamber. As discussed above, a 6% taper is the fundamental feature of all luer connectors and, consequently, luer connector caps. This was well known in the art well in the relevant timeframe for obviousness. (Ex. 1002, ¶ 195). Indeed, the 6% taper was standardized by the ISO in 1991. (Ex. 1010)(Ex. 1011)(Ex. 1002, ¶ 195).

9. A cap according to claim 1,	Tryggvason discloses that at least a portion of the wall of the chamber has a taper that narrows toward the interior of the chamber. Because Tryggvason can be used with "luer fittings",

wherein at least a portion of a wall of the chamber has a taper that narrows toward an interior of the chamber.	the wall of the chamber would necessarily have a 6% taper, corresponding to the taper in the luer fitting, which would narrow as the luer fitting progresses into the chamber of the luer cap. (Ex. 1003, 6:54-63)(Ex. 1002, ¶¶ 196, 197). Aalto also discloses a cap for a male luer connector with a chamber having a taper that narrows toward its interior. (Ex. 1002, ¶ 198). Aalto explains that its cap is for use with: "Luer fittings for Luer locks employ male and female tapered mating surfaces for a releasably secure connection between, for example, two portions of a conduit. For example, in the medical field, many intravenous fluid solution sets have at one end **a tapered male Luer fitting** for connection with a female Luer fitting disposed in the hub of a catheter disposed in a patient." (Ex. 1018, 1:14-20)(emph. add.)(Ex. 1002, ¶ 199). The tapered wall of the chamber of the cap in Aalto is seen in Figure 2 of Aalto, shown here, the taper **narrowing toward the interior of the chamber**. (Ex. 1002, ¶ 200). It is also described in the patent's specification: "Luer fitting 20 is forcefully held in mating contact with the **tapered inner surface 44**." (Ex. 1018, 4:16-17)(emph. add.)(Ex. 1002, ¶ 200). FIG. 2 
10. A cap according to claim 9, wherein the taper is near the opening of the	Because the tapered luer fitting is inserted into the opening of the chamber of Tryggvason, the taper of the wall of the chamber in Tryggvason is also "**near the opening of the chamber**" (to correspond to the 6% taper in the luer fitting that is inserted therein). (Ex. 1003, 6:54-63)(Ex. 1002, ¶ 201). The same is true for Aalto. As seen in Figure 2 of Aalto in claim 9 above, the taper [44] is "**near the opening of the**

chamber.	**chamber**" [40], to accommodate the tapered luer connector, and extends through the end of the chamber. (Ex. 1002, ¶ 202).

11. A cap according to claim 1, wherein the means for engaging helical threads includes threading disposed on the receiving portion to engage with threads of the male luer-lock connector	The means for engaging helical threads of the internally threaded skirt of the connector, discussed in claim limitation [1d.] above, disclosed in Tryggvason include **corresponding helical threads disposed on the receiving portion of the cap**. (Ex. 1003)(Ex. 1002, ¶ 203). This is shown in Figures 6A-6C of the patent, with 6A shown here, which show a female connector and corresponding cap. (Ex. 1003)(Ex. 1002, ¶ 204). The female connector shown in annotated Figure 6A has a **skirt, identified here, with internal helical threads.** (Ex. 1002, ¶ 205). The skirt is at the opening of the connector, or "receiving portion" of a corresponding male luer connector cap. (*Id.*, ¶ 206). The engagement is between the threading on the cap and corresponding threading on the connector. (*Id.*, ¶ 207). The patent specification further states that the helical threads disclosed in Figure 6 could be used on either the female connector and corresponding cap, or on a **male connector** and corresponding cap. (Ex. 1003, 7:50-52, "It should also be understood that, in all embodiments discussed herein, either one of the connectors 2, 4 could be used as patient connector")(Ex. 1002, ¶ 208).  FIG. 6A

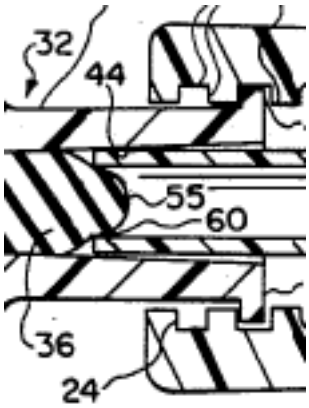
Claims 13 and 21 depend, respectively, from independent claims 1 and 18, and add the same claim element.

