

Petition for *inter partes* review
U.S. Pat. No. 8,647,308

Paper No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IVERA MEDICAL CORPORATION

Petitioner

v.

CATHETER CONNECTIONS, INC.

alleged Patent Owner

Patent No. 8,647,308

PETITION FOR INTER PARTES REVIEW
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 ET. SEQ.

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CERTIFICATE OF SERVICE61

TABLE OF EXHIBITS

Exhibit No.	Description
1001	U.S. Pat. No. 8,647,308 ("the '308 patent").
1002	Declaration of Karl Leinsing, MSME, PE.
1003	U.S. Pat. No. 4,624,664 ("Peluso").
1004	U.S. Pat. No. 7,316,669 ("Ranalletta").
1005	U.S. Pat. No. D493,526 ("Hwang").
1006	U.S. Pat. No. 1,793,068 ("Dickinson").
1007	U.S. Pat. No. 4,597,758 ("Aalto").
1008	U.S. App. Ser. No. 13/664,641, Response and Amendment dated June 24, 2013.
1009	U.S. Pat. No. 5,954,957 ("Chin-Loy").
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. App. Ser. No. 13/664,641, Office Action dated 7/30/13.
1013	U.S. App. Ser. No. 13/664,641, Response After Final Action dated September 16, 2013.
1014	U.S. App. Ser. No. 13/664,641, Notice of Allowance dated October 1, 2013.
1015	U.S. Patent No. 7,247,153 ("Guala").
1016	KippMed, VENTED AND NON-VENTED FEMALE LUER LOCK CAPS (1995).
1017	U.S. App. Ser. No. 13/664,641, Initial Claims dated October 31, 2012.
1018	Michel Holloway and Chikezie Nwaoha, DICTIONARY OF

	INDUSTRIAL TERMS 391 (2013).
1019	U.S. Pat. No. 3,987,930 ("Fuson").
1020	U.S. Pat. No. 5,620,427 ("Werschmidt").
1021	U.S. Pat. No. 8,740,864 ("Hoang").
1022	U.S. Pat. No. 4,778,447 ("Velde").
1023	U.S. App. Ser. No. 13/664,641, Office Action dated May 17, 2013.
1024	Joint Claim Construction and Prehearing Statement, <i>Catheter Connections, Inc. v. Ivera Medical Corp.</i> , No. 2:14-cv-00070-TC (D. Utah filed Feb. 4, 2014).
1025	Order and Memorandum Decision, <i>Catheter Connections, Inc. v. Ivera Medical Corp.</i> , No. 2:14-cv-00070-TC (D. Utah filed Feb. 28, 2014).
1026	<i>Ivera Medical Corporation Announces FDA 510(k) Clearance for Curot Tips™ Passive Disinfection Device</i> , CUROS, http://www.curos.com/ivera-medical-corporation-announces-fda-510k-clearance-for-curos-tips-passive-disinfection-device/ .
1027	K. K. Ramalingam, HANDBOOK OF MECHANICAL ENGINEERING TERMS 8 (2009).
1028	J. R. Davis, ASM MATERIALS ENGINEERING DICTIONARY 362 (1992).
1029	U.S. App. Ser. No. 13/664,641, Interview Summary dated June 24, 2013.
1030	U.S. Pat. No. 5,184,742 ("DeCaprio").
1031	Catheter Connections, Inc., DUAL CAP (2014).
1032	Baxa, SAFE AND SOUND. PRODUCT CATALOGUE (2009).
1033	U.S. Pat. No. 6,394,983 ("Mayoral").
1034	New York State Office of General Services, Purchasing Memorandum (Jan. 19, 2011).
1035	Baxter, PERITONEAL DIALYSIS: PD SOLUTIONS (2011).
1036	AlliedSignal Plastics, MODULUS DESIGN GUIDE (1996).

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1037	U.S. Pat. No. 4,390,104 ("Cummings").
1038	<i>New IV Products and Services</i> , 17(2) J. OF INTRAVENOUS NURSING 106 (1994).
1039	<i>Baxa Sterile Luer Lock Tip Caps, Red, 100/Case-5565001</i> , DME SUPPLY GROUP, http://www.dmesupplygroup.com/5565001.html?gclid=CjwKEAiA_s2IBRCe1YPXxtSe-DcSJACCIh3L_Kru3z8-4oPSPURTZb239UVuFCO_3lbPqzvapDCTGxoC3czw_wcB ; Luer Syringe Tip Cap 100/CS, WOLF MEDICAL SUPPLY, INC., http://www.wolfmed.com/baxter/luer-syringe-tip-cap-100-cs.html .
1040	Decision, Institution of <i>Inter Partes</i> Review, 37 C.F.R. § 42.108 in IPR2014-01124.
1041	Proof of Service in <i>Catheter Connections, Inc. v. Ivera Medical Corporation</i> , Case No. 2-14-cv-00070 (D. Utah).

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NOTICE OF LEAD AND BACKUP COUNSEL

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NOTICE OF EACH REAL-PARTY-IN-INTEREST

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

NOTICE OF RELATED MATTERS

U.S. Patent No. 8,647,308 ("the '308 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 a petition for *inter partes* review of related U.S. Patent No. 8,647,326, and the Board has instituted trial as to the petition in IPR2014-01124. (Ex. 1040).

NOTICE OF SERVICE INFORMATION

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GROUND 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 1-7 of U.S. Patent No. 8,647,308 ("the '308 patent")(Ex. 1001) be canceled based on the following grounds of unpatentability, explained in detail in the next section:

Ground 1. Claims 1, 2, 5, 6 and 7 are unpatentable under 35 U.S.C. § 103(a) over Peluso in view of Mayoral.

Ground 2. Claim 3 is unpatentable under 35 U.S.C. § 103(a) over Peluso in view of Mayoral, in further view of Hoang.

Ground 3. Claim 4 is unpatentable under 35 U.S.C. § 103(a) over Peluso in view of Mayoral and Hoang, in further view of Cummings.

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

This Petition is supported by the declaration of Karl R. Leinsing. (Ex. 1002).

A. Technology Background

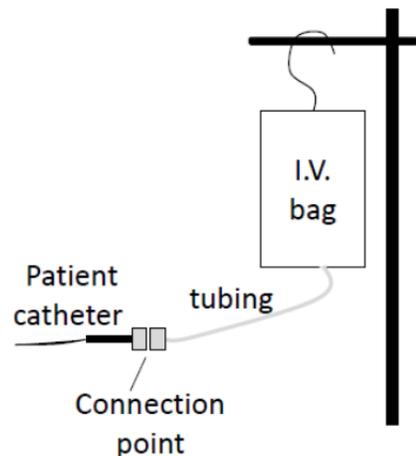
This *inter partes* review relates to medical implements that are used to withdraw blood from a patient (or to supply fluid into the bloodstream of a patient). Such implements can include, for example, syringes, intravenous (IV) tubing and catheters. (Ex. 1002, ¶ 31). These implements are often connected to fluid lines using a specialized connector called a "luer connector". (*Id.*, ¶ 32).

When subsequently disconnected, the luer connectors are covered by *caps*. (*Id.*, ¶ 33). The '308 patent at issue relates to such caps.

1. Luer Connectors

Because the term "luer connectors" appears in the claims of the '308 patent, and in the prior art, a brief explanation of the features of these standardized connectors is helpful.

Luer connectors are widely used with medical implements. (Ex. 1002, ¶ 34). 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. (*Id.*, ¶ 35). Luer connectors are placed at the connection point between



the catheter and IV tubing. In the above diagram, for example, a first connector is placed on the end of the patient's catheter, and a second, corresponding connector is placed on the end of the IV tubing. (*Id.*, ¶¶ 36-37).

Luer connectors have been in existence for over a century. "Luer" is an eponym for the 19th century German medical instrument maker Hermann Wülfiging Luer, who invented a way of putting a stopper tapered by 6% in a bottle and having it form a seal. (Ex. 1002, ¶ 37). The design was improved upon in 1929, when a method for locking luer connectors was developed and patented by Fairleigh S. Dickinson, in U.S. Patent No. 1,793,068. (Ex. 1006)(Ex. 1002, ¶ 38).

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 the locking mechanisms described in the Dickinson patent. (Exs. 1010 and 1011)(Ex. 1002, ¶ 39).

So that they can be attached to each other, one luer connector is a "*male*" luer connector, and the other a "*female*" luer connector. (Ex. 1002, ¶ 40). A simplified example of a male and female luer connector is shown here, in a figure from the ISO 594-1:1986

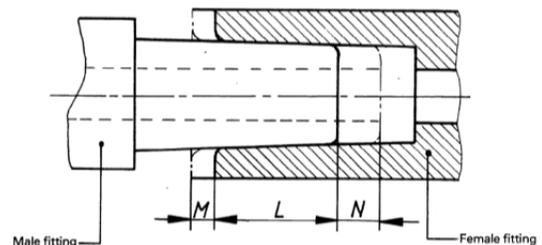


Figure 2 — Typical assembly of 6% (Luer) conical fittings

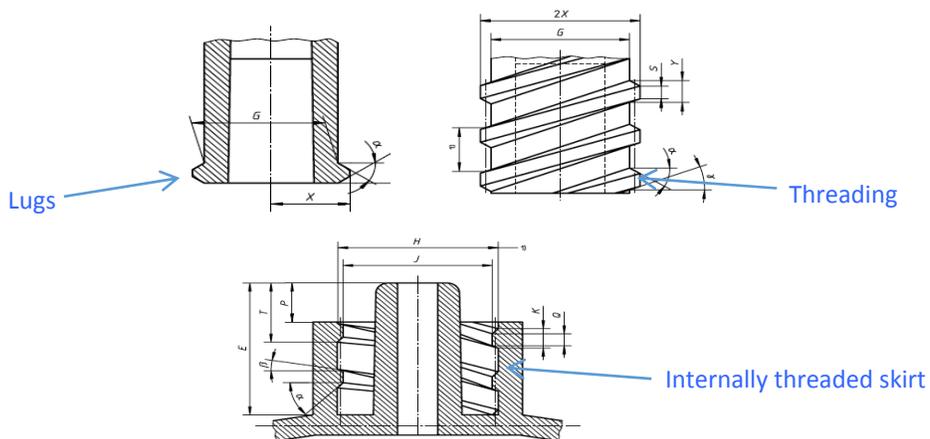
Standards. (Ex. 1010, p. 4)(Ex. 1002, ¶ 41).

To the left in the this figure is a male luer connector ("male fitting") with a post that has a 6% taper to its sides. (Ex. 1002, ¶ 42). The post may be a "lumen", and sometimes referred to as a "nozzle". A lumen or nozzle is simply 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, ¶ 43). The female luer connector has an open end, into which the male luer connector is received. The walls of the opening in 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, ¶ 44). In the diagram with the catheter, above, the catheter may remain in place in the patient's vein after the IV tubing is disconnected. The IV tubing may be disconnected to either change to another fluid bag, or to administer medications with a syringe. (*Id.*, ¶ 45). One or both of the connectors may also be left unconnected, pending later use. (*Id.*, ¶ 46).

The luer connectors shown in the diagram from ISO 594-1:1986 (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). (*Id.*, ¶ 47). Other luer connectors are "luer-lock" connectors. (*Id.*, ¶ 48). Luer-

lock connectors have the same features as luer-slip connectors, and are additionally secured to one another. 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, ¶ 49).



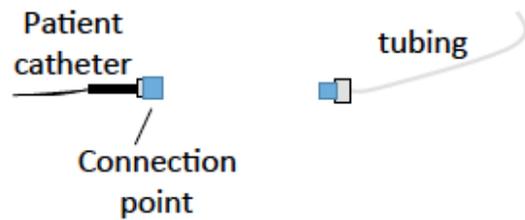
1) Double-start, right-hand thread of 2.5 mm pitch.

