**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**PATENT TRIAL AND APPEAL BOARD**

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BAXTER INTERNATIONAL INC.
Petitioner

v.

BECTON, DICKINSON AND COMPANY
Patent Owner

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CASE: IPR2020-00024
U.S. PATENT NO. 8,740,864

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# PETITION FOR *INTER PARTES* REVIEW

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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**Mandatory Notices (37 C.F.R. § 42.8(b))**

**A. Real Parties-In-Interest**

Baxter International Inc. ("Baxter" or "Petitioner"), with its head office at One Baxter Parkway, Deerfield, Illinois, 60015-4625, and Baxter Healthcare Corp. located at One Baxter Parkway, Deerfield, Illinois 60015, are the real parties-in-interest in this proceeding.

**B. Related Matters**

U.S. Patent No. 8,740,864 ("the '864 Patent") (Ex. 1001), was previously challenged in IPR2014-00880 filed by Excelsior Medical Company. Trial was instituted but the matter was terminated before final written decision.

The '864 Patent has also been involved in the following district court litigations, all of which have terminated without any adjudication on the merits of validity:

*Hospira, Inc. v. Ivera Medical Corp. et al.*, 1-14-cv-03513 (D.N.J., Jun. 3, 2014);

*Catheter Connections, Inc. v. Ivera Medical Corp. et al.*, 1-14-cv-03512 (D.N.J., Jun. 3, 2014);

*Excelsior Medical Corp. v. Ivera Medical Corp. et al.*, 1-14-cv-03502 (D.N.J., Jun. 3, 2014);

*Ivera Medical Corp. et al. v. Excelsior Medical Corp. et al.*, 3-14-cv-01348 (S.D. Cal. Jun. 3, 2014);

*Ivera Medical Corp. et al. v. Catheter Connections, Inc.*, 3-14-cv-01346 (S.D. Cal. Jun. 3, 2014); and

*Ivera Medical Corp. et al. v. Hospira, Inc.*, 3-14-cv-01345 (S.D. Cal. Jun. 3, 2014).

Additionally, Petitioner has concurrently filed petitions challenging U.S. Patent Nos. 9,283,367, 10,159,828, and 10,335,584 in IPR2020-00025, IPR2020-00026, and IPR2020-00027 respectively. These three patents are continuations of the '864 Patent.

### C. Lead and Backup Counsel and Service (37 C.F.R. § 42.8(b)(3)-(4))

| Lead Counsel | Backup Counsel |
|---|---|
| **Benjamin E. Weed**<br>Reg. No. 65,939<br>K&L GATES LLP<br>70 W. Madison Street, Suite 3100<br>Chicago, IL 60602<br>benjamin.weed.PTAB@klgates.com<br>T: (312) 781-7166<br>F: (312) 827-8152 | **Erik J. Halverson**<br>Reg. No. 73,552<br>K&L GATES LLP<br>70 W. Madison St., Suite 3100<br>Chicago, IL 60602<br>erik.halverson@klgates.com<br>T: (312) 807-4240<br>F: (312) 345-8529 |

Petitioner consents to electronic service by email.

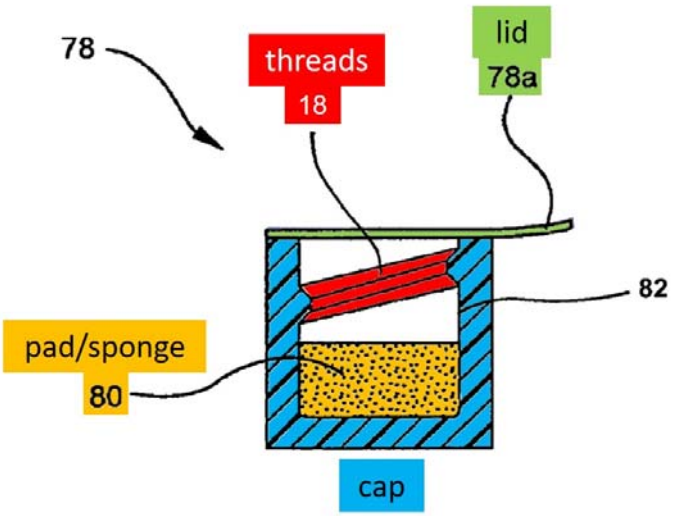
# I. INTRODUCTION

Baxter requests institution of *Inter Partes* Review ("IPR") of claims 1-19 ("Challenged Claims") of the '864 Patent and the subsequent cancellation of the Challenged Claims in view of the Grounds described below.

The purported invention of the '864 Patent is, at its core, a threaded cap. That patent repackages old, well-known technology, which implements the decades-old notion that certain things need to be covered and sanitized to remain sterile. In the case of the '864 Patent, a connector feeding into a patient fluid line is kept sanitized via: 1) a cap to cover the connector; 2) threads within the cap to engage the connector and maintain the cap in place (much like a twist off bottle cap); 3) a pad/sponge and disinfectant to sanitize the connector; and 4) a lid to ensure the disinfectant remains in the pad/sponge until engagement. That the invention is directed to old technology is evident from the Board's institution of a review of the '864 Patent in an earlier *inter partes* proceeding.[1]

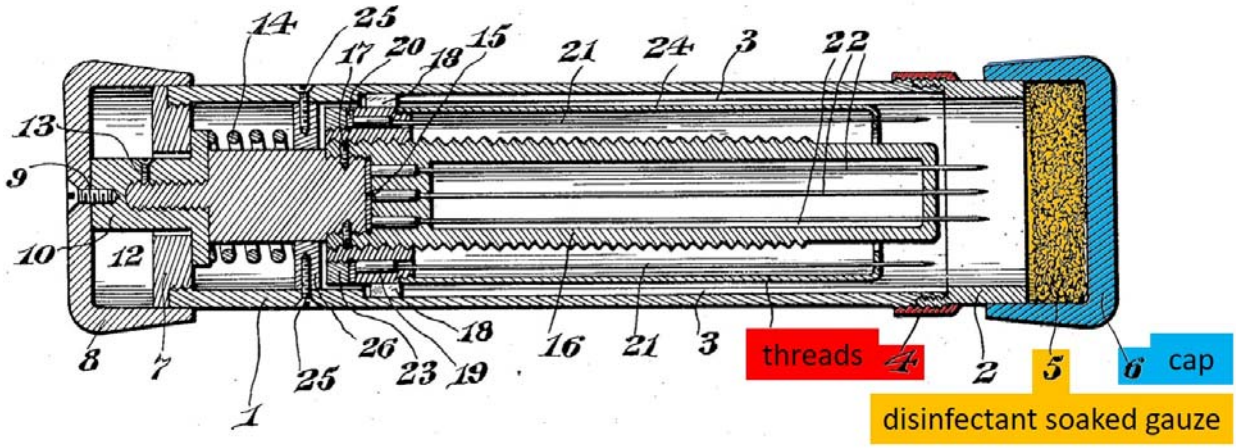
Figure 10b of the '864 Patent depicts an example embodiment of the Challenged Claims, with the cap (blue), threads (red), pad/sponge (orange), and lid (green):

[1] The Parties in that prior proceeding stipulated to dismissal before the PTAB reached a final adjudication of the claims, necessitating this petition.




(Ex. 1001, Fig. 10b, 4:58-62).

As shown herein, the '864 Patent neither invented the use of disinfecting caps, nor the use of pads/sponges with antiseptic material within those caps, as is illustrated by the below figure from a patent that issued in 1935, showing a "disinfecting cap 6," and "sterilizing gauze or cotton . . . soaked in a suitable disinfectant." (Ex. 1019, 1: 32-36, Fig. 1).



While disclosing the elements of the Challenged Claims, the later-in-time references relied upon in this petition more clearly depict the claimed components in the claimed manner, such that petitioner is not relying upon this 1935 reference for more than the understanding that this technology is not a recent development.

As explained herein, the '864 Patent does not add anything to the state of the art. Thus, Petitioner hereby requests *inter partes* review of the Challenged Claims of '864 Patent in light of the prior art identified herein.