13/21. A cap according to	The chamber of the cap disclosed in Tryggvason has a fixed volume. The chamber is discussed above in claim limitation

claim [1/18], wherein the chamber has a fixed volume.	1b/18b. As seen in Figure 4, shown there, the chamber of the cap is a fixed size that does not change as the cap is in use, and thus has a fixed volume. (Ex. 1002, ¶ 210).

Claims 14 and 22 depend, respectively, from independent claims 1 and 18, and add the same claim element.

14/22. A cap according to claim [1/18], wherein the movably disposed member is configured to retain the antiseptic inside the chamber prior to inserting the post into the chamber.	Tryggvason discloses that prior to use the antiseptic is maintained in the cap's chamber by the sealing member. (Ex. 1002, ¶ 212). Tryggvason discloses this claim element in reference to the cap for the female connector, stating: "A **sealed cavity** 14 is formed at the inner end portion of the bore, **by a seal or sealing element 15** being fitted into the bore 12."(Ex. 1003, 7:6-8)(emph. add.)(Ex. 1002, ¶ 213). Tryggvason explains that the cap for the male luer connector "has the same construction as the capping device" for the female connector. (Ex. 1003, 7:32-34). The cap for the male connector also has a sealed cavity. (Ex. 1002, ¶ 214). The antiseptic is retained within the sealed cavity. As explained in the specification: "A sealed cavity 14 is formed at the inner end portion of the bore, by a seal or sealing element 15 being fitted into the bore 12. **The cavity 14 is thus defined by the seal 15, a cylindrical wall portion 16 and a bottom end surface 17**. **The cavity 14 is wholly or partly filled with a liquid-containing disinfectant."**(Ex. 1003, 7:6-11)(emph. add.)(Ex. 1002, ¶ 215). The "disinfectant" in Tryggvason is an antiseptic agent, as explained in claim 1, limitation [1a/18a.] above. (Ex. 1003, 4:15-18) (Ex. 1002, ¶ 216).

15. A cap according to claim 1, wherein the member has a convex surface shaped to enter the lumen.	The member of Aalto has a convex surface shaped to enter the lumen. Aalto's member is described in claim limitation 1h/18h. above. (Ex. 1002, ¶ 217). As best seen in the expanded portion of Figure 5 of Aalto, shown right, the member (elastomeric insert) 55 has a convex surface that engages with the "interior edge of the lumen" (outlet) [60] when the cap and connector are attached. (Ex. 1002, ¶ 218). As is also seen in this figure, the member is shaped to enter into the lumen. (*Id.*, ¶ 219). This is explained in the specification: "The second-end side 55 of the **insert will be partially displaced into the outlet 60.**" (Ex. 1018, 4:19-20)(emph. add.)(Ex. 1002, ¶ 220). 
17. A cap according to claim 15, wherein the convex surface is dome shaped.	Aalto's member, described in claim limitation [1h]/[18h] and claim 15 above, is "dome shaped", as that term is properly construed. (Ex. 1002, ¶ 220). As explained above, the proper construction of the term "dome shaped" is "rounded or spherical convex shape". As best seen in the expanded portion of Figure 5 of Aalto, shown in claim 3 above, the convex surface in the member is "rounded" and thus "dome shaped". (Ex. 1002, ¶¶ 221, 222).

Ground 2. Claims 3 and 16 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto, in further view of Sweeney.

Claims 3 and 16 are invalid under 35 U.S.C. § 103 over Tryggvason in view of Aalto, as set forth in Ground 1, incorporated herein, in further view of U.S. Patent No. 5,533,980 ("Sweeney"). (Ex. 1020)(Ex. 1002, ¶ 223). Sweeney is prior art under § 102(b) as it issued in 1996. (Ex. 1020). The level of ordinary skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 20-21, 225).

Like claims 2, 4, 15 and 17, discussed above, claims 3 and 16 also relate to the shape of the member of the claimed cap, and specify a "conical" shape.

- Claim 3 states: "A cap according to claim 2, wherein the bulge is **conically shaped**."
- Claim 16 states: "A cap according to claim 15, wherein the convex surface is **conically shaped**."

In reference to Figure 37 of the '681 patent, the specification describes a member that is "shaped substantially as a **conical disk**". (Ex. 1001, 30:64-65)(emph. add)(Ex. 1002, ¶ 228).