Figure 1 — Male 6% (Luer) conical lock fitting with permanently connected internally threaded collar

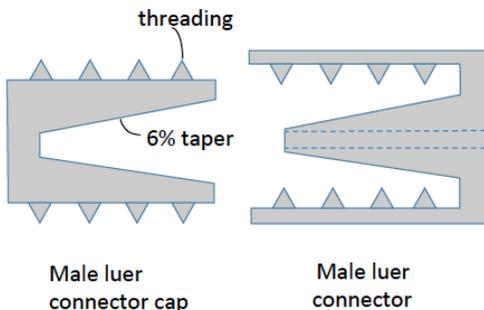
The two female luer-lock connectors at the top are shown with lugs (left) and threading (right). (Ex. 1002, ¶ 50). The fitting on the bottom in the above figure is a corresponding male luer-lock connector with a threaded skirt. The skirt, or collar, extends around the post of the male luer-lock connector. (*Id.*, ¶ 51). When connected, the lugs or threads on the female luer-lock connector interlock with the threads on the skirt of the male luer-lock connector. (*Id.*).

2. Caps for Luer Connectors

As mentioned above, at times there is no need to have the two medical implements in use connected, but at the same time it is desired to reserve one or both for future use. For example, IV tubing can be disconnected when not needed, leaving a patient's catheter in place for later use. When disconnected, the luer connectors can be covered with "caps", shown in blue here. (Ex. 1002, ¶¶ 52-53).



Just as a male luer connector and a female luer connector fit together, luer connector *caps* correspond in shape to the connectors that they are intended to



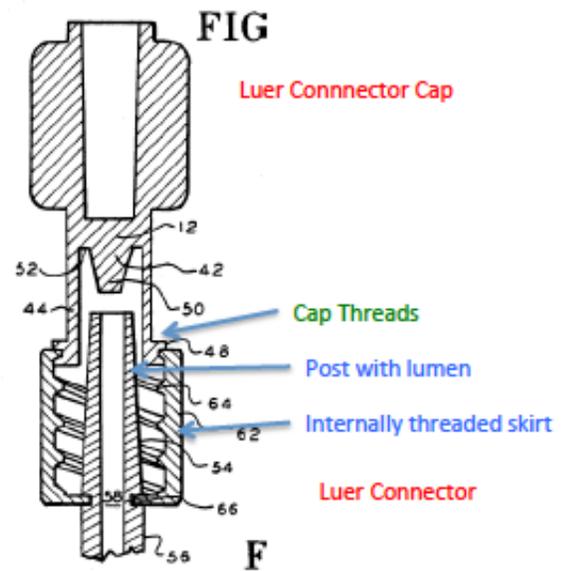
cover. (Ex. 1002, ¶ 54). In the example shown left, a male luer connector *cap* (left) connects to a male luer *connector* (right). (*Id.*) The male luer connector has an internally threaded skirt, which corresponds to the external threading on the male luer connector cap. The dotted blue lines indicate the lumen (or nozzle) that allows fluid to pass through the male luer connector. (*Id.*).

3. Sterile Protective Caps and Disinfecting Luer Caps

Caps for luer connectors have been known for decades, an early example being U.S. Patent 3,987,930 ("Fuson"), which issued in 1976. (Ex. 1019)(Ex. 1002, ¶

55). Fuson discloses a "dual purpose intravenous tubing cap [] provided for sealing both male and female Luer-tapered intravenous tubing end fittings". (Ex. 1019, 2:34-36)(Ex. 1002, ¶ 55).

Protective caps for luer connectors were oftentimes referred to as "deadender" caps. (Ex. 1002, ¶ 56). U.S. Patent No. 5,184,742 ("DeCaprio"), "Deadender Cap for Luer Fitting", issued in 1993. (Ex. 1030). DeCaprio discloses a "cap that is designed to be screwed into a standard medical Luer male thread connection to dead end that connection". (Ex. 1030, Abstract)(Ex. 1002, ¶ 57). Figure 3 of DeCaprio is shown here, with



external threads [48] on the cap, designed to connect with the internal threads [64] on the skirt [62] of the male luer connector. (Ex. 1030, 4:24-27)(Ex. 1002, ¶ 58).

The first luer connector caps were designed to protect the sterility of the connector against touch contamination. These are often called "sterile protective caps". (Ex. 1002, ¶ 59). While sterile protective caps served an important function, in some applications it was still required that medical personnel disinfect the luer connector prior to use. This was typically done with an isopropyl alcohol or betadine swab. (*Id.*, ¶ 60). As luer connector caps evolved, a disinfecting feature was added to the caps themselves to avoid this extra step, as well as to

guarantee that disinfection occurred. Generally, this was done by including an antiseptic within the cap body. (*Id.*, ¶ 61).

U.S. Patent No. 4,624,664 ("Peluso"), the principal reference of Ground 1, is an early example of a disinfecting luer connector cap. (Ex. 1003)(Ex. 1002, ¶ 62). Peluso issued in 1986. (Ex. 1003).

B. The '308 Patent

The '308 patent relates generally to caps for both male and female luer-lock connectors. (Ex. 1001)(Ex. 1002, ¶ 63). The claims of the '308 patent are directed to a disinfecting cap for "a 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, 7)(Ex. 1002, ¶64)(Ex. 1011).

The application for the '308 patent was filed October 31, 2012, from a series of continuation applications, starting with a provisional application filed January 16, 2007. (Ex. 1001). Because the prior art relied on in this Petition pre-dates even the '308 patent's earliest possible priority date, it is not necessary to address or determine whether the '308 patent is entitled to the benefit of an earlier filing date.

As discussed above, standardized caps for male luer connectors were well-known before the earliest possible filing date of the '308 patent. Consequently, the Applicants added limitations concerning the part of the cap they called the

"gripping" portion. Specifically, Applicants added limitations related to the "recesses" on the gripping portion. The shape of the "recesses" became the alleged distinction over the prior art. *See* Section I.B.2.

1. Patent Claims

Claim 1 reads as follows (with the gripping features that were alleged to distinguish over prior art in **bold** type):

1. A male disinfecting cap for disinfecting a male luer-lock connector of the type including a post having a lumen through which fluid flows and an internally threaded skirt surrounding the post, the cap comprising:

a cap body having an outer surface defining a gripping portion and only one receiving portion and defining a longitudinal axis, the receiving portion defining one chamber having a single opening, said opening being in the receiving portion, into which the post of the male luer-lock connector can be received, wherein an exterior surface of the receiving portion near the opening of the chamber fits within the skirt of the male luer-lock connector when the post is received into the single opening of the chamber, the exterior surface of the receiving portion having protrusions shaped to engage helical threads of the internally helically threaded skirt; the chamber defining an interior portion extending within the gripping portion of the cap body, wherein the gripping portion extends the cap body longitudinally beyond the skirt of the male luer-lock connector when the post is received into the chamber; and the **gripping portion comprising at**

least one recess having a length and depth, wherein the depth varied monotonically along the length of the recess; and
an antiseptic agent disposed in the chamber."

(Ex. 1001, claim 1)(emph. add.).

Independent claims 1 and 7 share the same elements with one exception, relating to the gripping features of the cap. (Ex. 1001). In claim 7, the claim element "and the gripping portion comprising at least one recess having a length and depth, wherein the depth varied monotonically along the length of the recess", is replaced with the following limitation:

"and the gripping portion comprising at least one recess having a bottom, the cap body having a cross sectional thickness at the bottom of the recess gradually increasing from a distal-most end of the cap body and towards the receiving portion;"

(Ex. 1001, claim 7).

The dependent claims of the '308 patent add limitations relating to a cover *for the cap* (claims 2-4), a taper extending along the wall of the cap's chamber (claim 5), and engagement between the wall of the chamber and the post of the male luer-lock connector (claim 6). (Ex. 1001).

2. Examination of the '308 Patent

During prosecution, Applicants attempted to distinguish the disinfecting cap claimed in the '308 patent over the prior art based only on the gripping features,

(ii) Amendment to Distinguish Peluso

The Examiner next rejected the amended claims over U.S. Patent No. 4,624,664 ("Peluso") (Ex. 1003), finding that Peluso disclosed all of the claimed elements (including the claimed "recesses,"), except that Peluso disclosed a cap for a female instead of a male luer-lock connector. (Ex. 1012, pp. 4-6). The Examiner further found, however, that that the difference between a cap for a female connector and a cap for a male connector was not patentable. This was because the difference between the two was merely whether the locking threads ("protrusions") were on the interior (female) or exterior (male) of the cap surface and, in the Examiner's words: "it would have been obvious to modify Peluso et al. to include protrusions on the exterior surface instead of the interior surface of the cap body, as taught by [U.S. Patent No. 5,954,957] Chin-Loy et al". (Ex. 1012, p. 6).

The Examiner was correct in finding that Peluso discloses all elements of the independent claims of the '308 patent, in the context of a female luer connector cap. This is independently demonstrated in the claim charts in Ground 1 below.

In response to the rejection, Applicants did not take issue with the Examiner's findings regarding Peluso and Chin-Loy, but instead made a second amendment relating to the claimed recesses:

Claim 1: "and the gripping portion comprising at least one recess having a longitudinally graded depth and wherein a smallest cross

~~sectional distance of the outer sidewall intersecting with the longitudinal axis at the gripping portion is smaller than a smallest outer diameter of the sidewall at the receiving portion; and"~~

Claim 11 [issued claim 7]: "the gripping portion comprising at least one recess having a bottom, the ~~sidewall~~ body of the cap having a cross sectional ~~distance~~ thickness at the bottom of the recess ~~intersecting with the longitudinal axis smaller than an outer diameter of the sidewall at~~ gradually increasing from a location within the gripping portion and towards the receiving portion; and"

(Ex. 1013, pp. 4, 6). By making this amendment, Applicants acquiesced to the Examiner's position that Peluso and Chin-Loy disclosed the other elements of the independent patent claims, including "recesses". *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).

Applicants then attempted to distinguish the patent claims based on the amendments to the gripping features. In Applicants' words:

"Peluso fails to teach or suggest the presently claimed invention. Peluso describes caps having a recess which forms a sharp 90° angle at the juncture of the receiving portion and the gripping portion. Also, the caps of Peluso have a constant thickness in the gripping portion. In contrast the present claims are directed to caps having either a recess with a longitudinally graded depth or caps with a decreasing wall

thickness in the bottom of the recess."

(Ex. 1013, p. 8). As explained below, Applicants' statements regarding the recesses of Peluso were incorrect, because the recesses of Peluso do not have a 90° angle, as would have been understood by one of skill in the art. *See* Section I.D.

Following another interview, the Examiner, as a condition of allowance and with permission from the Applicants, further amended the independent claims as follows:

"Claim 1: On lines 13-14, the phrase --longitudinally graded depth and-- has been replaced with the phrase --length and depth, wherein the depth varied monotonically along the length of the recess--.

Claim 11 [Claim 7 as issued]: On line 14, the phrase --body of the cap-- has been replaced with the phrase --cap body--. On line 16, the phrase --location within the gripping portion-- has been replaced with the phrase --distal-most end of the cap body--."

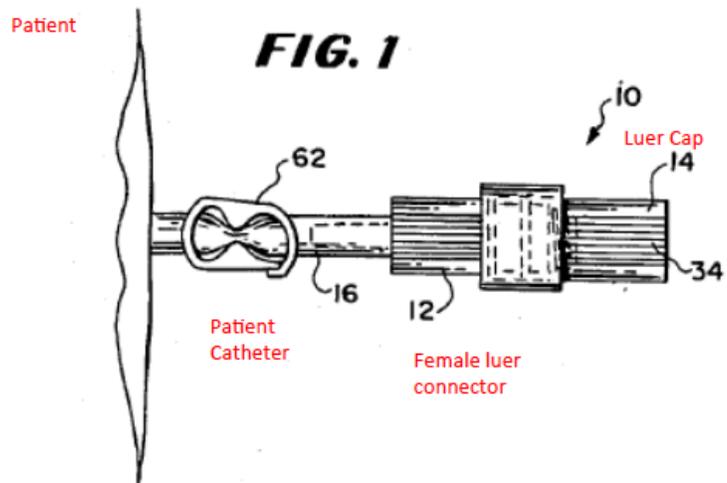
(Ex. 1014, p. 7). In connection with this amendment, the Examiner explained that issuance of the claims was based on the finding that the prior art did not disclose the specific recesses now claimed, in an antiseptic cap. (*Id.*, p. 8).