## II. TECHNOLOGY OF THE '864 PATENT

### A. Overview of Patient Fluid Lines, Cleaning Caps, and Cleaning

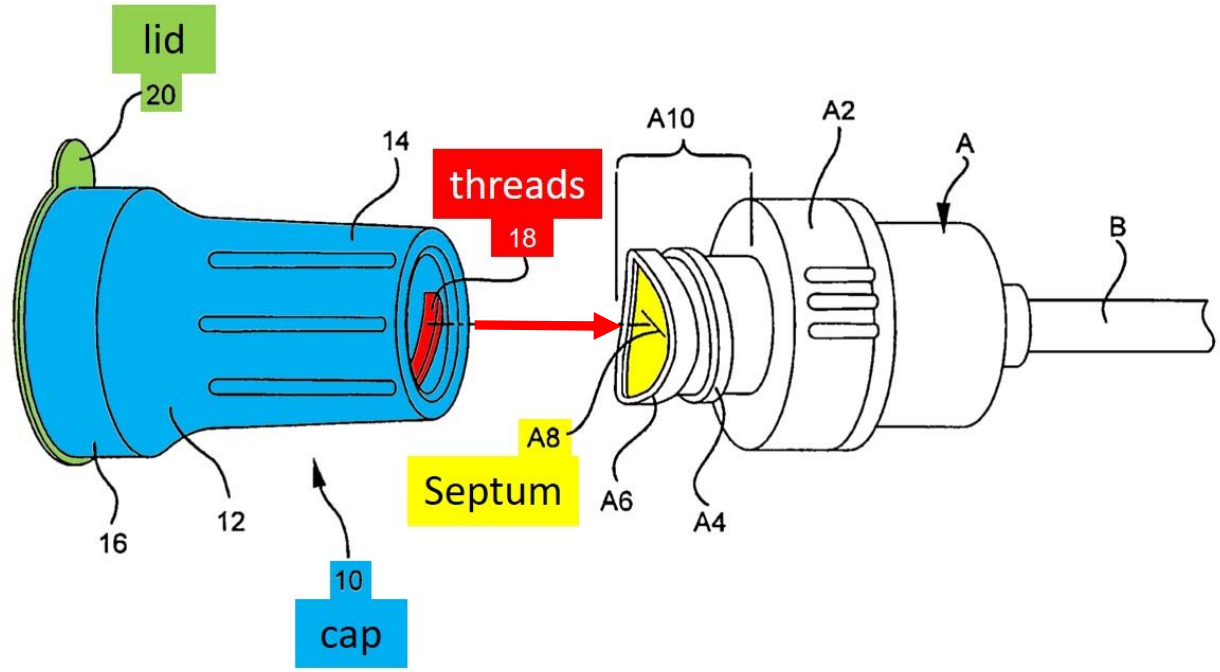
Connectors to patient fluid lines allow the administration of liquid drug formulations and other fluids via those lines without the use of syringes. (Ex. 1002, ¶¶19-20). These connectors rely upon antimicrobial solutions to disinfect them to avoid patient infections. (Ex. 1002, ¶20). One well-known way to disinfect these connectors, as identified in the prior art discussed herein, is to provide a disinfectant cap that screws on to the connector, thereby applying a disinfectant via a sponge contained within the cap. (Ex. 1002, ¶¶20-23).

### B. '864 Patent Overview

The '864 Patent is titled "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner," and relates to a device for antiseptically maintaining a clean patient fluid line access valve. (Ex. 1001, 1:34-35 & Fig. 5). Figure 1 of the '864 Patent is

an exploded view of the claimed cleaner cap (10) and access valve (A), along with a line (highlighted in red below) depicting the threading engagement of the connector by the cleaner cap. (Ex. 1001, 1:43-45; 1:66-2:1; Ex. 1002, ¶22).

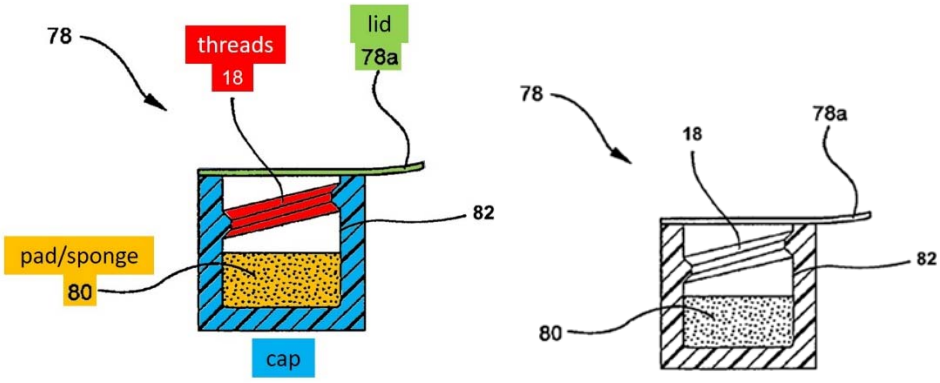
FIG. 1




Cap (10) includes a housing (12) having open cap end (14) and cleaning end (16). (Ex. 1001, 2:1-3). To prevent infection between patient treatments, cleaning end (16) is covered by lid (20), which is removed to expose cleaning wet pad (22) (depicted in Figure 2). (Ex. 1001, 2:19-20, 24-28; Ex. 1002, ¶23). The open cap end (14) contains threading (18) for interlocking with the threading (A4) of access portion (A10) of the connector (A). A10 further includes the exposed surface of the septum (A6) and at least a portion of the exposed surface of housing (A2). (Ex.

1001, 2:3-7, 10-12, 18-19, & 60-63; Fig. 3). In alternative embodiments (depicted in Figure 7), the pad in the cap may be either dry pad or wet. (Ex. 1001, 4:63-65).

A different version of the claimed cap can be found in Figure 10b, with corresponding parts colored (left, below) as they are colored with regard to Figure 1:




As is shown above, the "invention" of the '864 Patent is simply a threaded cap with a sponge contained within the cap. (Ex. 1002, ¶24). This Petition explains that the Patentee did not invent such a device. Accordingly, the '864 Patent does not represent any improvement over the then-existing state of the art.

### C. Prosecution History of the '864 Patent

U.S. Patent App. Ser. No. 11/281,711 ("the '711 Application") was filed on November 17, 2005, and represents the priority application for the '864 Patent. (Ex. 1001, Cover). During prosecution, the '711 Application received five substantive rejections. In the notice of allowance, the Examiner concluded that the closest art

failed to, in the Examiner's mind, disclose the claimed arrangement. (Ex. 1003, 273-274).

The art relied upon herein (e.g., the combination of *Menyhay* and *Genatempo*; and the combination of *Connell*, *Raulerson* and *Genatempo*; as well as the additional disclosures of *Raad* and *Miyahara*) expressly teaches a threading engagement that provides contact between an access valve end face and a disinfecting wet pad. (*See e.g.*, Section VII). Thus, such prior art renders the Challenged Claims of the '864 Patent obvious.

### D. Prior Proceedings

#### 1. Prior IPR

The Board previously instituted IPR of claims 10, 12 and 14[2] of the '864 Patent as obvious in view of *Menyhay* and *Genatempo*. (Ex. 1005, 155).

The Board preliminarily determined that claim 10 is unpatentable over the combination of *Menyhay* and *Genatempo*, finding both that: (1) these references would have been combined by a POSA; and (2) the resulting combination would have rendered obvious at least independent claim 10 (to which then un-challenged, yet presently challenged independent claim 1 is substantially similar). (Ex. 1005, 166). The PTAB declined to institute then-challenged claims 11 and 13 based on

[2] Pre-*SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1359-60 (2018).

purportedly deficient evidence. (Ex. 1005, 167-169, 170-171). The subject matter of claims 11 and 13 has been thoroughly addressed herein. The parties jointly moved for dismissal of the proceeding prior to a final decision. (Ex. 1005, 184).

### 2. Prior Litigation of the '864 Patent

In a prior district court proceeding, *Ivera Med. Corp. et al. v. Hospira, Inc.*, 3-14-cv-01345 (S.D. Cal.), the district court did not reach a determination on the merits of validity of the '864 Patent before the parties terminated the proceeding.

## III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(A))

Petitioner certifies that: (1) the '864 Patent is available for IPR; (2) Petitioner is not barred or estopped from requesting review on the grounds identified herein; and (3) Petitioner has not filed a complaint relating the '864 Patent.

## IV. PAYMENT OF FEES (37 C.F.R. §§ 42.15 AND 42.103)

Petitioner authorizes the USPTO to charge any required fees to Deposit Account 02-1818.

## V. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSA") is a hypothetical person who is presumed to know the relevant prior art. *See Gnosis S.P.A et al. v. S. Ala. Med. Sci. Foundation*, Case IPR2013-00116, Paper 68 at 9, 37 (P.T.A.B. June 20, 2014). That person has ordinary creativity, is not an automaton, and is capable of combining

teachings of the prior art. *Id*. (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-421 (2007)).

With respect to the '864 Patent, a POSA as of November 17, 2005 would have had an undergraduate degree, or equivalent thereof, in mechanical engineering or biomedical engineering with at least three years of experience in product design with experience in, for example, catheters, medical ports, and other patient fluid line access valve caps. (Ex. 1002, ¶¶26-28; Exhibit 1005, 150). Such a person would have had knowledge of design considerations known in the fluid line industry, including patient safety considerations, would have been familiar with then existing products and solutions, and would have understood how to search available literature for relevant publications. (Ex. 1002, ¶27).

## VI. CLAIM CONSTRUCTION

In *inter partes* reviews filed after November 13, 2018, claims are construed according to the *Phillips* standard consistent with Article III federal courts. 83 Fed. Reg. 51340, 51340-41 (Oct. 11, 2018) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)). Claims are to be construed under the same standard as in federal court, in view of the specification and intrinsic record. *Id.* During the afore-discussed prior IPR proceeding, Patent Owner proposed a number of arguments about claim construction which are now part of the intrinsic record, and must be considered when determining proper construction. *Aylus Networks, Inc. v.*

*Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017). However, none of Petitioner's challenge grounds turn on these various claim constructions being adopted or rejected for purposes of this *inter partes* review. Patent Owner's arguments, and the Board's preliminary constructions, from the '864 Patent IPR are included below for completeness.