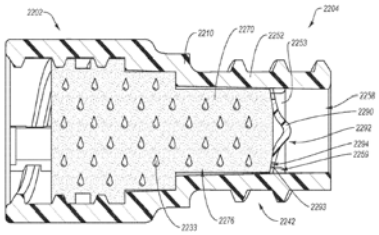


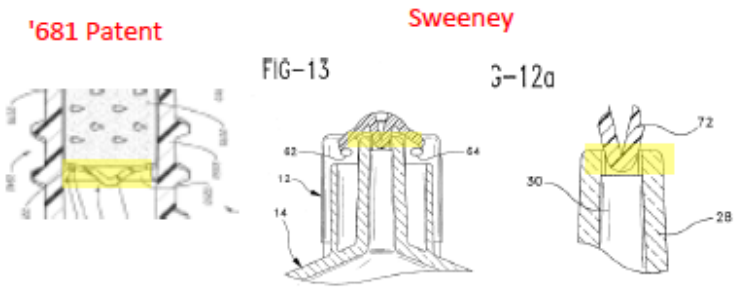
FIG. 37

DeCaprio, discussed above, discloses a male luer connector having a conically shaped member that engages with an interior edge of an opening of the lumen. *See* Section I.D.3. (Ex. 1002, ¶ 229). This claim limitation is also disclosed in Sweeney, wherein the member is both a "bulge" ("protuberance") as in claim 3, and a "convex surface" as in claim 16 of the '681 patent. (Ex. 1002, ¶ 230).

Sweeney discloses a "Protective Cap Assembly for a Medical Device Passageway". (Ex. 1020). The protective cap includes "a central sealing projection 72 for sealingly engaging portions of tip 28 of syringe 14 in proximity to passage 30" that "may be formed in **a generally frusto-conical configuration** which can conveniently seal the tip 28 of the syringe barrel by blocking passage

30." (Ex. 1020, 6:25-30)(Ex. 1002, ¶¶ 231-232).

The sealing projection of Sweeney is shown right below at [72] in Figure 12*a*, and also in Figure 13 of the patent, where the cap is attached to the syringe. (Ex. 1020)(Ex. 1002, ¶ 233). Also shown left below is an expanded portion of Figure 37 of the '681 patent, rotated to be in the same position as the figures in Sweeney. (Ex. 1002, ¶ 234). The "conically" shaped member is highlighted in each of these figures. (*Id.*).



It would have been obvious to one of skill in the art to use the shape of the sealing projection in Sweeney in combination with the member of Aalto, in the cap of Tryggvason. (Ex. 1002, ¶ 235). Sweeney, like Tryggvason and Aalto, discloses a cap for a medical fluid passageway. (Ex. 1020)(Ex. 1002, ¶ 237). As noted by the Examiner during prosecution of the '681 patent, this type of change to the shape of the member disclosed in Aalto, to the conical shape shown in Sweeney, "is generally recognized as being within the level of ordinary skill in the art." (Ex. 1014, p. 7, also explaining that such change "is deemed to have been known by

those skilled in the art since the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement")(citations omitted). *See also Corning Optical Communications RF, LLC v. PPC Broadband, Inc.*, No. IPR2013-00340 (PTAB Nov. 21, 2014)("[a] change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results.").

The combination of Tryggvason, Aalto, and Sweeney represents the use of a known disinfecting cap for a male luer connector with a movable member (Tryggvason), with a known male luer connector cap with a member shaped to engage against an interior edge of an opening of the lumen (Aalto), with a known protective cap for a medical passageway with a conically shaped seal (Sweeney), that would have been an insignificant design choice, each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 237). The '681 patent acknowledges the interchangeability of the shape of the member: "In other embodiments, the sealing member 2290 can define other shapes, such as, for example, square, oval, diamond, or other non-circular shapes." (Ex. 1001, 31:1-3)(emph. add.)(Ex. 1002, ¶ 236). *See KSR Int'l Co. v. Teleflex, Inc*., 127 S.Ct. 1727, 1739-42 (2007). There do not appear to be any secondary indicia of non-obviousness present. (Ex. 1002, ¶ 238). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

Accordingly, Tryggvason in view of Aalto, in further view of Sweeney, teaches claims 3 and 16 of the '681 patent.