C. Peluso Prior Art

Peluso, mentioned above, discloses a disinfecting cap for a female luer connector that "can be used in different operative environments". (Ex. 1003, 2:56-57)(Ex. 1002, ¶ 67). The example provided in Peluso is a cap used to disinfect luer

connectors used with a peritoneal dialysis system. (Ex. 1003, 2:57-58)(Ex. 1002, ¶ 68).

As seen in Figure 1 here, with identifying terms added, "[t]he connector 12 is carried at the end of the catheter 16 which communicates with the peritoneal cavity of a patient." (Ex. 1003,



2:57-61)(Ex. 1002, ¶ 69). In this figure, the patient is to the left, with a catheter [16] attached to a female luer connector [12]. The female luer connector is then "capped" by the luer cap [14]. (Ex. 1003, Fig. 1)(Ex. 1002, ¶ 70).

The cap in Peluso protects the luer connector on the patient's catheter while the catheter is not in use, and when the cap is later removed the connector [12] is reattached to a corresponding male luer connector:

"In use, the protective cap 14 is removed to expose the connector 12, when desired. This is shown in Figure 2. **The connector 12 can then be conveniently attached to a suitable mating connector 18.**"

(Ex. 1003, 3:3-6) (emph. add.)(Ex. 1002, ¶ 71). The "suitable mating connector" would be a corresponding *male* luer connector. (Ex. 1002, ¶ 71).

The cap in Peluso is also a disinfecting cap. Peluso describes "[a] closure

system [that] includes a connector and protective cap in which there is a liquid antiseptic". (Ex. 1003, Abstract)(Ex. 1002, ¶ 72). Peluso's specification explains:

"The cap 14 not only serves to protect the interior portions of the connector 12 from touch contact, but it also serves to provide an **active antibacterial effect** to prevent contamination of the connector 12 and adjacent portions of the catheter 16 or extension set."

(Ex. 1003, 2:63-3:2)(Ex. 1002, ¶ 72).

1. '308 Patent Terms in the Context of Peluso

The '308 patent uses terms that it is helpful to discuss in the context of Peluso.

First, the claimed cap of the '308 patent is for use with a luer *connector* that has a "skirt" and "post" with a "lumen". (Ex. 1001, cl. 1, 7)(Ex. 1002, ¶74). The claimed *cap* has a "gripping portion" and a "receiving portion", and "one chamber" having a "single

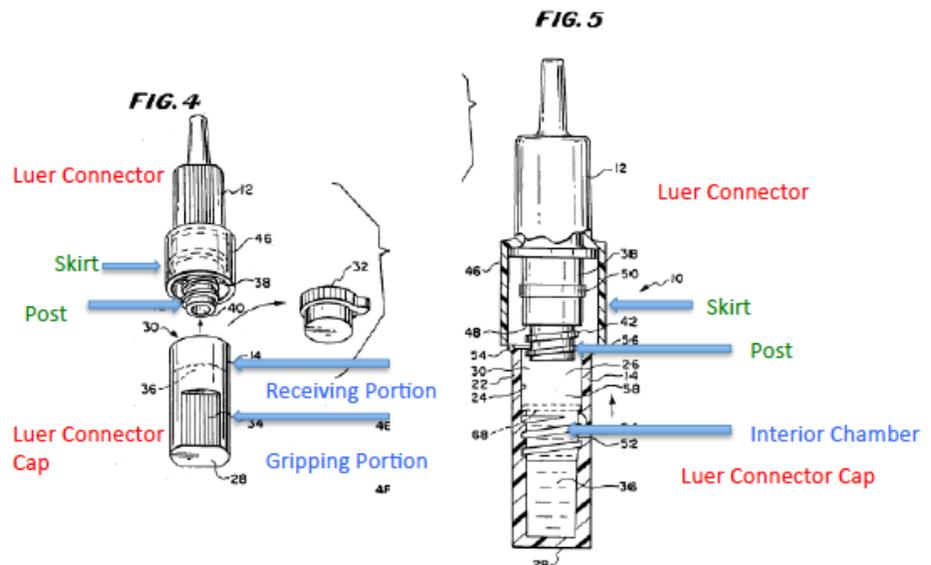
opening," where the chamber extends into the gripping portion of the cap. (Ex.

1001)(Ex. 1002, ¶

75). Figures 4 and 5

of Peluso are shown here, with these parts of the cap identified. (Ex. 1002, ¶ 76).

As described in Peluso's specification:



"As best shown in FIGS. 4 and 5, the protective cap 14 comprises a generally cylindrical body having an external wall surface 22 and an internal wall surface 24. The interior wall surface 24 defines an **interior chamber** 26. The chamber 26 has a closed end 28 and an open end 30. The open end 30 is sealed prior to use by a removable plug 32.

The exterior wall surface 22 of the cap 14 may include a **flattened, roughened portion 34 to facilitate the patient's grip on the cap 14** during its attachment and removal from the connector 12. ...

As best shown in FIGS. 4 and 5, the connector 12 includes a fitment 38 and a **annular skirt 46 which peripherally surrounds the fitment [post] 38**. While the luer fitment 38 may vary, in the illustrated embodiment, the fitment 38 comprises a **female luer having a standard tapered interior bore 40**. In the illustrated embodiment, the fitment 38 also includes a **threaded distal end 42**."

(Ex. 1003, 3:31-4:6)(emph. add.)(Ex. 1002, ¶ 77).

Peluso is unusual because the cap is designed for female luer connectors *with a skirt*. "Skirts" are normally used by male luer-lock connectors. (Ex. 1002, ¶ 78). In a male connector, the skirt has the locking threads on its interior surface. This allows the male "post" with the 6% tapered sides to be thread-free. (*Id.*, ¶ 79). In a female connector, however, the skirt is not necessary, because the male post fits *into* the female receptacle. (*Id.*). Thus, the locking threads in a female connector can be placed on the *outside* of the receptacle. Peluso diverges from this prior art

by providing its female connector with a skirt typically used by male connectors.

(*Id.*, ¶ 80). Peluso is thus more like the male luer connector recited in the claims of the '308 patent than other caps for female luer connectors. (*Id.*, ¶ 81).

Peluso also discloses a cap where the exterior of the cap "fits within" the skirt of the female luer connector, similarly to the cap of the '308 patent "wherein an

FIG. 7

exterior surface of the receiving portion near the opening of the chamber fits within the skirt of the male luer-lock connector when the post is received into the single opening of the chamber". (Ex. 1001, cl. 1, 7)(Ex. 1002, ¶ 82).

This is seen in Figure 7 of Peluso, left, where the portion of the cap between the skirt and the post is highlighted in blue. (*Id.*).

The gripping portion of Peluso also extends the cap body beyond the skirt of the female luer connector when the cap and connector are attached to one another, similarly to how the '308 patent's cap "extends the cap body longitudinally [and distally] beyond the skirt of the male luer-lock connector when the post is received into the chamber". (Ex. 1001, cl. 1, 7)(Ex. 1002, ¶ 83). The gripping portion of the cap body extending beyond the skirt when the cap and connector are attached is highlighted in yellow in Figure 7 above. (*Id.*).

2. Modification to Peluso for Use with a Male Luer Connector

The cap disclosed in Peluso for use with a female luer connector with a skirt and an externally threaded post could be used with a male luer connector with a post and internally threaded skirt by moving the threads from the interior cap wall to the exterior cap wall. (*Id.*, ¶ 84). Peluso discloses a cap with threading on its interior surface that engages with the external threading on the post of the female luer connector. (Ex. 1002, ¶ 85). Peluso calls its post a "fitment":

"As can also be seen in FIG. 5, **the interior cap wall surface 24 includes an interior threaded portion 52. This mates with the threaded distal end 42 of the luer fitment [post] 38.** The inner diameter of the threaded portion 52 is generally equal to the outer diameter of the threaded distal end 42 of the fitment 38."

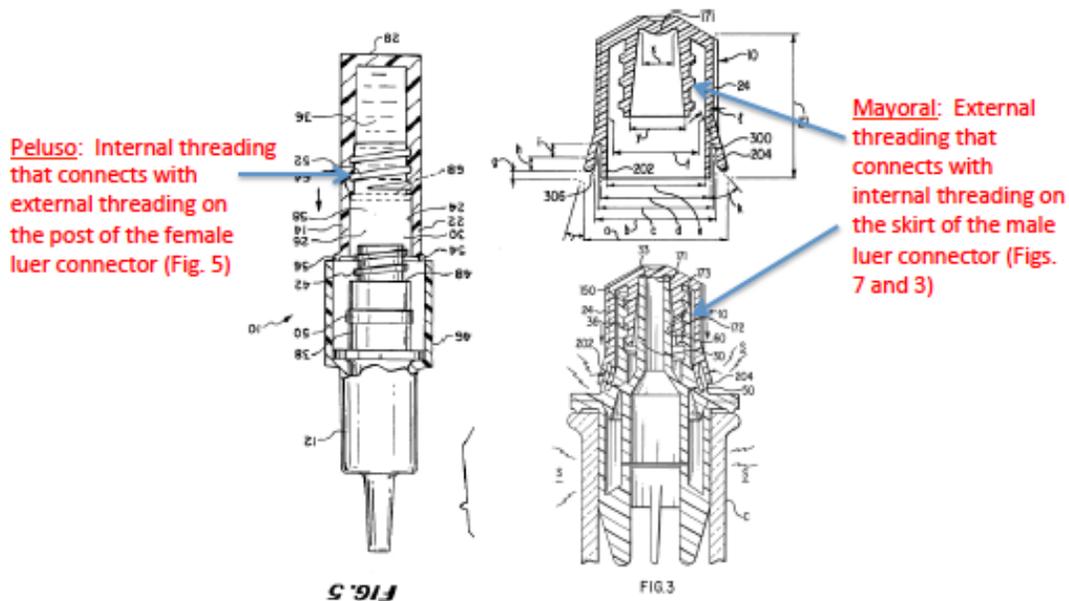
(Ex. 1003, 4:1-4) (Ex. 1002, ¶ 86). With the above modification, the external threads of Peluso would then be positioned inside the skirt of a male connector, which normally has threads on the interior surface of the skirt. (*Id.*, ¶ 134). As soon as Peluso's cap is converted for use with a male connector, it would have been obvious to size the inside diameter of the chamber the same standardized 6% taper found on the post that fits into that taper, and the outside of the chamber to fit within the skirt of the male luer connector. (*Id.*, ¶ 135).

Because the '308 patent claims are directed to caps to be used with *male* luer connectors, this Petition also relies on U.S. Patent No. 6,394,983 ("Mayoral").

(Ex. 1033). Mayoral discloses a *male* luer-lock connector cap "for covering a portion of a fitting or connector on a medical device or other apparatus through which fluid is transferred" that "is especially suitable ... for a Luer lock type of fluid transfer device such as a hypodermic syringe". (*Id.*, 1:5-10)(Ex. 1002, ¶ 87).

The cap in Mayoral is for use with a male luer-lock connector having a skirt with internal threading. (Ex. 1002, ¶ 88). Mayoral calls the skirt a "collar" and the lumen a "nozzle", and explains, "such syringes typically have a 6% [sic] **Luer taper conical nozzle fitting with a surrounding annular collar** that has a double-start, right hand, **internal thread** as shown in ... the International Standard ISO 594-2". (Ex. 1033, 1:15-21)(emph. add.)(Ex. 1002, ¶ 88).

The cap of Mayoral is shown in the below diagram in Figures 3 and 7, right. (Ex. 1033, Fig. 7)(Ex. 1002, ¶ 89). Figure 5 of Peluso, left, is inverted in this diagram to be in the same direction as Mayoral. (Ex. 1002, ¶ 89). As can be seen here, if the threads of Peluso were moved to the external wall of the cap, the cap of Peluso could be used with a male luer connector, like that shown in Mayoral. (*Id.*, ¶ 90). The reasons why one of skill in the art would have been motivated to make this modification are discussed in Ground 1, below. *See* Section III.B.