**A. "external threads on the access portion proximate the septum"**

The Board has previously preliminarily construed this limitation to "require the external threads to be located on the access portion very near the end face as compared to other parts of the access portion." (Ex. 1005, 161).

**B. "length"**

The Board preliminarily construed length to refer to a measurement from one end of a thread to the other end of that thread. (Ex. 1005, 162).

**C. "access portion"**

The Patent Owner previously argued that "access portion" should be construed as "the exposed surface of the septum and the exposed surface of the housing that surrounds the septum." (Ex. 1005, 148-149 *citing* Ex. 1001, 2:3-7).

**D. Remaining Terms**

Petitioner submits that the remaining claim elements should be given their plain and ordinary meaning as would be understood by a POSA.

## VII. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFORE (37 C.F.R. § 42.22(a) AND 42.104(b))

Petitioner requests the institution of IPR and the cancellation of the Challenged Claims on the following Grounds:

| Ground | Basis | Relied-On References | Claims |
|---|---|---|---|
| 1 | § 103 | *Menyhay* and *Genatempo* | 1-19 |
| 2 | § 103 | *Menyhay*, *Genatempo*, and *Raad* | 8, 13 |
| 3 | § 103 | *Menyhay*, *Genatempo*, and *Miyahara* | 2, 11, 16 |
| 4 | § 103 | *Connell*, *Raulerson*, and *Genatempo* | 1-19 |
| 5 | § 103 | *Connell*, *Raulerson*, *Genatempo*, and *Raad* | 8, 13 |
| 6 | § 103 | *Connell*, *Raulerson*, *Genatempo*, and *Miyahara* | 2, 11, 16 |

Petitioner also provides the declaration of Mr. Richard Meyst, an expert in the field of the '864 Patent and the prior art, in support of these Grounds. (Ex. 1002, ¶¶1-28; Ex. 1004).

### A. The Petition Should Be Instituted Over 35 U.S.C. §§ 325 and 315

Claims 10-14 of the '864 Patent were previously challenged in 2014 in IPR2014-00880. IPR was instituted, but the parties filed a joint motion to terminate the proceeding approximately one month after institution. As neither Baxter nor the public has had the benefit of a decision on the merits with regard to these (or any)

claims of the '864 Patent, institution is proper in this case. *See e.g.*, *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1354 (Fed. Cir. 2005).

The *NVIDIA*/*General Plastic* factors further warrant against the Board exercising its discretion to deny this Petition. *See General Plastic Industrial Co., LTD. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017). Petitioner has never filed a petition at all, much less a petition directed to the same claims as are challenged in this Petition. (*Id.* Factor 1). Accordingly, factors two, four, and five weight against denial. (*Id.* (factors that involve the same petitioner)). Factor three, which relates to whether petitioner gained any insight from patent owner or the Board in the form of a Preliminary Response or Institution Decision is neutral as the Board's analysis only addressed a subset of the Challenged Claims, under a different claim construction standard, in a pre-*SAS* world. (*Id.* (that each have been filed and are publically available)). Additionally, no final written decision was ever reached, outweighing any timing issue, such that the public good would be served by a final decision with regard to the art of record as it relates to the Challenged Claims. *See Lear v. Adkins*, 395 U.S. 653, 656 (1969).

As a subset of the grounds have already been found to merit institution, and references and combinations have been preliminarily deemed combinable and applicable to the art, this Petition is not taxing on the Board's resources nor does it negatively impact the Board's one-year guideline of 35 U.S.C. §316(a)(11).

(*General Plastic*, IPR2016-01357, factors 6 and 7). While the Board may account for other factors in its §325(d) analysis, Petitioner believes that the aforementioned factors weigh in favor of institution and reserves the right to address additional factors that may be raised by Patent Owner. *See* 35 U.S.C. §325(d).

Moreover, as there was no final decision issued in the prior review, no provisions of 35 U.S.C. §315(e) warrant denial of this Petition.

### B. A Description of the Prior Art

As discussed below, the cited prior art references include all of the claimed components that perform predictable functions, supporting a determination of unpatentability. *See KSR v. Teleflex*, 550 U.S. at 420-21.

#### 1. *Menyhay*

U.S. Patent No. 5,554,135 to Menyhay ("*Menyhay*") issued on September 10, 1996, and is prior art to the '864 Patent under at least 35 U.S.C. §102(b). (Ex. 1007, Cover). [3]

[3] The '864 Patent, whose earliest possible priority date is November 7, 2005, is a pre-AIA patent; all citation to 35 U.S.C. §§102 and 103 are pre-AIA versions of those statutes.

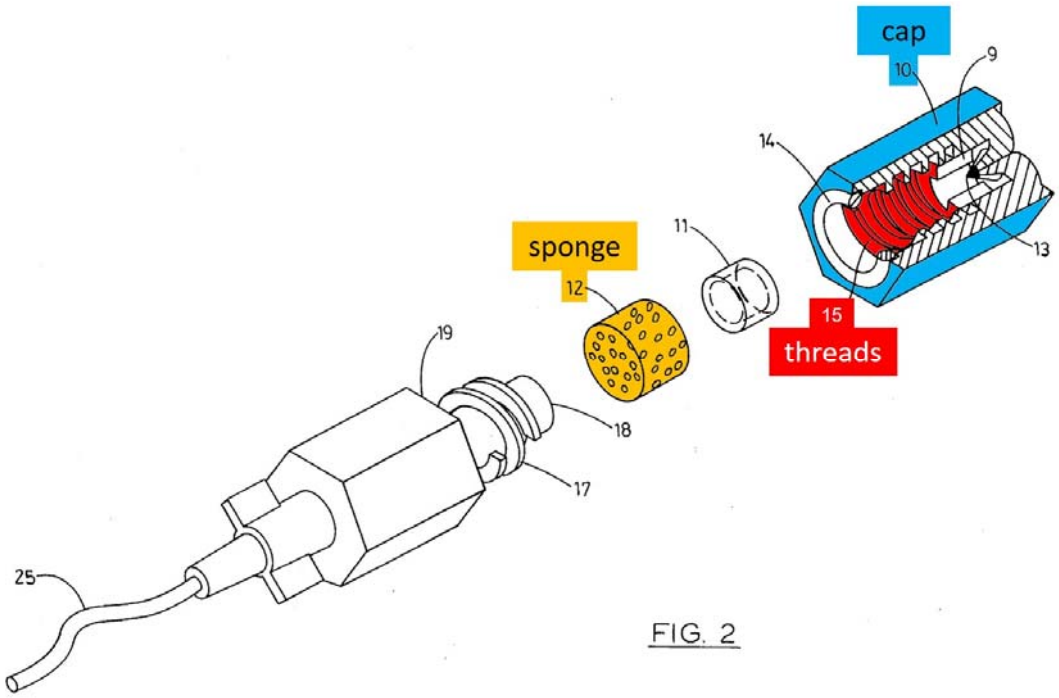
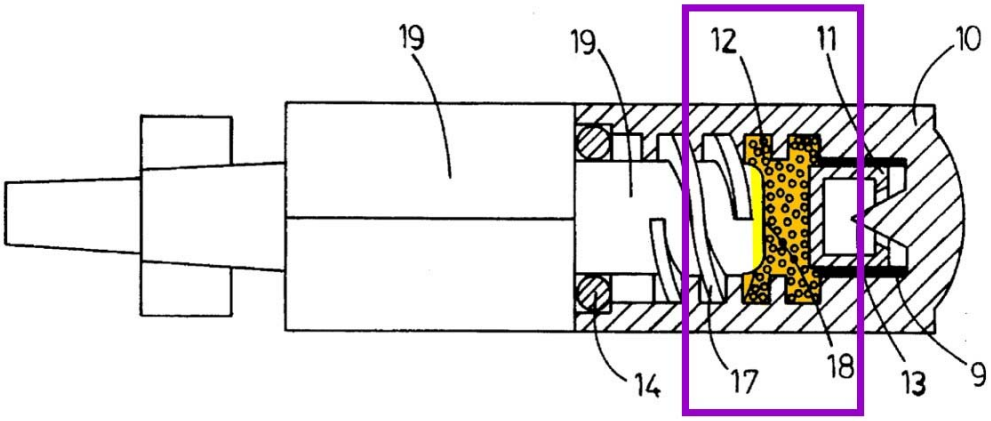