Ground 3. Claims 5 and 12 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto, in further view of Buchman.

Claims 5 and 12 are invalid under 35 U.S.C. § 103 over Tryggvason in view of Aalto, as set forth in Ground 1, incorporated herein, in further view of U.S. Published App. No. 2008/0132880 ("Buchman")(Ex. 1005)(Ex. 1002, ¶ 239). Buchman is prior art under section § 102(b) because it was published June 5, 2008. (Ex. 1005). Buchman is also prior art under § 102(e) because it is entitled to the effective date of its provisional application, U.S. Provisional Application Ser. No. 60/774,708 filed February 17, 2006. Buchman's claims are supported by the disclosure in the provisional application. (Exs. 1024, 1028)(Ex. 1002, ¶ 241). The level of one of skill in the art is discussed in the Leinsing Declaration. (Ex. 1002, ¶¶ 20-21, 242).

Claims 5 and 12 add a "biasing structure" to the claimed cap:

- Claim 5 states: "A cap according to claim 1, further comprising a biasing structure disposed in the chamber on the side of the member facing an interior of the chamber."
- Claim 12 states: "A cap according to claim 1, further comprising a biasing structure disposed in the chamber to impose a thrust on the member when the male luer-lock connector is inserted into the receiving portion."

The disclosures of Tryggvason and Aalto are discussed in the Technical Introduction and in Ground 1 above. As explained above, the proper construction of the term "biasing structure" is "a structure that applies a returning force to an object in a particular direction". *See* Section II.F. The proper construction of the claim term "thrust" is "propulsive force in a particular direction". *See* Section II.G.

Buchman discloses a catheter cleaning device and cap intended for use with luer connector: "In one embodiment, the invention provides a catheter cleaning device that is a cap design. The cap design for a catheter cleaning device is screwed on to a standard luer fitting of a needleless injection port." (Ex. 1005, ¶ 35)(Ex. 1002, ¶ 245).

Like Tryggvason, the cap of Buchman includes a movable member, which it calls a "mobile frit" [30]. Buchman also discloses a biasing structure, which in the case of Buchman is a "spring" [60]. (Ex. 1005)(Ex. 1002, ¶ 246). These claim elements are seen in Figure 1 of Buchman, annotated right, and described in Buchman's specification:

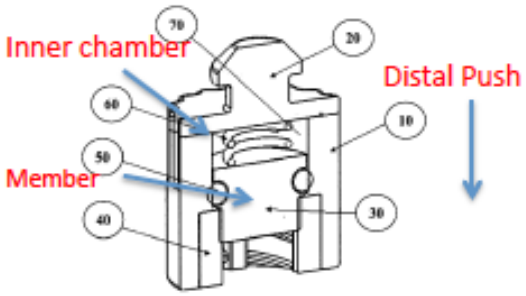


FIGURE 1

> "An exemplary catheter cleaning device that is a cap design contains a body 10 and a connector/top 20, as shown in FIG. 1. … The other parts of a catheter cleaning device that is a cap design include **mobile**

> **frit 30** for slow transfer of cleaning solution, open cell scrubbing surface such as a wiping foam or sponges 40 to clean the port threads, O-ring 50 to seal the solution into its reservoir and **a spring 60 to push frit 30 distally when the devices is not installed onto a port.** Reservoir 70 is for an antimicrobial solution such as IPA and CHG antimicrobial cleaning solution."

(Ex. 1005, ¶ 36)(emph. add.)(Ex. 1002, ¶ 247). Thus, the cap in Buchman works similarly to that in the '681 patent, and also Tryggvason. (Ex. 1002, ¶ 248).

As can be seen in Figure 1, the biasing structure (spring) of Buchman [60] is positioned on the inner side of the chamber from the member (mobile frit) [30], as in claim 5 of the '681 patent. (Ex. 1005, Fig. 1)(Ex. 1002, ¶ 249). As described in the above quoted portion of the specification, the biasing structure (spring) [60] provides pushes the member (mobile frit) [30] distally (toward the opening of the cap). (Ex. 1005, ¶ 36)(Ex. 1002, ¶ 250). One of ordinary skill in the art would have understood that when the cap was in use and attached to the luer connector, the biasing structure (spring) [60] would exert a propulsive force, or "thrust", on the member (movable frit) [30], as in claim 12 of the patent. (Ex. 1002, ¶ 251).