D. Recesses

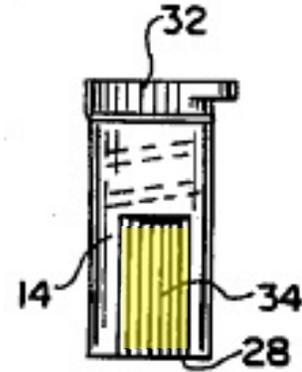
As discussed above, during prosecution Applicants attempted to distinguish the invention over the prior art based on the claimed recesses, as amended to overcome Peluso. *See* Section III.B.2.

1. Recesses of Claim 1 – "Varied Monotonically"

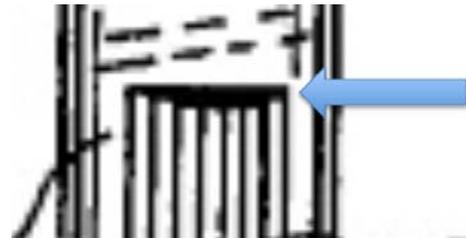
Claim 1 was amended to state that the depth of the recesses "varied monotonically" along their length. (Ex. 1014, p.7). As explained below, the claim term "varied monotonically" is properly construed as "varying in such a way that it either: (i) decreases or stays the same and never increases, or (ii) increases or stays the same and never decreases." *See* Section II.C.

Recesses that "vary monotonically" are disclosed in both Peluso and Mayoral. (Ex. 1002, ¶ 91). Applicants for the '308 patent admitted during prosecution that

Peluso discloses a gripping portion having "recesses". (Ex. 1013, p. 8)("Peluso describes caps having a recess..."). Peluso's recesses are seen here, in the cap portion of Figure 3 of the patent, and specifically the gripping portion [34] highlighted here. There is one recess on each side of the cap body. (Ex. 1002, ¶ 92).



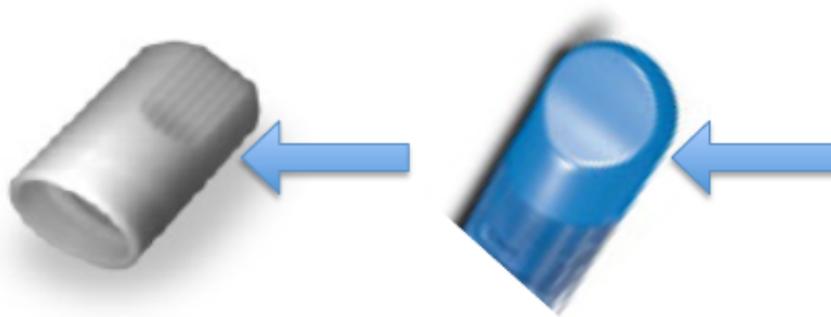
Applicants' assertion during prosecution that Peluso's recesses were different from those claimed in the patent, because Peluso's recess "forms a sharp 90° angle at the juncture of the receiving portion and the gripping portion", was not correct. (Ex. 1013, p. 8) (Ex. 1002, ¶93). To the contrary, one of skill in the art would have recognized that the recesses in Peluso would have extended on a gradual radius or ramp, as indicated by the half-moon shape in the expanded portion of Figure 3 here. (*Id.*, ¶ 94).



The angled change in the depth of the recesses is also seen in the commercial embodiment of Peluso, the Baxter MiniCap, which was sold before the earliest possible priority date of the '308 patent. (Exs. 1035, p. 8, and 1034, p. 11)(Ex. 1002, ¶ 95). As seen below, both the Baxter MiniCap (left), and Patent Owner's Dual Cap product that is claimed to embody the claims of the '308 patent (right), disclose the same angled recesses. (Exs. 1035 and 1031)(Ex. 1002, ¶ 96).

Peluso's Baxter MiniCap

Patent Owner's DualCap



Mayoral also discloses "recesses" on its gripping portion. (Ex. 1002, ¶ 97). The gripping portion of Mayoral is found around the exterior surface of the cap, which Mayoral calls the "depending skirt", seen at [24] in Figure 7 below. (Ex. 1033)(Ex. 1002, ¶ 98). Mayoral recesses are found between "ribs" that surround the depending skirt. (Ex. 1002, ¶99). Mayoral's specification explains:

"[t]he cap includes a domed top wall 20 and a depending skirt 24. **On an outside of the depending skirt 24 are arranged a plurality of ribs 28 extending parallel to an axis of the skirt and providing a frictional gripping surface for removing and installing the cap 10.** The ribs 28 extend in a spaced apart fashion around an outer circumference of the skirt 24."

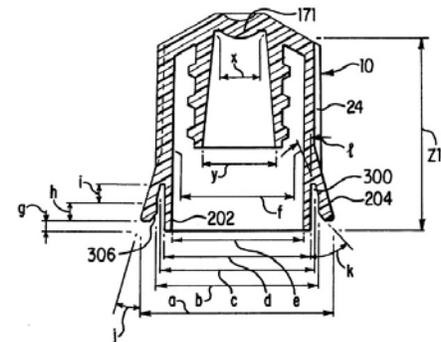


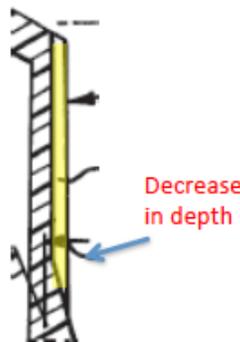
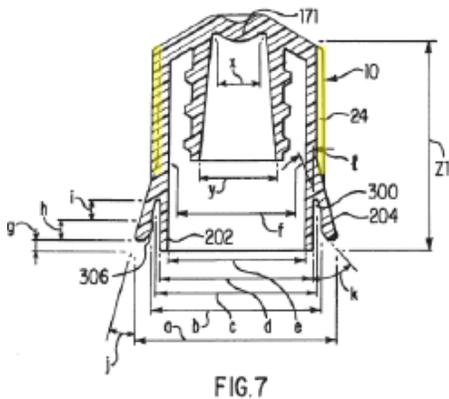
FIG. 7

(Ex. 1033, 4:42-47)(emph. add.)(Ex. 1002, ¶ 99). While one of ordinary skill in the art would understand the term "ribs" as referring to raised portions created by adding material during the design process, Mayoral's "ribs" are created by

removing material, and are thus consistent with Petitioner's construction of the claim term "recesses" in the related litigation, as discussed in Section II.D below.

(Ex. 1002, ¶ 99).

The depth of the recesses of Mayoral "varies monotonically," as in claim 1 of



the '308 patent, decreasing or staying the same along their length, without increasing. (Ex. 1002, ¶ 101). This can be seen in Figure 7, above, with the

recess highlighted in yellow. (*Id.*). An expanded view is also shown. In these figures, [10] refers to the cap, and [24] to the depending skirt. (Ex. 1002, ¶ 101).

The slope of the recesses of both Peluso and Mayoral would have been obvious to one of skill in the art also based on an understanding of the manufacturing process of the caps. (*Id.*, ¶ 102). The caps are injection molded parts, and it is desired, if not necessary, to have a sloped design, rather than a 90° angle, for the ejection of the parts from the mold. (*Id.*, ¶ 103)(Ex. 1036, p. 2). Further, it was well known that a gradual slope was preferable in the manufacture of molded parts, for reasons including decreasing stress concentrations. (Ex. 1002, ¶ 104)(*See, e.g.*, Ex. 1036, p. 2).

2. Recesses of Claim 7 – Gradually Increasing Wall Thickness

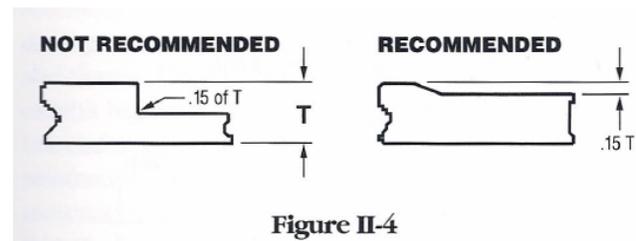
During prosecution Claim 7 was amended to state "the gripping portion compris[es] at least one recess having a bottom, the cap body having a cross sectional thickness at the bottom of the recess gradually increasing from a distal-most end of the cap body and towards the receiving portion". (Ex. 1001, claim 7). As explained below, the claim term "cap body having a cross sectional thickness" is properly construed as "cap body having a cross sectional *wall* thickness." See Section II.E.

It would have been obvious to one of skill in the art at the time of the invention of the '308 patent that any change in wall thickness of an injection molded part, like the claimed luer caps, should be gradual. (Ex. 1002, ¶ 105). This is also

discussed in the 1996 Design

Considerations cited above, where it is

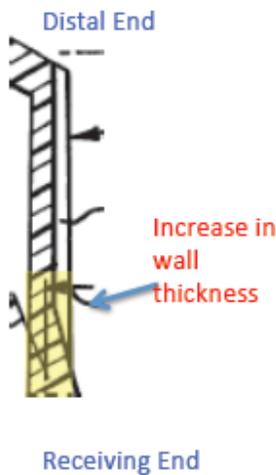
explained that "[f]or non-uniform



walls, the change in thickness should not exceed 15% of the nominal wall (see Figure II-4) and should transition gradually". (*Id.*, ¶ 106)(Ex. 1036, p. 2).

Mayoral discloses a male luer connector cap where the cap body has a cross sectional wall thickness at the bottom of the recess gradually increasing from a distal-most end of the cap body and towards the receiving portion. (Ex. 1002, ¶

107). This is seen in the expanded image of from Figure 7, here, with the increase

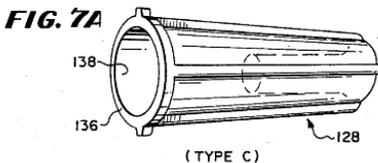


in the wall thickness shown in the cross sectional view with diagonal lines. (*Id.*, ¶ 108)(Ex. 1033). As can also be seen here, the gradual increase in wall thickness occurs at the bottom of the recess and toward the receiving end of the cap, as in claim 7 (and corresponding to the sloped decrease in depth of the recess discussed above). (Ex. 1002, ¶ 109).

E. Crowded Field of Gripping Features for Male Luer-Connector Caps

At time of the invention of the '308 patent—at the very earliest 2007—there were numerous other caps for male luer-lock connectors, both patented and commercially available. (*Id.*, ¶ 110). These known caps disclosed various gripping features, all having the same purpose of assisting the user in applying and removing the caps. (*Id.*, ¶ 111). One of skill in the art would have recognized that changing the gripping features would have had an insignificant effect on the cap's ability to connect to a luer connector. (*Id.*, ¶ 112).

One example of a protective luer connector cap is U.S. Patent No. 4,597,758, to



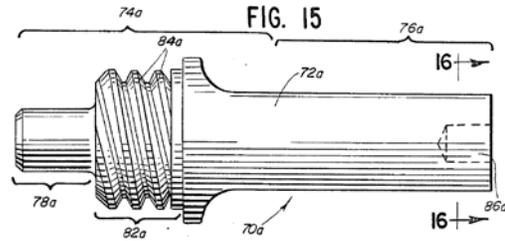
Aalto, filed in **1982**. (Ex. 1007). Aalto discloses a

cap for use with a male luer-lock connector that has an internally threaded skirt. (Ex. 1007)(Ex. 1002, ¶ 113). Also disclosed in Aalto

is an earlier, prior art protective cap, shown in Figure 7A, also with a tapered

interior column for accepting a male luer connector, and lugs for connecting with the skirt of the male luer connector. (Ex. 1007, 6:43-45)(Ex. 1002, ¶ 113). The gripping features can be seen at [128]. (Ex. 1007)(Ex. 1002, ¶ 113).

U.S. Patent No. 4,778,447 ("Velde") was filed in **1983**. (Ex. 1022). Velde discloses a medical connector cap, with external threads at the receiving portion end of the cap, seen in Figure 15 here. (*Id.*)(Ex.



1002, ¶ 114). The gripping features of Velde are seen at 70a. (Ex. 1002, ¶ 114). While Velde does not specify luer connectors, it does disclose a cap for medical connectors, including medical tubing. (Ex. 1022)(Ex. 1002, ¶ 114).