FIG. 2

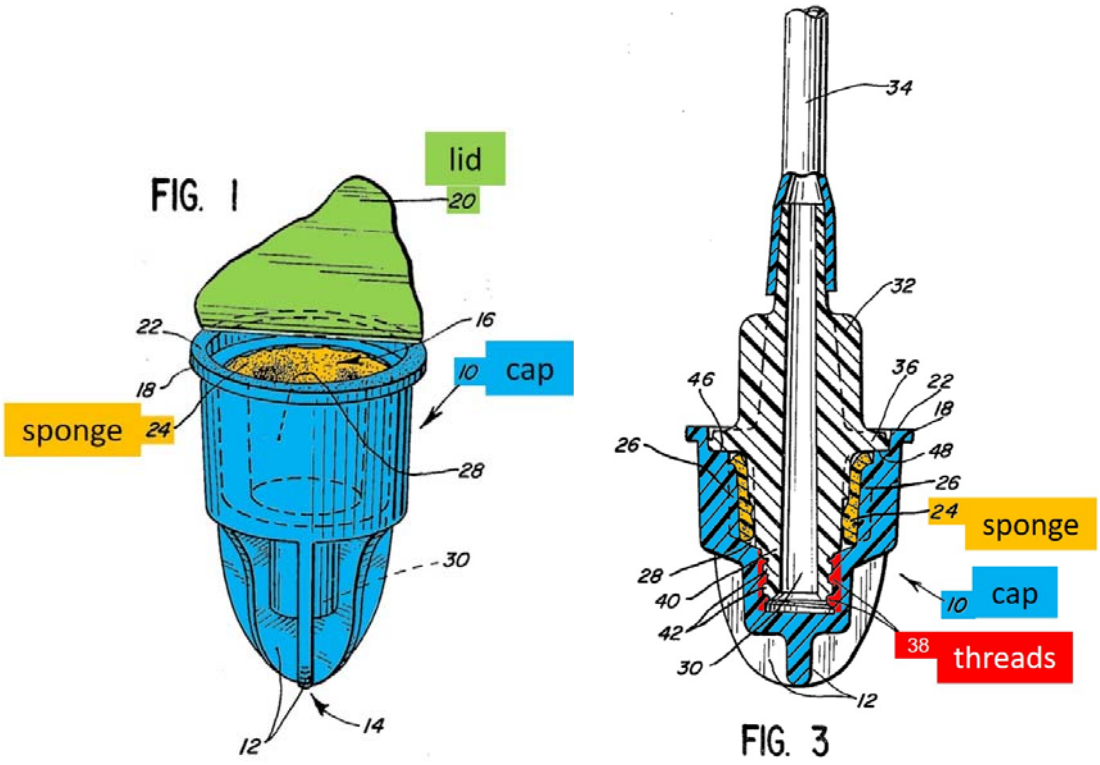
As shown in annotated Figure 2 above, *Menyhay* discloses an external connector port 19 with an access portion having external threads 17 and an end face with a septum 18. (Ex. 1007, 6:53-58, Fig. 2). *Menyhay* describes a cylinder or cap 10 (annotated in blue) closed on one end that can be threadingly attached to port 19 via threads 17 of the port and threads 15 of the cap (annotated in red). (Ex. 1007, 6:40-52; Ex. 1002, ¶30). Sponge 12 (annotated in orange) and an antiseptic solution are located within cylinder 10 (which can be a solution of povidone iodine and isopropyl alcohol). (*Id.*). As the cylinder and connector port are screwed together, the wetted sponge contacts the septum 18 (annotated in yellow), as shown below in the purple box. (*Id.* at 6:59-7:3).




*Menyhay* explains that one way of providing its antiseptic solution to the sponge is to include a breakable capsule 11 and an internal projection 13, such that the act of threading the cap and port together causes the projection 13 to break the capsule 11, releasing the stored solution onto the sponge 12. (*Id.* at 6:40-52; Ex. 1002, ¶¶31-32).

**2. *Genatempo***

U.S. Patent No. 4,440,207 to Genatempo et al. ("*Genatempo*") issued on April 3, 1984, and is prior art to the '864 Patent under at least 35 U.S.C. §102(b). (Ex. 1006, Cover).




As shown in Figure 1, replicated above, *Genatempo* discloses a protective cap 10 containing an absorbent material 24 impregnated with an antiseptic liquid. (Ex. 1006, 2:62-68, Abstract; Ex. 1002, ¶34). As shown in Figure 3, also replicated above, cap 10 is placed in contact with a connector 32 that is attached to medical tubing, thereby assisting in the prevention or limitation of contamination of the connector 32. (Ex. 1006, 3:22-51). A lid 20 covers the open end of cap 10 to prevent loss of liquid through spillage and evaporation. (Ex. 1006, 2:62-68; Fig. 1; Ex. 1002, ¶35). Further, *Genatempo* describes threading 38 on the internal wall of the cap that engages with external threads 42 of connector 32. (Ex. 1006, 3:37-39, Fig. 3).

*Genatempo* ensures that cleaning occurs through the migration of the antiseptic. (Ex. 1006, 3:43-45; Ex. 1002, ¶¶35-36).

### 3. *Raad*

U.S. Patent Publication No. 2005/00013836 to Raad ("*Raad*") (Ex. 1016) published on January 20, 2005, was filed June 7, 2004, and is prior art under at least 35 U.S.C. §102(a). *Raad* is titled "antimicrobial flush solutions" and describes solutions that comprise alcohol and an antimicrobial agent, the solution being useful for reducing contamination on surfaces of medical devices, organic surfaces (e.g., skin), and hospital equipment. (Ex. 1016, Abstract; Ex. 1002, ¶¶37-38). *Raad* further notes that povidone-iodine and chlorhexidine are examples of antimicrobials that are known antiseptic agents. (Ex. 1016, ¶28).

*Raad* claims the use of an antiseptic agent that is selected from a group that includes, among others, isopropanol, povidone-iodine, and chlorhexidine, as well as using such a solution for cleaning a surface to reduce the number of microbial organisms on that surface. (Ex. 1016, claims 10, 20; Ex. 1002, ¶39). *Raad* also discloses that the surface may include a catheter, and using the solution to clean a surface of that catheter. (Ex. 1016, ¶¶26-27). *Raad* confirms that a POSA as of 2005 would have been aware of the antimicrobial properties of chlorhexidine. (Ex. 1002, ¶¶38-39).

### 4. *Miyahara*

U.S. Patent Publication No. 2004/0111078 to Miyahara ("*Miyahara*") was filed on July 28, 2003, and published June 10, 2004. (Ex. 1009, Cover). *Miyahara* is prior art under at least 35 U.S.C. §102(b).

*Miyahara* discloses a connector system for sterile connection that includes a cap with an antiseptically impregnated sponge for cleaning a male-type connector. (Ex. 1009, ¶¶12-13; Ex. 1002, ¶41). As shown in Figure 3, replicated below, *Miyahara* further discloses the rotational advancement of the connector into the cap using a protrusion 21 and guide groove 13 to facilitate the cleaning of the connector by way of rotational advancement. (Ex. 1009, ¶¶41, 50, 55-57; Ex. 1002, ¶44).

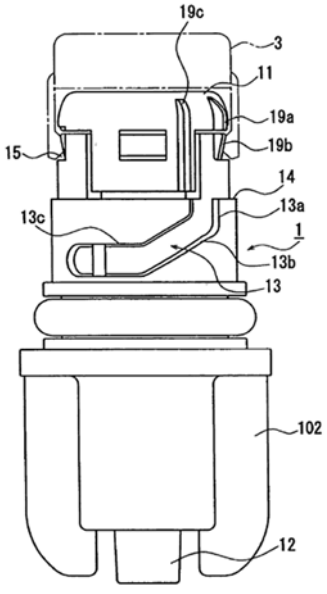


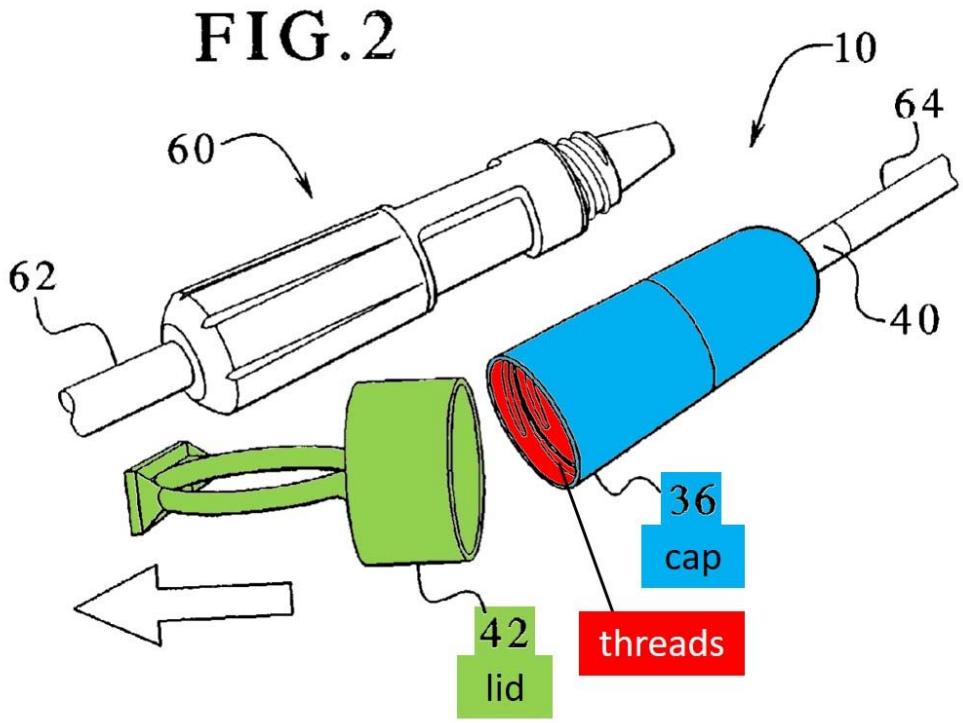

FIG. 3

(Ex. 1009, Fig. 3, depicting guide grove 13; Ex. 1002, ¶44).