Notably, during prosecution of the '681 patent, the Examiner found that Buchman disclosed a "biasing structure" that could impose "thrust", explaining:

> "**Buchman et al., however, teaches a cap (Fig 1) having a movable member 30 (Fig 1) and a biasing structure 60 (Fig 1) disposed on a**

> **side of the member facing an interior of the chamber 70 (Fig 1) that the movable member is in (as seen in Fig 1) to impose a thrust on the member when a male connector is inserted into the chamber (Col 5, Lines 37-39)** for the purpose of pushing the member back in position after it has been depressed and thus limiting the amount of agent escaping past the member when a connector is not installed in the cap (Col 5, Lines 37-41). **Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Tryggvason et al./Chin-Loy et al. to include a biasing member, as taught by Buchman et al**. for the purpose of pushing the member back in position after it has been depressed and thus limiting the amount of agent escaping past the member when a connector is not installed in the cap (Col 5, Lines 37-41)."

(Ex. 1014, p. 10)(emph. add). Following this finding, Applicants amended the claims to add the limitation relating to the specific shape of the member, as discussed above. (Ex. 1015, p. 5).

One of ordinary skill would have understood the benefit of using a biasing member or structure to maintain the connection between the member and the connector. (Ex. 1002, ¶ 252). One of skill in the art further would have been motivated to use the biasing structure (spring) of Buchman, in the cap of Tryggvason, to maintain the secure connection between the member and the connector during use to maintain a seal and reduce leakage. (Ex. 1002, ¶ 253).

The combination of Tryggvason, Aalto and Buchman represents the use of a known disinfecting cap with a movable member (Tryggvason) with the known cap for a male luer connector with a member that engages against an interior edge of an opening of the lumen (Aalto), with the biasing structure from the known disinfecting cap for a catheter (Buchman), each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 254). *See KSR Int'l Co. v. Teleflex, Inc*., 127 S.Ct. 1727, 1739-42 (2007). There do not appear to be any secondary indicia of non-obviousness present. (Ex. 1002, ¶ 255). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

Accordingly, Tryggvason in view of Aalto, in further view of Buchman, teaches claims 5 and 12 of the '681 patent.

Ground 4. Claims 6, 7, 8, 19 and 20 are unpatentable under 35 U.S.C. § 103(a) over Tryggvason in view of Aalto, in further view of Hoang.

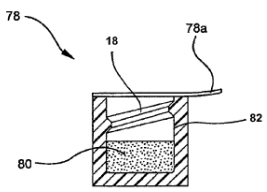
Claims 6, 7, 8, 19 and 20 are invalid under 35 U.S.C. § 103 over Tryggvason in view of Aalto, as set forth in Ground 1, incorporated herein, in further view of U.S. Patent No. 8,740,864 ("Hoang"). (Ex. 1009)(Ex. 1002, ¶ 256). Hoang is prior art under § 102(e) as it was filed in 2005 and issued in 2014. (Ex. 1009). The level of skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 20-21, 258).

Claims 6, 7, 8, 19 and 20 all relate to a "cover" for covering the *cap* of the '681 patent:

- Claim 6 states: "A cap according to claim 1, further comprising a cover disposed over the opening of the chamber."
- Claim 7 states: "A cap according to claim 6, wherein the cover comprises an impervious pliable material."
- Claim 8 states: "A cap according to claim 7, wherein the impervious pliable material is a foil."
- Claim 19 states: "A cap according to claim 18, further comprising a cover disposed over the opening of the chamber."
- Claim 20 states: "A cap according to claim 19, wherein the cover comprises an impervious pliable material."

The disclosures of Tryggvason and Aalto are discussed in detail in Ground 1 above, incorporated herein. Hoang, like Tryggvason, discloses a disinfecting cap for a medical connector. (Ex. 1009)(Ex. 1002, ¶ 260).

FIG. 10B



Hoang shows, in Figure 10B here, a stand-alone disinfecting cap that contains a pad [80] with an antimicrobial agent that comes into contact with the connector when inserted therein. (Ex. 1009, 3:37-42; 4:58-62)(Ex. 1002, ¶ 261). The cap shown in Hoang can be used with a "luer" connector. (Ex. 1002, ¶ 262).