In **1994**, Baxa Corporation introduced its "red tip" Luer-Lock Tip Cap, shown below. (Exs. 1032, p. 19, 1038, 1039)(Ex. 1002, ¶ 115). The lugs of the Baxa cap



are on the external portion of the cap, near the opening for the luer connector, and thus configured to fit



with a male luer connector. (Ex. 1032, p. 19)(Ex. 1002, ¶ 115). The gripping portion of the red tip caps is shown right. (Ex. 1002, ¶ 115).

Baxa Corporation is also the assignee of U.S. Patent No. 7,247,153, to Guala, "Cannula with Protection Cap for Medical Infusion Lines and the Like", filed July

2003. (Ex. 1015). The cap is shown in Figure 1 of the patent, right. (*Id.*)(Ex. 1002, ¶ 116). The gripping features disclosed in Guala are seen at [10] here. (Ex. 1002, ¶ 116).

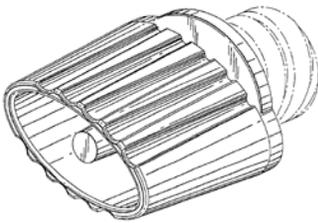
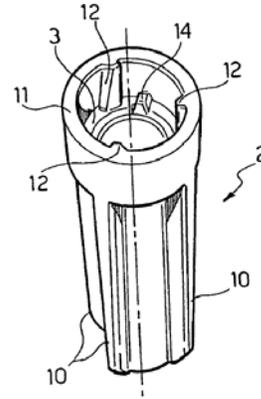
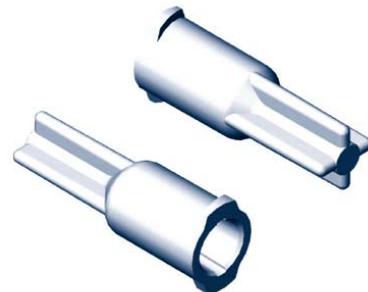


FIG.1

Also in **1994**, U.S. Patent No. D493,526 ("Hwang") was filed. (Ex. 1005). Figure 1 of Hwang, "Syringe Tip Cap", below, shows a receiving portion with external threading, and a gripping portion into which a post or lumen would extend. (*Id.*)(Ex. 1002, ¶ 117). While Hwang does not specify use with a luer connector, the taper of the interior portion and the threaded receiving portion both indicate that the cap could be used with a male luer-lock connector with a post and threaded skirt. (Ex. 1002, ¶ 117).

The white protective luer caps shown here were sold by Kipp Group at least as early as January **1995**. (Ex. 1016)(Ex. 1002, ¶ 118).

Kipp was the assignee of U.S. Patent No. 5,620,427 to Werschmidt, "Luer-Lock System" filed April **1995**, which discloses a male luer connector with tapered engagement surfaces. (Ex. 1020)(Ex. 1002,



¶ 118). The caps shown here are the commercial embodiment of the Werschmidt

patent. (Ex. 1002, ¶ 118).

U.S. Patent No. 7,316,669 ("Ranalletta"), filed in 2002, discloses a "protective cap for medical male luer fittings." (Ex. 1004)(Ex. 1002, ¶ 119). As seen here in Figure 3A of the patent, the cap is for use

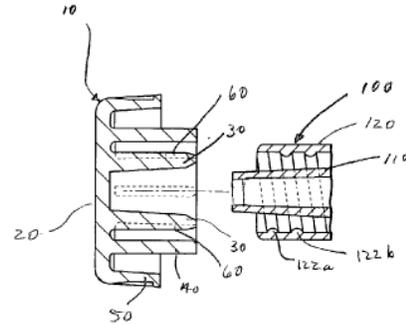
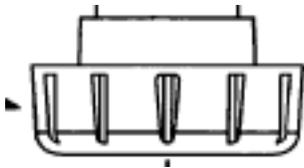


FIG.3A

with a male luer connector that has an internally threaded skirt [100]. (Ex. 1002, ¶



119). The gripping features of Ranalletta, are also shown in the cap portion of Figure 2 of the patent, left. (*Id.*).

II. CLAIM CONSTRUCTION

A. Overview of the challenged claims

Claims 1 and 7 are independent claims, and claims 2, 3, 4, 5 and 6 depend from claim 1.

B. Applicable legal standard for claim construction

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

"[T]he PTO must give claims their broadest reasonable construction consistent with the specification. [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 claim construction standard used in district courts differs from the standard applied before the USPTO. Claim constructions herein are directed to the USPTO standard, and are not necessarily the constructions that the Petitioner believes would be adopted in court. The Petitioner does not acquiesce or admit to the constructions reflected herein for any purpose outside of this proceeding.

C. Claim 1 — "varied monotonically"

The term "varied monotonically" is used in claim 1. This term does not appear in the specification of the '308 patent. In the related litigation, the parties agreed that this term should be construed as "varying in such a way that it either: (i) decreases or stays the same and never increases, or (ii) increases or stays the same and never decreases." (Ex. 1024). This is consistent with the commonly accepted meaning of the term "monotonically," as *entirely* increasing or decreasing. (*See* Ex. 1018, p. 3). Accordingly, this is also the proper construction of this term herein.

D. Claims 1 and 7 — "recess"

The construction of the term "recess", which is used in claims 1 and 7, is disputed in the related litigation. Petitioner has asserted that the appropriate construction of the term is "an area where material has been removed to create a hollow", while Patent Owner has asserted that a recess can be made by either

adding or removing material. (Ex. 1025). Petitioner's construction is supported by the Applicants' amendments to the patent specification in adding the term "recesses" during prosecution, and also the understanding of one of ordinary skill in the art of the term "recesses", and the meaning set forth in multiple technical dictionaries. (Exs. 1027, p. 2 and 1028, p. 3). Without full briefing on claim construction, on Patent Owner's motion for preliminary injunction, however, the court preliminarily agreed with the Patent Owner's construction. (Ex. 1025).

Because the prior art relied on by Petitioner in the Grounds herein discloses recesses that are made by removing material during the design process (Ex. 1002, ¶¶ 99, 183, 189), which would fall within either proposed construction of the claim term, it is not necessary to construe this claim term for purposes of this Petition.

E. Claim 7 — "cap body having a cross sectional thickness"

The term "cap body having a cross sectional thickness" is used in claim 7, in the following context:

"the gripping portion comprising at least one recess having a bottom, the **cap body having a cross sectional thickness** at the bottom of the recess gradually increasing from a distal-most end of the cap body and towards the receiving portion"

(Ex. 1001, claim 7)(emph. add.). The term "cap body having a cross sectional thickness" does not appear in the specification of the '308 patent. (Ex. 1001).

As a preliminary matter, and as discussed above, during prosecution Applicants

amended the language of claim 7 (then claim 11), to omit the language "sidewall having a cross sectional **distance** at the bottom of the recess intersecting with the longitudinal axis smaller than an outer diameter of the sidewall", and replaced that language with "body of the cap having a cross sectional **thickness** at the bottom of the recess gradually increasing from a location within the gripping portion and towards the receiving portion". (Ex. 1013, p. 6). *See* Section I.B.2.

One of ordinary skill in the art would understand that while the term "distance" might relate to the diameter across the cap body, the term "thickness" would refer to the wall thickness of the cap. (Ex. 1002, ¶ 123).

Following this amendment, Applicants attempted to distinguish their invention over Peluso and Chin-Loy, stating:

"Applicants submit that the claims as amended herein are patentable over the cited art because the combination of references fails to teach or suggest ... a cap body having "**a cross sectional thickness at the bottom of the recess** [which] gradually increas[es] from a location within the gripping portion and towards the receiving portion" as recited in [issued claim 7].

Peluso fails to teach or suggest the presently claimed invention.

Peluso describes caps having a recess which forms a sharp 90° angle at the juncture of the receiving portion and the gripping portion. **Also, the caps of Peluso have a constant thickness in the gripping portion. In contrast the present claims are directed to caps having**

either a recess with a longitudinally graded depth or **caps with a decreasing wall thickness in the bottom of the recess.**"

(Ex. 1013, p. 8)(emph. add.).

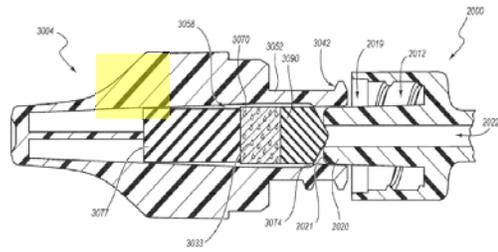
A gradual thickening of the cap wall is shown in the cross sectional view of the claimed cap, shown in Figure 66A of the '308

patent, here. (Ex. 1001, Fig. 66A)(Ex. 1002,

¶ 124) . The recess is shown at 3004 (and

indicated with the blue arrow), and it can be

seen that the thickness of the wall of the cap body is gradually thicker from the bottom of the recess toward the receiving end of the cap. (Ex. 1002, ¶ 125).



As see in Fig. 66A, the gradual increase of the wall thickness does not encompass the entire length of the cap body. (Ex. 1001)(Ex. 1002, ¶ 126). The increase stops near the receiving portion. Thus, the claim language "from a distal-most end of the cap body and towards the receiving portion" implies only a *direction* increasing wall thickness. The phrase does not, however, imply exactly where the increase must start or stop. (*Id.*, ¶ 127).

Accordingly, the proper construction of the claim term "cap body having a cross sectional thickness" is "cap body having a cross sectional *wall* thickness".

III. DETAILED EXPLANATION OF REASONS FOR UNPATENTABILITY

Ground 1. Claims 1, 2, 5, 6 and 7 are unpatentable under 35 U.S.C. § 103(a) over Peluso in view of Mayoral.

Claims 1, 2, 5, 6 and 7 are invalid under 35 U.S.C. § 103(a) over U.S. Patent No. 4,624,664 ("Peluso")(Ex. 1003) in view of U.S. Patent No. 6,394,983 ("Mayoral")(Ex. 1033). Peluso is prior art under § 102(b) as the patent issued in 1986. (Ex. 1003)(Ex. 1002, ¶ 129). Mayoral is prior art under § 102(b) as the patent issued in 2002. (Ex. 1033)(Ex. 1002, ¶ 130). The level of skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 23-30, 131).

A. Peluso

An explanation of Peluso is provided in the technical introduction, above. In summary, as set forth in the claim charts below, Peluso discloses: (a) a cap for a luer connector; (b) a receiving portion and a gripping portion, where the receiving portion has a single chamber with a single opening; (c) a chamber that extends into the gripping portion of the cap; (d) a gripping portion that extends the cap beyond the skirt of the luer connector when the cap is attached to the connector; (e) recesses along the length of the gripping portion; and (f) an antiseptic within the cap for disinfecting the luer connector. *See* Section I.C. (Ex. 1002, ¶ 132).

B. Motivation to Combine Peluso with the Male Cap of Mayoral

While Peluso does not expressly disclose a cap for use with a *male* luer

connector, it would have been obvious to make a Peluso cap for a male connector. (Ex. 1002, ¶ 133). Because Peluso's female connector already has a "skirt" that is typical of male connectors, the only required change for Peluso's cap would be the provision of threads on the exterior surface of the receiving portion of the cap. (*Id.*, ¶ 134). The external threads of Peluso would then be positioned inside the skirt of a male connector, which normally has threads on the interior surface of the skirt. (*Id.*). It would have been obvious to size the inside diameter of the chamber the same standardized 6% taper found on the post that fits into that taper, and the outside of the chamber to fit within the skirt of the male luer connector. (*Id.*, ¶ 135).

A cap for a male connector with threads on the outside of the receiving portion is found in Mayoral. (Ex. 1033, 1:8-10)(emph. add.)(Ex. 1002, ¶ 136). As discussed above and set forth in the claim charts below, Mayoral also discloses a number of other claim elements of the '308 patent, including: (a) a cap for a male luer connector having a post with a lumen, and an external skirt with internal threading; (b) a gripping portion and a receiving portion; (c) protrusions (threads) that engage with corresponding threads on the male luer connector; (d) recesses that extend longitudinally and distally along the length of the cap; and (e) recesses that "vary monotonically" and create a variable wall thickness. *See* Section I.C.2. (Ex. 1002, ¶ 137).