### 5. *Connell*

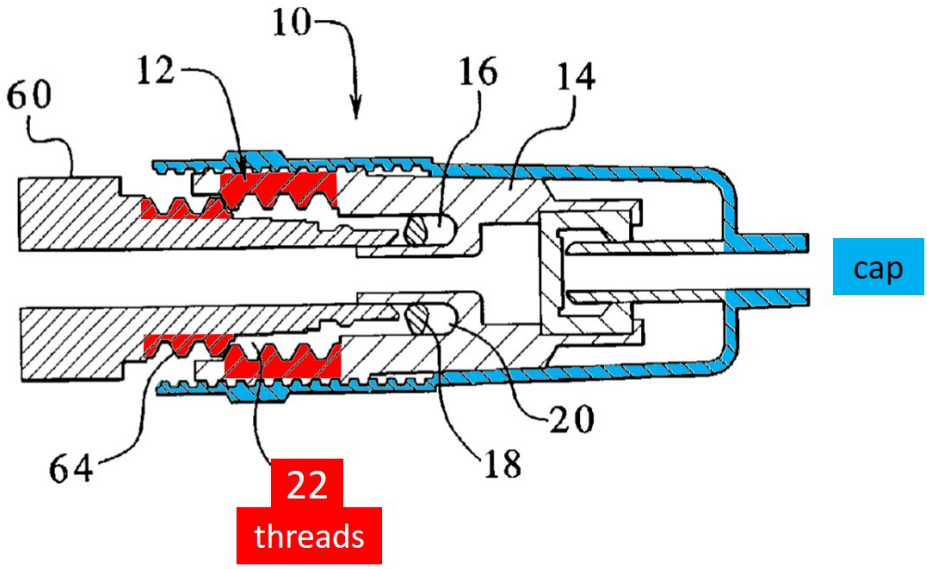
U.S. Patent Publication No. 2003/0153865 to Connell et al. ("*Connell*") published August 14, 2003. (Ex. 1010, Cover). *Connell* is therefore prior art under at least 35 U.S.C. §102(b).

As shown in Figure 2, replicated below, *Connell* discloses a cap and connector that provide for disinfecting a patient line. (Ex. 1010, ¶¶14-15; Ex. 1002, ¶46).




Within the cap, sealed disinfectant is stored for use in cleaning the threading and end of the connector. (Ex. 1010, ¶¶15-18, 55, Fig. 2).

FIG.4




*Connell* discloses threading on a cap that engages with threading on the connector and is used to advance the two components towards each other. (Ex. 1010, ¶¶77, 91; Ex. 1002, ¶50). The cap 10 is sized to receive septum 30. (Ex. 1010, ¶80; Ex. 1002, ¶54). Seal 18 maintains the disinfecting fluid until ready for use. (Ex. 1010, ¶95; Ex. 1002, ¶¶47-48, 52-53). Figure 4, replicated above, in addition to Figures 5-7 depict the threading advancement of the pieces together and subsequent disinfecting of the connector. (Ex. 1010, ¶¶100-104).

### 6. *Raulerson*

U.S. Patent Publication No. 2006/0030827 to Raulerson, *et al.* ("*Raulerson*") was filed on July 13, 2005, and was published on February 9, 2006, and claims priority to Provision Application No. 60/587,790. (Ex. 1011; Ex. 1013). *Raulerson* is prior art under 35 U.S.C. §102(e)by virtue of its provisional filing date of July 14,

2004. The as-filed provisional specification, *Raulerson Provisional*, is substantially similar to the specification of *Raulerson*; *Raulerson* only adds Figure 7 and corresponding paragraphs. (*Compare* Ex. 1013 *with* Ex. 1011; *see also* Ex. 1018). Petitioner does not rely upon the substance of Figure 7 or those paragraphs of *Raulerson* for its challenge, nor does any of independent claim 16 of *Raulerson* rely upon the added language for §112 support. *See Amgen v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017) (extending *Dynamic Drinkware, LLC, v. National Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015) to published patent applications such as *Raulerson*).

As shown in Figure 1, replicated below, *Raulerson* teaches a luer cleaner (100) that includes an end opening into a cavity with a plurality of bristles extending into the cavity to engage the outer surfaces of a luer proximal end (190) disposed within the cleaner. (Ex. 1011, Abstract; Ex. 1002, ¶56).

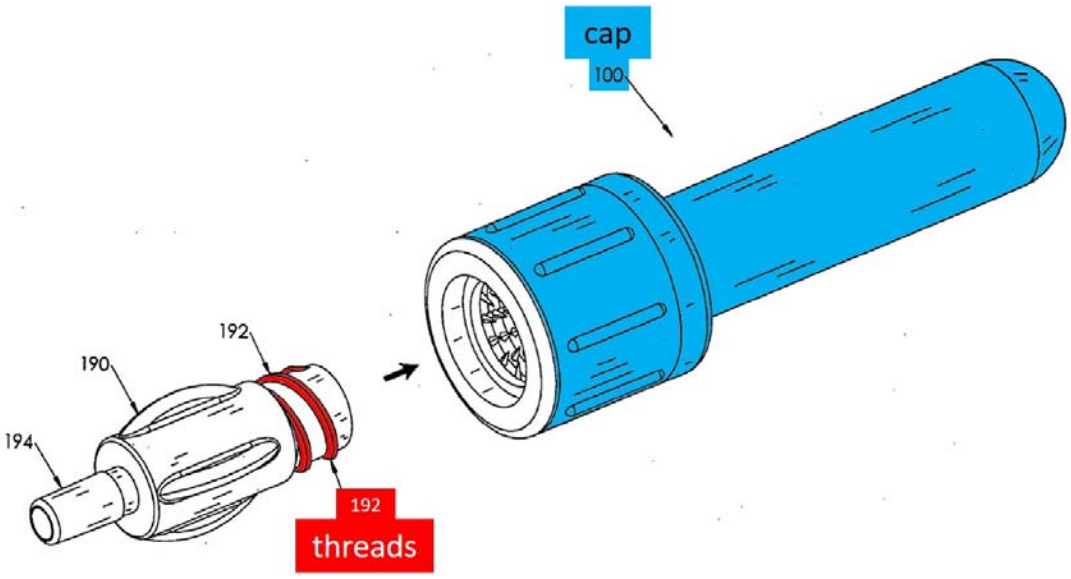



FIG. 1

Luer cleaner 100 is insertable over a luer connector 190 and rotatably axially around the luer. (Ex. 1011, ¶14; Ex. 1002, ¶57). Scrubber 130 is disposed within passage 110 and engages the luer threads of a luer inserted in cleaner 100. (Ex. 1011, ¶21).

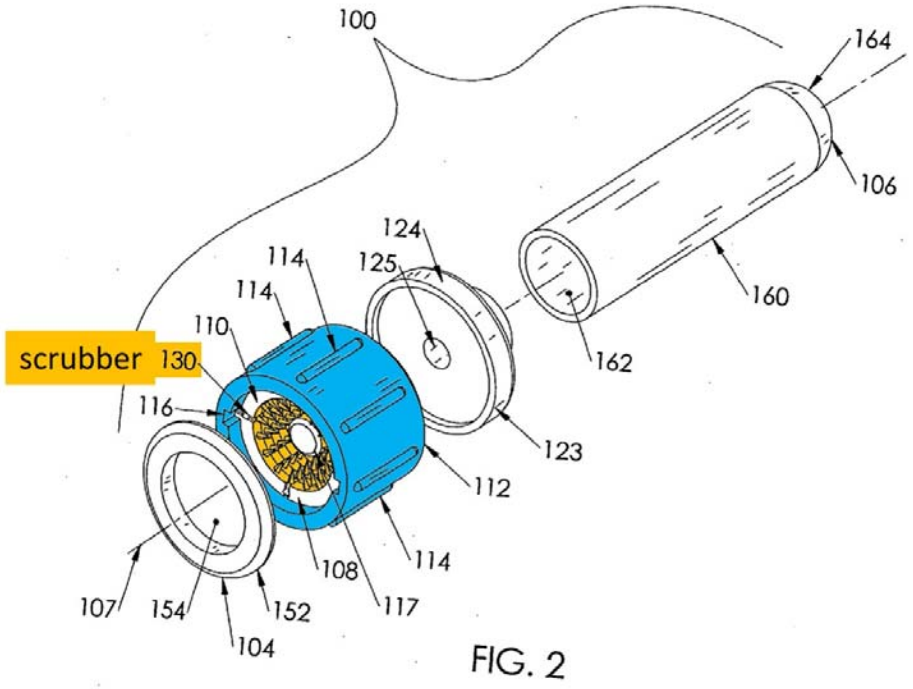



FIG. 2

As shown in Figure 2, above, cap 152 is disposed over open end 104 of the luer cleaner. (Ex. 1011, ¶27). Luer cleaner 100 includes antiseptic fluid 168 which assists in the cleaning of containments from the exterior of luer 190 and luer threads 192. (Ex. 1011, ¶31; Ex. 1002, ¶¶57-58).