Hoang also discloses a cover that extends over an open end of the cap, as in claims 6 and 19 of the '681 patent, called a "lid" in Hoang and shown in Figure 10B [78*a*]. (Ex. 1009)(Ex. 1002, ¶ 263).

Hoang further discloses that the "lid" is made of "foil" (as in claim 8 of the '681 patent), which is material that "completely seals the opening" and creates a "moisture barrier," and is therefore "impervious". (Ex. 1009)(Ex. 1002, ¶ 264). 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. 1009, 2:20-23)(emph. add.)(Ex. 1002, ¶ 264). Figure 10B also shows the "lid" is to be pulled from the cap, in bent fashion, for removal. Accordingly, the lid must also be pliable, as is expected for "foil". (Ex. 1009)(Ex. 1002, ¶ 265). Thus, Hoang discloses the "impervious, pliable" lid of claims 7 and 20 of the '681 patent. (Ex. 1002, ¶ 266).

Tryggvason discloses that it can be "covered" by packaging: "The resulting capping device may then again be sterilized, before being encased in a sterile pack or wrapping for distribution". (Ex. 1003,12:33-35)(Ex. 1002, ¶ 267).

One of skill in the art would have been motivated to use the cover (lid) of Hoang on the cap of Tryggvason, by the cost savings in the materials during the manufacturing process by including a cover instead of separate packaging, and also because of the increased convenience. (Ex. 1002, ¶ 268). Once it was disclosed in

Hoang that the foil seal could adhere to the plastic of the cap, it would have been obvious to use the lid of Hoang with the cap of Tryggvason, for the ease and cost savings during the manufacturing process. (*Id.*, ¶ 269).

During prosecution of the application for the '681 patent, the Examiner rejected the dependent claims that included an impervious, pliable foil cover, finding that:

> Hoang et al., however, teaches using a cover 20 (Fig 2) made of foil (Para 12) over the opening of cap 10 (Fig 2) that has fluid 22 (Fig 2) therein for the purpose of providing a moisture barrier (Para 12). Therefore, it would have been **obvious to one of ordinary skill in the art at the time the invention was made** to modify Fisher et al./Chin-Loy **to include a foil cover on the cap, as taught by Hoang et al., for the purpose of providing a moisture barrier** (Para 12)."

(Ex. 1026, p. 9)(emph. add.)(Ex. 1002, ¶ 270). Applicants did not take issue with the Examiner's findings that it would have been obvious to one of skill in the art to modify Fisher and Chin-Loy to include an impervious pliable cover made of foil over the opening of the cap, as taught by Hoang. (Ex. 1029, p. 9-12). It would have also been obvious to combine Hoang with Tryggvason and Aalto, for reasons similar to those employed by the Examiner in combining Hoang with Fisher and Chin-Loy (providing a moisture barrier). (Ex. 1002, ¶ 271).

The combination of Hoang with Tryggvason and Aalto further represents the incorporation of a known disinfecting cap for a male luer connector with a

movable member (Tryggvason) with the known male luer connector cap having a member shaped to engage against an interior edge of an opening of the lumen (Aalto) and the cover (lid) of a known disinfecting luer cap (Hoang) that would commonly be connected to other medical implements with a standard luer connector, each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 272). *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1739-42 (2007). *See, e.g., Ivera Medical Corp. v. Excelsior,* No. IPR2014-01124, Institution of *Inter Partes* Review (Patent Trial and Appeal Board Jan. 21, 2015)(granting review of related U.S. Pat. No. 8,647,326, wherein Petitioner asserted that it would have been obvious to use Hoang's cover (lid) in combination with other luer connector caps)(Ex. 1030, pp. 22-25). There do not appear to be any secondary indicia of non-obviousness present. (Ex. 1002, ¶ 273). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

For the foregoing reasons, Tryggvason in view of Aalto, and in further view of Hoang, teaches claims 6, 7, 8, 19 and 20 of the '681 patent.

IV. CONCLUSION

The Petitioner therefore requests institution of trial and cancellation of claims 1-22 of U.S. Patent No. 8,641,681.

Date: February 4, 2015 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, February 4, 2015, on the Patent Owner's counsel of record at the United States Patent & Trademark Office having the following address:

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Date: February 4, 2015 Signed: /Matthew A. Smith/ RN 49,003