Male connectors and caps for male connectors were also well-known, as taught in the "deadender" cap of DeCaprio, and in the other connectors discussed in Section I.E and Mayoral. (Ex. 1002, ¶ 138).

It would have been obvious to one of skill in the art to modify the female luer-lock cap of Peluso with Mayoral, to correspond to a male luer-lock connector. (Ex. 1002, ¶ 139). When luer connectors are disconnected from one another, every female connector has a corresponding male connector, and both are left open when disconnected. Thus, both female and male luer connectors would share the same need for a cap. (*Id.*, ¶ 140). Peluso states this:

"In use, the protective cap 14 is removed to expose the connector 12, when desired. This is shown in Figure 2. **The connector 12 can then be conveniently attached to a suitable mating connector 18.**"

(Ex. 1003, 3:3-6) (emph. add.)(Ex. 1002, ¶ 71). The "suitable mating connector" would be a corresponding *male* luer connector. (Ex. 1002, ¶ 71). The '308 patent admits that the benefit of the cap to both the male and female connectors is similar: "[w]hen the medical connectors are separated from each other, there are two connectors that **each can benefit** from being covered by a cap". (Ex. 1001, 5:60-62)(emph. add.)(Ex. 1002, ¶ 141).

Changing the female cap to its well-known complementary male form would have been obvious. *See, e.g., Ivera Medical Corp. v. Excelsior*, No. IPR2014-

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01124, Institution of *Inter Partes* Review (Patent Trial and Appeal Board Jan. 21, 2015)(granting review of related U.S. Patent No. 8,647,326, wherein Petitioner asserted that it would have been obvious to combine the features of the male luer connector cap of Mayoral with a female disinfecting cap (Hoang)) (Ex. 1040, pp. 22-25); *see also Ex parte Heinz*, 2006 Pat. App. LEXIS 3428, *20 (BPAI 2006)("If a person of ordinary skill in the art is presented with a female connector on an automotive wiring harness, they will instantly recognize that a male connector is required to connect with the female connector and vice-versa."); *see also* MPEP § 2144.04.VI.A (mere reversal of parts is obvious).

Moreover, there is no critical difference between a female and a male cap. The '308 patent also admits that the female and male embodiments are equivalent:

"any suitable feature of the illustrative embodiments ... which are described with respect to a female-type cap similar to the cap 102, may be applied to or incorporated within a male-type cap, similar to the cap 104."

(Ex. 1001, 11:7-11, citing U.S. Appl. Pub. No. 2009/0062766)(emph. add.)(Ex. 1002, ¶ 142).

It is also worth noting that during prosecution of the application for the '308 patent, the Examiner explained that it would have been obvious to switch the positioning of the interlocking threads of Peluso, in view of Chin-Loy. (Ex. 1012).

The Examiner explained,

"Peluso et al. disclose protrusions 52 (Fig 6) on an interior surface to engage with threads on the post of the male luer-lock connector (as seen in Fig 6) but do not alternatively disclose protrusions on an exterior surface to engage with threads on a skirt of such a connector. Chin-Loy et al., however, teach a cap 10 (Fig 1) for covering a male luer-lock connector 44 (Fig 4) of the type including a post 46 (Fig 4) and an internally helically threaded skirt 48 (Fig 4) wherein the cap has an exterior surface 26 (Fig 1) with protrusions 58,60 (Fig 1) shaped to engage helical threads of the skirt (Col 4, Lines 23-30 and 50-59) on a proximal end thereof (as seen in Fig 1) for the purpose of ensuring attachability to dialysate and blood ports in various countries and regions in the world (Col 3, Lines 29-34 and 47-50). **Therefore, it would have been obvious to modify Peluso et al. to include protrusions on the exterior surface instead of the interior surface of the cap body, as taught by Chin-Loy et al.,** for the purpose of ensuring attachability to dialysate and blood ports in various countries and regions in the world (Col 3, Lines 29-34 and 47-50)."

(Ex. 1012, p. 6)(emph. add.).

For the same reasons that it would have been obvious to combine the teachings of Peluso with Chin-Loy, it would have been obvious to combine Peluso with Mayoral. (Ex. 1002, ¶ 143). As discussed by the Examiner in reference to Chin-Loy, there is additional motivation to combine based on the already present similarity between Peluso's female luer connector with surrounding skirt and a

standard male connector. (*Id.*).

One of skill in the art would have also been motivated to modify Peluso to work with a male luer connector (as in Mayoral) that would meet the ISO 594-2 Standards (1998), which standardized the locking mechanism for luer connectors. (Ex. 1033, 1:18-25, specifically referencing ISO 594-2 standards)(Ex. 1002, ¶ 145). *See e.g., Mobotix Corp. v. e-Watch, Inc.*, No. IPR2013-00337, Final Written Decision (Patent Trial and Appeal Board Oct. 10, 2014)(finding that one of ordinary skill would have understood that the technology at issue could be modified to use the accepted standard); *Ex parte Call*, Appeal 2009-008728, 2010 Pat. App. LEXIS 16880 at *12 (Patent Trial and Appeal Board Aug. 26, 2010)("we disagree with Appellant that it would not have been obvious to one of ordinary skill in the art to have ensured that the [prior art] was in a format that conformed to an industry standard"). In particular, one of skill in the art would have been motivated to do so to benefit from the use with other medical implements under the same ISO 594-2 Standards. (Ex. 1002, ¶ 145).

The combination of Peluso or Mayoral represents the incorporation of a known disinfecting cap for a female luer connector (Peluso) with the known thread arrangement in a protective cap for medical male luer connectors (Mayoral), that would commonly be connected to other medical implements with a standard luer connector, without change in the function of the cap, and without unpredictable

results. (Ex. 1002, ¶ 153). *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1739-42 (2007).

C. Recesses of Peluso and Mayoral

As explained above, and in the claim charts below, Peluso and Mayoral both disclose recesses that meet the limitations of claim 1 ("at least one recess having a length and depth, wherein the depth varied monotonically along the length of the recess"), and Mayoral discloses a cap body with recesses that meets the limitations of claim 7 ("and the gripping portion comprising at least one recess having a bottom, the cap body having a cross sectional thickness at the bottom of the recess gradually increasing from a distal-most end of the cap body and towards the receiving portion;"). *See* Section I.D.

For claim 1, it would have been obvious to use either the recesses of Peluso, or those of Mayoral, both of which "vary monotonically". (Ex. 1002, ¶ 147). Peluso and Mayoral both disclose recesses that extend longitudinally and distally along the length of the gripping portion of the cap. Both inventions are caps for medical connectors, and the gripping features would be interchangeable. (*Id.*, ¶ 148).

At the time of the invention of the '308 patent, the field of caps for male luer connectors having an internally threaded skirt was crowded; some examples are discussed in the Technology Background above. *See* Section I.E. (*Id.*, ¶ 149).

The known caps disclose numerous different gripping features, all of which serve

the same purposes of assisting a user with applying and removing the cap in relation to the luer connector. (*Id.*).

Indeed, there is no significant interaction between the precise shape of the gripping features and the function of the cap to cover a connector; in other words, the gripping features from one cap can be used interchangeably on another. (*Id.*, ¶ 150). The use of the gripping features disclosed for the male luer cap of Mayoral on the cap of Peluso in such a crowded field of male luer connector caps with various gripping features, with no change to the operation of the cap, would have been obvious to one of skill in the art. *See Universal Athletic Sales Co. v. American Gym, Recreational & Athletic Equip. Corp.*, 397 F. Supp. 1063, 1070 (W.D. Pa. 1975)("this simplistic device in a crowded art is obvious and not patentable"); *De Burgh v. Kindel Furniture Co.*, 125 F. Supp. 468, 480 (D. Mich. 1954)("combinations for improvements in a crowded art should be closely scrutinized. This patent combines an aggregation of old elements and parts from the prior art and from conveyers in prior use, with some minor unpatentable modifications or variations in construction and function. These minor improvements in construction and function do not constitute invention.").

The equivalence of various gripping features is admitted in the '308 patent. The patent states that differences between various forms of gripping features are not critical, and do not lead to surprising results. (Ex. 1001)(Ex. 1002, ¶ 151). The

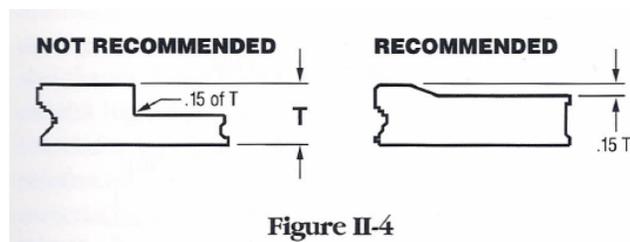
'308 patent specification acknowledges that there are numerous gripping features that could be incorporated into the patented invention:

"The outer surface [of the gripping portion] can be smooth, as shown, which can enhance comfort to a patient if the cap 1002 contacts the patient when coupled with a medical connector. **In other embodiments can include gripping features, which can ... aid in rotating the cap 1002 relative to a medical connector. Such gripping features can include, for example, ridges, grooves, and/or [sic] protrusions similar to the ridges 105, grooves 107, and protrusions 108** described above and/or an elastomeric or other coating or layer having a relatively high coefficient of friction."

(Ex. 1001, 11:48-59)(emph. add.)(Ex. 1002, ¶ 151).

For claim 7, it would have been obvious to one of skill in the art that the thickness of the cap wall would increase from the bottom of the recess, toward the receiving end of the cap, as seen in Mayoral. (Ex. 1002, ¶ 152). It further would have been obvious to one of skill in the art at the time of the invention of the '308 patent that any change in wall thickness of an injection molded part, like the claimed luer caps, should be gradual, as discussed in the 1996 Design

Considerations cited above, with Figure II-4 shown here. (Ex. 1002, ¶¶ 105, 106)(Ex. 1036, p. 2).

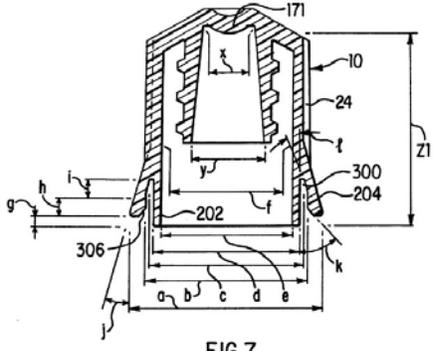


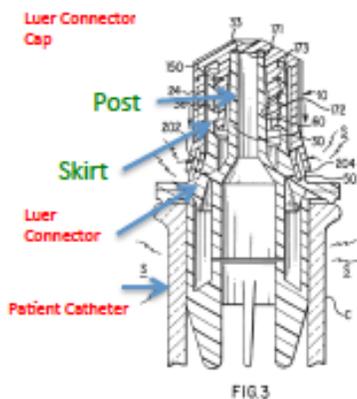
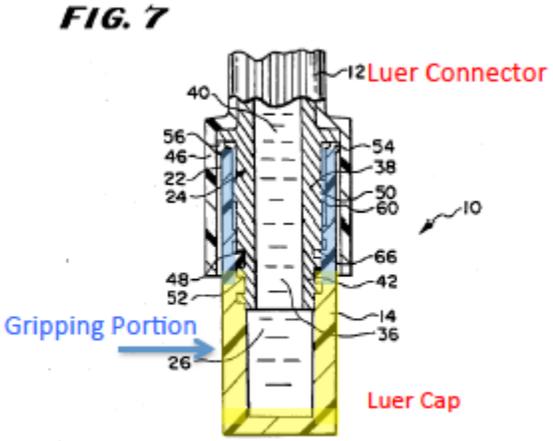
The combination of Peluso or Mayoral represents the incorporation of a known

disinfecting cap for a female luer connector (Peluso) with known gripping features (Peluso and Mayoral), as motivated by known and understood design considerations, without change in the function of the cap, and without unpredictable results. (Ex. 1002, ¶ 153). *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, ¶ 154). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

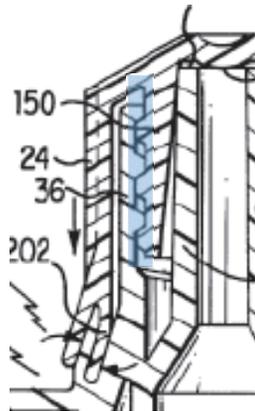
Peluso in view of Mayoral teaches claims 1, 2, 5, 6 and 7 of the '308 patent, as shown in the following claim chart. Petitioner relies on the combination of Peluso with Mayoral for the characteristics of a cap for a male connector, and gripping features that meet the claim language. As explained above, Mayoral shares other similarities with Peluso, and meets additional claim limitations.