### C. Ground 1: Challenged Claims are Obvious in Light of *Genatempo* and *Menyhay*.

Independent claims 1, 10 and 15, and claims 2-9, 11-14, and 16-19 depending therefrom, are obvious in view of *Genatempo* and *Menyhay*. (Ex. 1002, ¶¶74-85). While each of *Genatempo* and *Menyhay* were considered during prosecution, they were not considered in combination, and have not been considered in the context of the testimony of Petitioner's expert, Mr. Meyst.

#### 1. Basis for Combination

As a preliminary matter, the Board has already found that a POSA would have combined *Menyhay* and *Genatempo*, that the combination would have been made with an expectation of success, and that the resulting combination would render unpatentable claim 10. (Ex. 1005, 166). In that regard, *Genatempo* identifies the same problem and solution (medical connectors protective caps "which securely receive and provide an antibacterial effect to the connector" (Ex. 1006, 1:41-45), as that of the '864 Patent (using "a housing for covering the access portion of the access valve" in order "to reduce catheter-related infections."). (Ex. 1001, 1:25-40).

Further, a POSA would have known to preload sponge 12 of *Menyhay* (Ex. 1007, 6:49-64) with the antiseptic solution as suggested by *Genatempo* (Ex. 1006, Abstract) to ensure full-wetting of the sponge and thus avoiding dry spots in the event that the capsule of *Menyhay* fails to break sufficiently to wet sponge 12. (Ex.

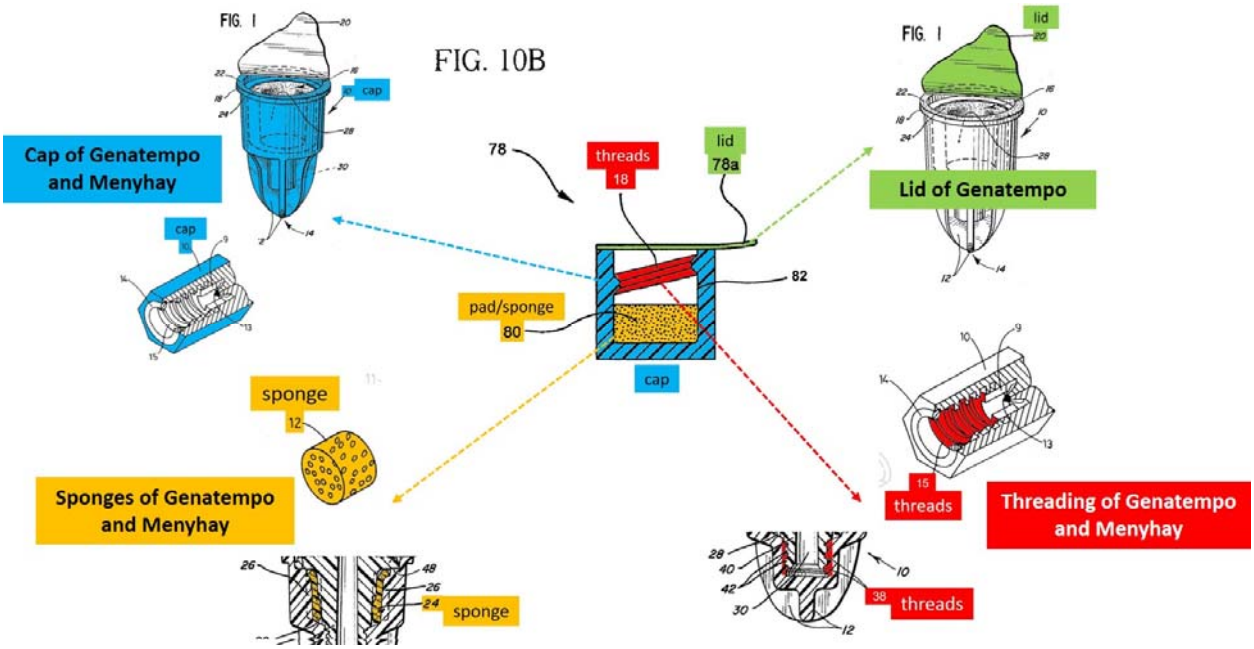
1002, ¶¶75-76). A POSA would have also understood that preloading *Menyhay's* sponge as suggested by *Genatempo*, along with the additional sponge location of *Genatempo* would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety. (Ex. 1002, ¶¶75-78). Further, the compression of these fully pre-wetted sponges would provide for the flowing of the stored antiseptic liquids across exposed surfaces. (Ex. 1002, ¶77).

Having combined *Menyhay* with *Genatempo* in the manner described above, a POSA would have also had need to modify the configuration to include a lid or seal (as suggested by *Genatempo*) to ensure the resulting preloaded sponge neither dries out nor expels its liquid prematurely. (Ex. 1002, ¶¶76, 79). This lid would perform the same function in the resulting combination as in *Genatempo*, ensuring the cleaning cap is sealed and that the solution does not evaporate. (Ex. 1006, 2:62-3:8). Such a combination would have been made in an effort to provide an improved cleaning cap. (Ex. 1002, ¶¶76-79).

The Challenged Claims are a rearrangement of known parts (as evidenced by, for example, *Menyhay* and *Genatempo*) in a known manner to provide a predictable result (as evidenced by Mr. Meyst's testimony). *In re Kuhle,* 526 F.2d 553, (CCPA 1975); *KSR*, 550 U.S. at 420; MPEP §2144.04.VI.C. Under controlling Supreme Court obviousness law, claims of a patent are obvious if they are a rearrangement of known features that perform as expected. *KSR*, 550 U.S. at 420-21. While no longer

required in a post-*KSR* world, a patent claim is also obvious if the elements of the claim were known in the art and a teaching, suggestion or motivation (TSM) is present in the art to modify the references. *Id*. at 415. And, "design incentives and other market forces can prompt variations of it…[such that] [i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417. A motivation to combine prior art references to arrive at a claimed invention also exists when there is a known need or problem with an obvious solution that the patent addresses. *Id*. at 420.

The Federal Circuit has held that it is appropriate to rely on expert testimony about ordinary skill in the art in determining obviousness. *Genzyme Therapeutic Prods. LP v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1372 (Fed. Cir. 2016). Nothing requires that an obviousness combination lay out every detail of an actual implementation. *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017). All that is required is a reasonable expectation of success, not "absolute predictability" or "absolute certainty." *Soft Gel Techs., Inc. v. Jarrow Formulas, Inc.*, 864 F.3d 1334, 1342 (Fed. Cir. 2017). As set forth in the declaration of Mr. Meyst (Ex. 1002), a POSA would have been motivated to combine *Genatempo* and *Menyhay* to arrive at an improved cap/cleaning device for medical connectors and ports. (Ex. 1002, ¶¶74-79).




(Ex. 1002, ¶79).

The image above depicts an example of what results from the combination of *Menyhay* and *Genatempo*. As supported by Mr. Meyst, the resulting combination suggests to a POSA a disinfectant system where the connector includes external threads to, *inter alia*, permit threading engagement between an access end and a disinfectant cap. (*See e.g.*, Ex. 1007, Abstract, 4:10-30; Ex. 1002, ¶79). The combination further includes a sponge that is pre-impregnated with an antiseptic cleaning solution. (*See e.g.*, Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23, Fig. 3; Ex. 1002, ¶79). Additionally, in the resulting combination, the cap has threading to engage with threading of the connector. (*See e.g.*, Ex. 1007, Figs. 2-3; Ex. 1006, Fig. 3; Ex. 1002, ¶79). The threading would cause the advancement of the connector into the cap when rotated, which causes cleaning of the threads and septum at the end of the

connector cap through the advancement of the face into the wetted sponge. (*See e.g.*, Ex. 1007, 6:54-7:3, Figs. 2-3; Ex. 1002, ¶79). Additionally, the cap includes a peelable lid to ensure that the solution did not prematurely evaporate or become contaminated prior to use. (*See e.g.*, Ex. 1006, 2:63-66, Fig. 1; Ex. 1002, ¶79). The predictable nature of this art supports the proposed combination. *KSR*, 550 U.S. at 420.

### 2. The Challenged Claims of the '864 Patent are Obvious

#### a. Representative Independent Claim 1 and the Claims Depending Therefrom

The '864 Patent has three independent claims: Claims 1, 10 and 15. The obviousness analyses for these claims, and the claims depending therefrom, are substantially similar. The prior art includes a cleaning cap (annotated in blue in the above figure), threading to advance the cap onto an access portion (annotated in red), a sponge within the cap to assist in cleaning of the inserted access portion (annotated in orange), and a peelable lid (annotated in green). (Ex. 1002, ¶79). The cited art renders obvious claim 1 of the '864 Patent.

#### b. Claim 1

##### i. Preamble

The preamble of claim 1 recites "a device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and

external threads on the access portion proximate the septum." *Menyhay* discloses a port injection cover that includes an antiseptic solution, and internal threads within the cover that are designed to engage with external threads of the port. (Ex. 1007, 4:13-22; Ex. 1002, ¶¶30-31). *Menyhay* states that threads of port 19 and threads of cover 10 will engage to screw the pieces together. (Ex. 1007, 6:53-53). The port of *Menyhay* satisfies the "patient fluid line access valve" of claim 1, and cover 10 of *Menyhay* equates to the claimed "device." (Ex. 1002, ¶31; Ex. 1007, 6:56-57). Further, port 19 of *Menyhay* includes a rubber septum 18. (Ex. 1007, 6:52-53). *Genatempo* also discloses an antimicrobial protective cap. (Ex. 1006, 1:9-11).

**ii. Part [a]**

Part [a] of claim 1 recites "a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve."

*Menyhay* discloses "a cylinder 10 [annotated in blue below] that is open on one end, having a set of screw threads 15 on the inside" that mate with threads 17 of a connector. (Ex. 1007, 6:38-56, Fig. 2; Ex. 1002, ¶¶31-32).

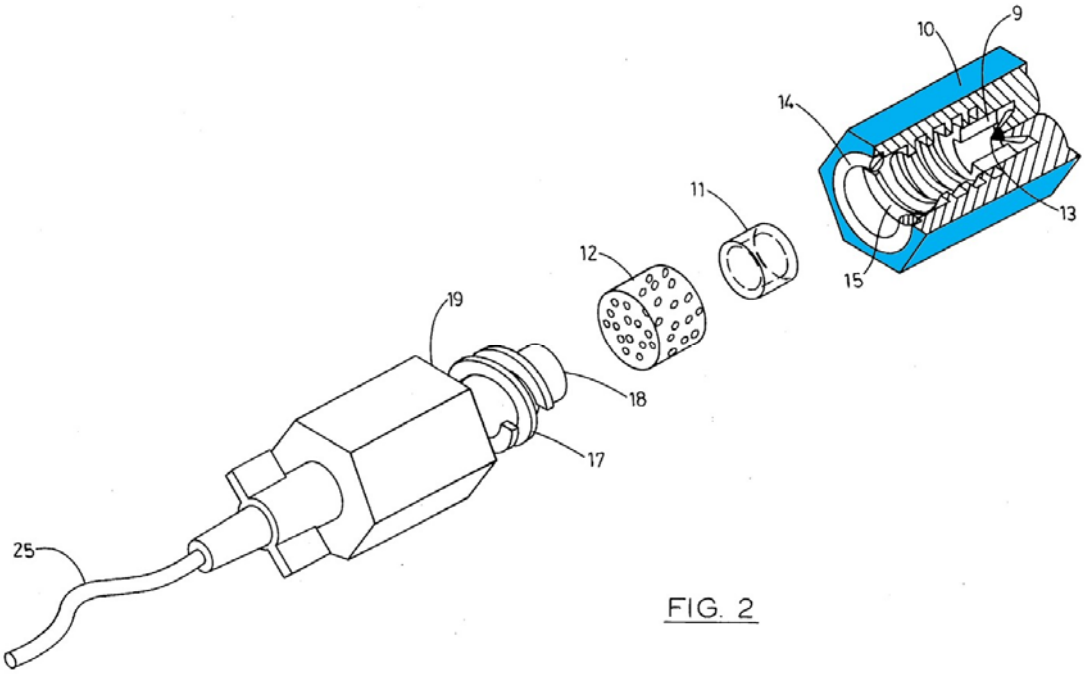



FIG. 2

*Genatempo* also discloses a cap (annotated in blue) with threading that engages with threading on a connector. (Ex. 1006, 3:37-39, Fig. 3; Ex. 1002, ¶¶34-35).

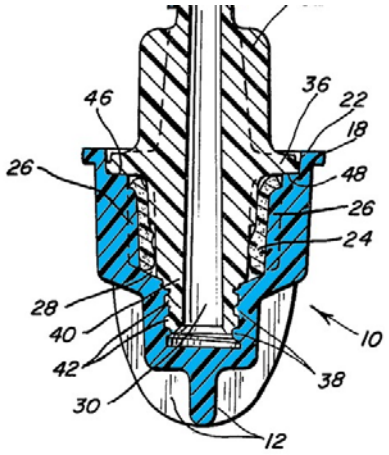



FIG. 3

### iii. Part [b]

Part [b] recites "a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve."

*Menyhay* discloses sponge 12, annotated in orange below, impregnated with antiseptic agents from capsule 11. (Ex. 1007, 6:64-7:3, Fig. 2; Ex. 1002, ¶32).

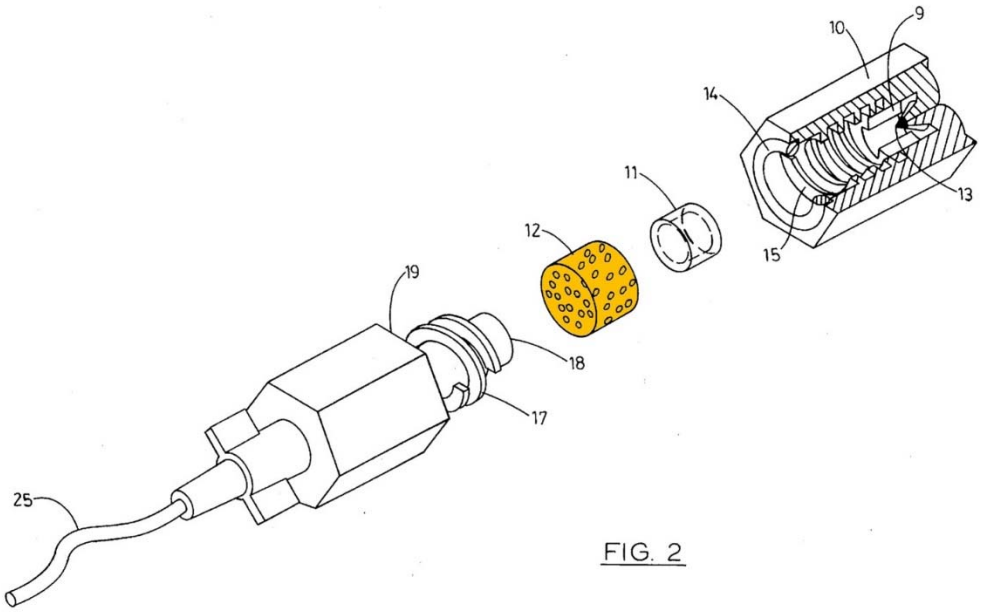



FIG. 2

*Genatempo* states that during the manufacture of cap 10, the pad is impregnated with the antiseptic before receiving connector 32. (Ex. 1006, 3:22-23, Fig. 3; Ex. 1002, ¶¶35-36). Before using protective cap 10 of *Genatempo*, removable lid 20 is removed, exposing the wet pad and antiseptic solution. (Ex. 1006, 2:64-68; Ex. 1002, ¶36).

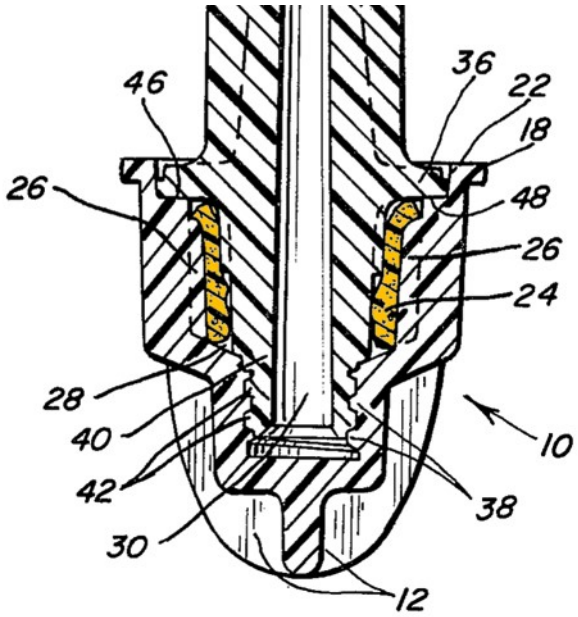



FIG. 3

A POSA would have been motivated to adopt the sealed cap structure of *Genatempo* to provide for a full wetting of the sponge within the cap at manufacture, as opposed to risking, with the configuration in *Menyhay*, that the sponge not become fully wetted in the time between breaking the seal and the disinfecting process. (Ex. 1002, ¶¶75-76; Ex. 1006, 1:44-52). Additionally, when the combination is made the solution in the pre-wetted sponge has a risk of spilling out and/or evaporating (Ex. 1006, 2:62-3:8), and the lid ensures that this does not occur. (Ex. 1002, ¶79).