<p>1[a]. A male disinfecting cap for disinfecting a 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:</p>	<p>Peluso discloses a disinfecting cap, describing a cap in which there is a "liquid antiseptic". (Ex. 1002, ¶ 155). The specification explains:</p> <p>"a closure system includes a connector and protective cap in which there is a liquid antiseptic". (Ex. 1003, Abstract)(emph. add.)(Ex. 1002, ¶ 155).</p> <p>"A liquid antiseptic 36 is carried within the cap chamber 26 to provide an active bacteriocidal effect when the cap 14 is attached to the connector 12." (Ex. 1003, 3:42-44)(emph. add.)(Ex.1002, ¶ 155)</p>
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	<p>"On an outside of the depending skirt 24 are arranged a plurality of ribs 28 extending parallel to an axis of the skirt and providing a frictional gripping surface for removing and installing the cap 10."</p>  <p>FIG. 7</p> <p>(Ex. 1033, 4:42-47)(emph. add.)(Ex. 1002, ¶ 167).</p>
<p>[c] the receiving portion defining one chamber having a single opening said opening being in the receiving portion,</p>	<p>The "receiving portion" of the cap in Peluso is the end toward the "open end" [30] of the cap, seen in Figure 3 above, and in Figure 5, below. (Ex. 1002, ¶ 168).</p> <p>The receiving portion defines one chamber 26 that has a single opening ("an open end") [30]. The specification explains:</p>

	 <p>Mayoral discloses a receiving portion into which the post of the male luer-lock connector can be received. (Ex. 1002, ¶ 173). Figure 3, here, shows the post in the receiving portion of the cap. (<i>Id.</i>).</p>
<p>[e] wherein an exterior surface of the receiving portion near the opening of the chamber fits within the skirt of the male luer-lock connector when the post is received into the single opening of the chamber,</p>	 <p>Peluso discloses, in Figure 5, shown above, an exterior surface [22] of the receiving portion near the opening of the chamber. (Ex. 1002, ¶ 174). In Figure 7, the cap and connector are attached to one another. As highlighted in blue in this Figure here, the receiving portion of the cap is within the skirt of the connector, between the post and the skirt of the luer connector, when the cap and connector are attached to one another. (Ex. 1002, ¶ 175).</p> <p>The "connector 12 includes a luer fitment 38 and an annular skirt 46 which peripherally surrounds the fitment 38." (<i>Id.</i>)(Ex. 1003, 3:47-49)(emph. add.).</p>
<p>[f] the exterior surface of the receiving portion having protrusions shaped to engage</p>	<p>Peluso shows protrusions (helical threads) in the internal portion of the cap to fit the external threads on the post ("bore") of a female luer-lock connector. These can be seen in Figures 5 and 7, shown above (Ex. 1003)(Ex. 1002, ¶ 177).</p> <p>Mayoral discloses a male luer-lock connector cap with</p>

helical threads of the internally helically threaded skirt;



protrusions (threads) on the **exterior surface of the receiving portion** that engage the helical threads of the internally helically threaded skirt. The engagement is shown in the expanded portion of Figure 3, highlighted here. (Ex. 1002, ¶ 178).

The specification of Mayoral explains how the corresponding threading on the cap "**engages with**" the threading on the luer fitting ("connector"):

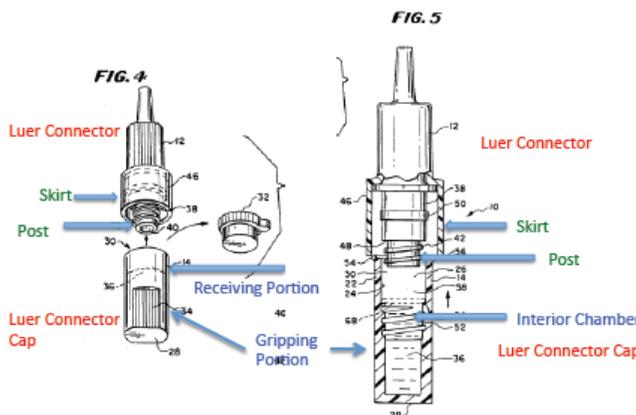
"FIGS. 3 and 3A illustrate the cap 10 completely installed on the fitting 14. **The female thread form 40 is tightly engaged with the male thread form 151 of the cap**". (Ex. 1033, 6:33-35)(emph. added.)(Ex. 1002, ¶ 179).

The corresponding threads of the skirt of the male luer connector are helical, as explained in claim limitation 1[a] above. (Ex. 1033)(Ex. 1002, ¶ 180).

[g] the chamber defining an interior portion extending within the gripping portion of the cap body,

Peluso discloses, in Figure 5, above, a chamber [26] that extends within the gripping portion of the cap body [36]. (Ex. 1002, ¶ 181). The chamber extends the length of the cap body, through the receiving portion and into the gripping portion.

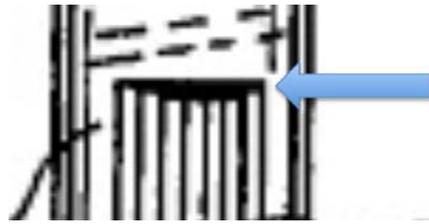
(Ex. 1002, ¶ 182). The chamber, and gripping portion, are shown in Figures 4 and with identifiers added here.



The specification explains:

"As best shown in FIGS. 4 and 5, the protective cap 14 comprises a generally cylindrical body having an

	<p>exterior wall surface 22 and an interior wall surface 24. The interior wall surface 24 defines an interior chamber 26. The chamber 26 has a closed end 28 and an open end 30.” (Ex. 1003, 3:30-35)(emph. add.)(Ex. 1002, ¶ 183).</p>
<p>[h]wherein the gripping portion extends the cap body longitudinally beyond the skirt of the male luer-lock connector when the post is received into the chamber;</p>	<p>The gripping portion in Peluso extends the cap body beyond the skirt of the luer connector when the post is received into the chamber. (Ex. 1002, ¶ 184). This is shown in Figure 7, where it can be seen that when the connector [12] is inserted into and attached to the cap [14], the cap body [14] extends (see highlighted portion in yellow) beyond the skirt [46], with the post in the chamber of the cap. (<i>Id.</i>, ¶ 185).</p> <div data-bbox="857 682 1425 1129" data-label="Image"> </div>
<p>[i] and the gripping portion comprising at least one recess having a length and depth, wherein the depth varied monotonically along the length of the recess; and</p>	<p>Peluso discloses a gripping portion that includes a recess having a length and depth that varies monotonically. (<i>Id.</i>, ¶ 186).</p> <p>The gripping portion of Peluso is discussed and shown in claim limitation 1[b] above. The recess in Peluso, highlighted here, "varies monotonically", as that term is construed above. This is seen in the relevant portion of Figure 3, shown above, where the half-moon shape shows a gradual increase in the recess as it approaches the receiving end of the cap. (<i>Id.</i>, ¶ 187).</p> <p>The half-moon shape in the expanded part of Figure 3 below, shows a gradual radius or ramp. If the recess ended with a sharp 90° angle at the juncture of the receiving portion and the gripping portion, then the half-moon shape would be replaced by a straight line. The view of Figure 3 is straight at</p>



the cap from the side (as surface 28 is not shown), thus the half-moon shape does not represent a wall that is straight down, but rather one that has an angle of greater than 90° degrees to the remainder of the exterior surface. (*Id.* ¶ 188).

Mayoral also discloses a gripping portion that includes a recess having a length and depth, wherein the depth varies monotonically, as that claim term is construed above, along the length of the recess. (*Id.*, ¶ 190).

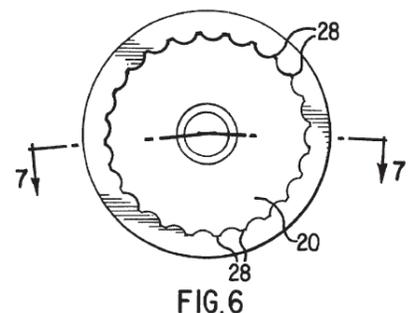
The gripping portion of Mayoral is found around the exterior surface of the cap, which Mayoral calls the "depending skirt", as discussed in claim limitation 1[b] above. (*Id.*, ¶ 191)(Ex. 1033). Mayoral recesses are found between "ribs" that surround the depending skirt. (Ex. 1002, ¶ 191). The patent specification explains:

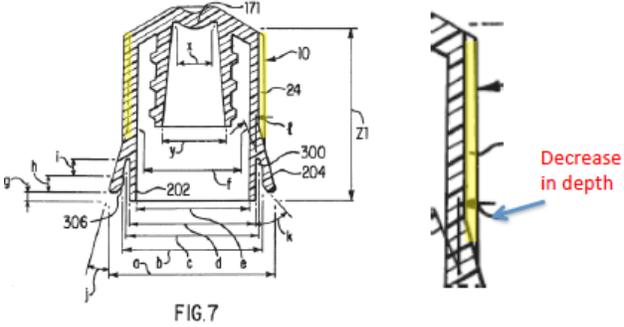
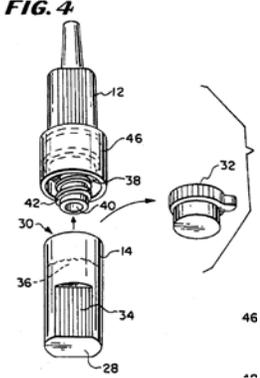
"[t]he cap includes a domed top wall 20 and a depending skirt 24. **On an outside of the depending skirt 24 are arranged a plurality of ribs 28 extending parallel to an axis of the skirt and providing a frictional gripping surface for removing and installing the cap 10.** The ribs 28 extend in a spaced apart fashion around an outer circumference of the skirt 24."

(*Id.*)(Ex. 1033, 4:42-47)(emph. add.).

Mayoral's recesses [28] can be seen in the view from the top of the cap [20], surrounding the cap in Mayoral's Figure 6, here. (Ex. 1033)(Ex. 1002, ¶ 192).

The depth of the recesses of Mayoral "**varies monotonically**," as that term is appropriate construed, as in claim 1 of the '308 patent, decreasing or staying the same along their length,



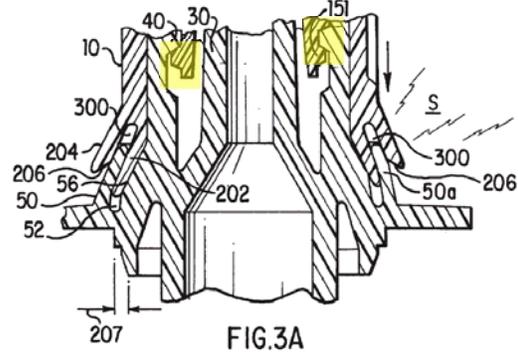
	<p>without increasing. This can be seen in Figure 7, with the recess highlighted in yellow. An expanded view is also shown. In these figures [10] refers to the cap, and [24] to the depending skirt. (Ex. 1002, ¶ 193).</p>  <p>FIG. 7</p> <p>The recess in Mayoral decreases in depth or stays the same, without increasing, along its length, as seen highlighted here in the expanded view of Figure 7. (Ex. 1002, ¶ 194).</p>
<p>an antiseptic agent disposed in the chamber.</p>	<p>Peluso discloses that there is an antiseptic disposed in the chamber of the cap. The specification explains,</p> <p>"a closure system includes a connector and protective cap in which there is a liquid antiseptic". (Ex. 1003, Abstract)(emph. add.).</p> <p>"A liquid antiseptic 36 is carried within the cap chamber 26 to provide an active bacteriocidal effect when the cap 14 is attached to the connector 12." (Ex. 1003, 3:41-45)(emph. add.).</p> <p>The liquid antiseptic is further seen at [36] in Fig. 5, shown above. (Ex. 1002, ¶¶ 196-197).</p>
<p>2. A cap according to claim 1, further comprising a cover disposed over the opening of the chamber.</p>	<p>Peluso discloses a cover [32] disposed over the opening of the chamber, as can be seen in Figures 3, above and 4, here. (Ex. 1002, ¶¶ 198, 200). Peluso calls its cover a "plug", and explains:</p> <p>"As shown in Fig. 3, the open end 30 is sealed prior to use by a removable plug 32." (Ex. 1003, 3:35-36)(emph. add.)(Ex. 1002, ¶ 199).</p>  <p>FIG. 4</p>

<p>5. A cap according to claim 1, further comprising a taper extending along a portion of a wall of the chamber.</p>	<p>Mayoral also discloses a taper extends along the wall of the chamber, as can be seen in Figure 7, where in the taper can be seen in the highlighted portion in claim 1 above. (Ex. 1002, ¶ 201). The specification of Mayoral confirms that the nozzle (post or lumen) of a conventional male luer fitting that corresponds to the chamber of the cap is tapered, describing a cap for a syringe "typically have a 6% [sic] Luer taper conical nozzle fitting with a surrounding annular collar that has a double-start, right hand, internal thread as shown in ... the International Standard ISO 594-2". (Ex. 1033, 1:18-21)(emph. add.)(Ex. 1002, ¶ 202).</p>
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Regarding Claim 5, as soon as Peluso's cap is converted for use with a male connector, it would have been obvious to use the same standardized 6% taper on the inside surface of Peluso that is found on the post that fits into that taper. (Ex. 1002, ¶ 203).

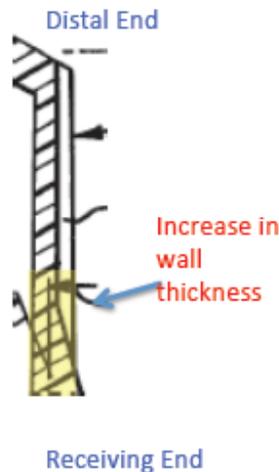
<p>6. A cap according to claim 5, wherein the wall of the chamber is configured to engage with at least a portion of the post of the male luer-lock connector.</p>	<p>Peluso discloses that the internal wall of the chamber engages with the post of a female luer connector. This is explained in the specification in reference to Fig. 5 of the patent, as the "threaded portion" on the "interior cap wall", "mat[ing] with the threaded portion of the luer connector". (Ex. 1002, ¶ 204). The specification states:</p> <p>"As can also be seen in FIG. 5, the interior cap wall surface 24 includes an interior threaded portion 52. This threaded portion 52 mates with the threaded distal end 42 of the luer fitment 38." (Ex. 1003, 4:1-4)(emph. add.)(Ex. 1002, ¶ 204).</p> <p>Mayoral discloses that the wall of the chamber is configured to engage with the post of the <i>male</i> luer-lock connector, in Figure 3 above, and 3A shown here. (Ex. 1002, ¶ 205). The specification explains,</p>
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	<p>"FIGS. 3 and 3A illustrate the cap 10 completely installed on the fitting 14. The female thread form 40 is tightly engaged with the male thread form 151 of the cap. The V-shaped sealing channel 200 is completely engaged with the cap seal ring 202 having been deformed outwardly by the tapered surface 56 to be fit within the socket 52."</p> <p>(Ex. 1033 at 6:33-38)(emph. add.)(Ex. 1002, ¶ 205).</p>
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Claim 7 shares a number of elements with claim 1. These elements are addressed under claim 1. The elements that the two claims do not share are separately addressed in the chart below.

<p>7. and the gripping portion comprising at least one recess having a bottom, the cap body having a cross sectional thickness at the bottom of the recess gradually increasing from the distal-most end of the cap body and towards</p>	<p>Mayoral discloses a luer connector cap where the gripping portion has a recess, and a cap body having a cross sectional thickness at the bottom of the recess gradually increasing from the distal-most end of the cap body towards the receiving portion of the cap. (Ex. 1002, ¶ 208). The gripping portion [34], is discussed above.</p> <p>The cross sectional thickness that gradually increases is highlighted in the expanded section of Figure 7, here. This increase occurs at the bottom of the recess, and towards the receiving portion. (Ex. 1002, ¶ 209).</p>
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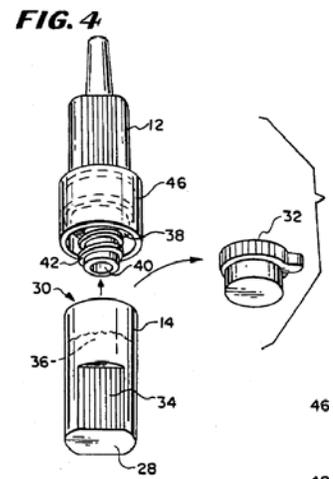
the receiving portion	
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Ground 2. Claim 3 is unpatentable under 35 U.S.C. § 103(a) over Peluso in view of Mayoral, in further view of Hoang.

Claim 3 is invalid under 35 U.S.C. § 103 over Peluso in view of Mayoral, as set forth in Ground 1, incorporated herein, in further view of U.S. Patent No. 8,740,864 ("Hoang"). (Ex. 1021). Hoang is prior art under § 102(e) as it was filed in 2005 and issued in 2014 (Ex. 1021)(Ex. 1002, ¶ 211). The level of skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 23-30, 212).

Claim 3 of the '308 patent states: "3. A cap according to claim 2, wherein the cover comprise [sic] an impervious pliable material." (Ex. 1001).

The disclosure of Peluso is discussed in detail in Ground 1 above, incorporated herein. As established there, Peluso discloses a cover for its disinfecting luer connector cap. The cover in Peluso is called a "plug," and is shown here, at [32] in Figure 4 of the patent. (Ex. 1003)(Ex. 1002, ¶ 214). See also Ground 1, claim 2. Peluso does not expressly teach that the material of the plug (cover) is impervious or pliable.

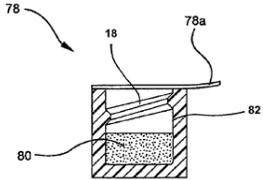


(Ex. 1002, ¶ 215).

Hoang, like Peluso and the '308 patent, also discloses a disinfecting cap for a

medical connector. More specifically, Hoang shows, in Figure 10B, below, a

FIG. 10B



stand-alone disinfecting cap that contains a pad [80] with antimicrobial agent that comes into contact with the connector when inserted therein. (Ex. 1021, 3:37-42; 4:58-62)(Ex. 1002, ¶ 217). The cap shown in Hoang can be

used with a "luer" connector. (Ex. 1002, ¶ 217).

Hoang also discloses a cover that extends over an open end of the cap, called a "lid" in Hoang and shown in Figure 10B, 78a. (Ex. 1021)(Ex. 1002, ¶ 218). Hoang further discloses that the "lid" is made of "foil," which is material that "completely seals the opening" and creates a "moisture barrier," and is therefore "impervious". (Ex. 1021)(Ex. 1002, ¶ 219). 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. 1021 at 2:20-23)(emph. add.)(Ex. 1002, ¶ 219).

Figure 10(b) also shows the "lid" is to be pulled from the cap, in bent fashion, for removal. Accordingly, the lid must also be pliable, as is expected for "foil". (Ex. 1021)(Ex. 1002, ¶ 220).

One of skill in the art would have been motivated to use the cover (lid) of Hoang on the cap of Peluso, because of the cost savings during the manufacturing

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process. (Ex. 1002, ¶ 221). 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 Peluso, for the ease and cost savings during the manufacturing process. (*Id.*). 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. 1040, pp. 22-25).

During prosecution of the application for the '308 patent, the Examiner rejected the claims as unpatentable over Hoang in view of Chin-Loy, discussed above, finding that Hoang disclosed a cover made of an impervious pliable material:

"Re claims 3 and 4, Chin-Loy et al. disclose all the claimed features except a cover over the opening of the chamber. **Hoang et al., however, teaches a cover 20 (Fig 2) made of an impervious pliable material (Para 12) over the opening of the chamber 16b (Fig 2) for the purpose of providing a moisture barrier to the fluid held therein (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 Chin-Loy to include a impervious pliable cover over the opening, as taught by Hoang et al., for the purpose of providing a moisture barrier to the fluid held therein (Para 12).**"

(Ex. 1023, p. 5)(emph. add.). Applicants did not take issue with the Examiner's

findings that Hoang disclosed a cover made of an impervious pliable material, or that it would have been obvious to one of skill in the art to modify Chin-Loy to include an impervious pliable cover over the opening, as taught by Hoang (instead attempting to distinguish Hoang on other grounds). (Ex. 1008, p. 8). It would have been obvious to combine Hoang with Peluso and Mayoral, for reasons similar to those employed by the Examiner in combining Hoang with Chin-Loy (providing a moisture barrier). (Ex. 1002, ¶ 222).

The combination of Hoang with Peluso and Mayoral represents the incorporation of a known disinfecting cap for a female luer connector (Peluso) with the known protective cap for medical male luer connectors (Mayoral), 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, ¶ 223). *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, ¶ 154). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

For the foregoing reasons, Peluso in view of Mayoral, and in further view of Hoang, teaches claim 3 of the '308 patent.

Ground 3. Claim 4 is unpatentable under 35 U.S.C. § 103(a) over Peluso in view of Mayoral and Hoang, in further view of Cummings.

Claim 4 is invalid under 35 U.S.C. § 103 over Peluso in view of Mayoral and Hoang, as set forth in Ground 2, incorporated herein, in further view of U.S. Pat. No. 4,390,104 ("Cummings"). Cummings is prior art under § 102(b) as the patent issued in 1983. (Ex. 1037)(Ex. 1002, ¶ 225-6). The level of skill in the art is discussed in the Leinsing declaration. (Ex. 1002, ¶¶ 23-30, 227).

Claim 4 of the '308 patent states, "A cap according to claim 3, wherein the impervious pliable material comprises plastic". (Ex. 1001).

As explained in Ground 2 above, Hoang disclosed a cover ("lid") for a luer connector cap, that "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. 1021, 2:20-23)(emph. add.)(Ex. 1002, ¶ 231).

Cummings discloses "[a] flexible **plastic sealing cover**" wherein "an upper layer of **plastic film is substantially impervious to moisture and bacteria**". (Ex. 1037, Abstract)(emph. add.). The cap of Cummings is for use in sealing IV solution containers in a sterile manner. (Ex. 1037 at 5:8-9)(Ex. 1002, ¶¶ 229-230).

It would have been obvious to one of skill in the art to use the plastic cover of

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Cummings that includes a moisture barrier ("is substantially impervious to moisture and bacteria"), on the cap of Peluso, in view of Hoang. (Ex. 1002, ¶ 232).

The combination of Cummings with Peluso, Mayoral and Hoang represents the incorporation of a known disinfecting cap for a male luer connector (Peluso) with the known protective cap for medical male luer connectors (Mayoral), the cover (lid) of a known disinfecting luer cap (Hoang), and a plastic cover for IV solutions (Cummings), each without change of their known functions, and without unpredictable results. (Ex. 1002, ¶ 233). *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, ¶ 154). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

For the foregoing reasons, Peluso in view of Mayoral and Hoang, and in further view of Cummings, teaches claim 4 of the '308 patent.

IV. CONCLUSION

The Petitioner therefore requests institution of trial and cancellation of claims 1-7 of U.S. Patent No. 8,647,308.

Date: February 2, 2015

Signed: /Matthew A. Smith/ RN 49,003

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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 2, 2015, on the Patent Owner's counsel of record at the United States Patent & Trademark Office having the following address:

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