**iv. Part [c]**

Part [c] recites "threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening."

*Menyhay* states that threads 17 engage with threads 15 to attach the two components. (Ex. 1007, 6:38-56, Figs. 2-3). The threads 15 of *Menyhay*, annotated in red below, are located near the opening of cap 10. (Ex. 1007, Fig. 2; Ex. 1002, ¶31).

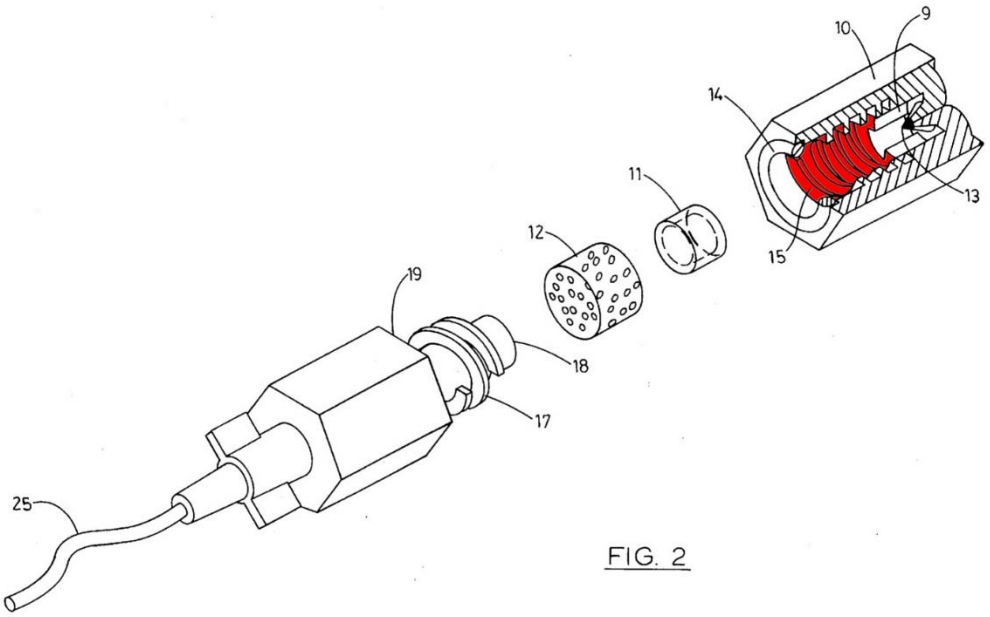



FIG. 2

*Genatempo* also discloses threads for engaging with a connector. (Ex. 1006, 2:21-24; Ex. 1002, ¶35).

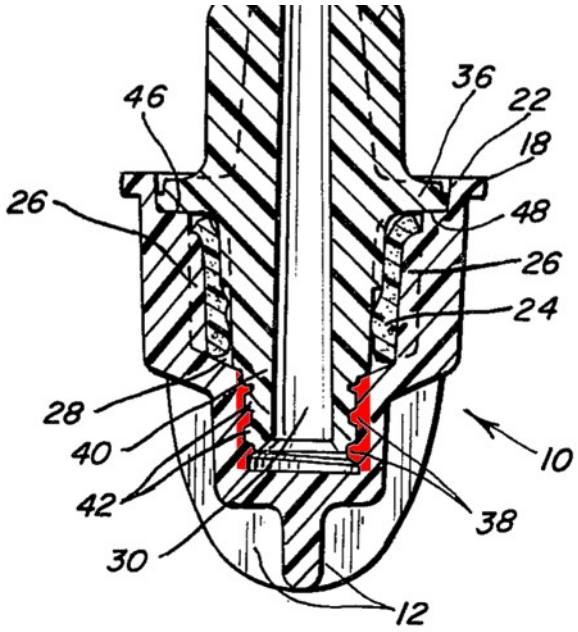
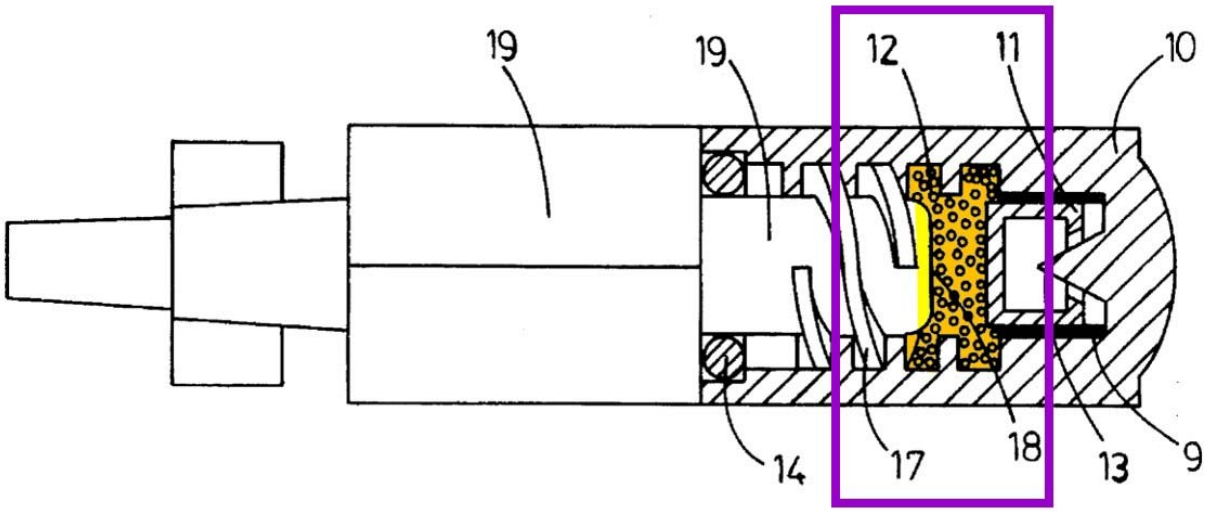



FIG. 3

**v. Part [c.i]**

Part [c.i] recites "the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve."

*Menyhay* states that threads 17 engage with threads 15 to attach the two components. (Ex. 1007, 6:38-56, Figs. 2-3; Ex. 1002, ¶¶31-32).



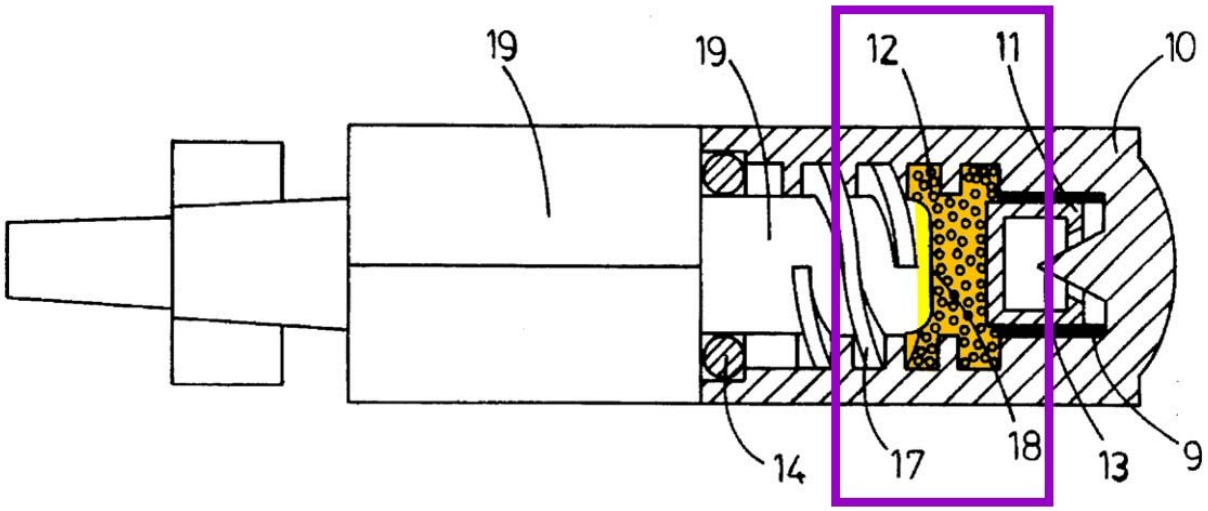

Further, when attached, sponge 12 (orange above) contacts septum 18 (yellow above), "aseptically bathing the port until the cover is removed," as shown in purple above. (Ex. 1007, 6:67-7:3; Fig. 3; Ex. 1002, ¶30).

**vi. Part [c.ii]**

Part [c.ii] recites "to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad." *Menyhay* discloses that the threading assists in disinfecting the end face of the septum. (Ex. 1007, 6:67-7:3; Ex. 1002, ¶32). *Genatempo* states that sponge 24 stores an antiseptic to provide an antimicrobial effect to the connector tube 40 and threads through migration of the antiseptic. (Ex. 1006, 3:42-45; Ex. 1002, ¶35).

### vii. Part [d]

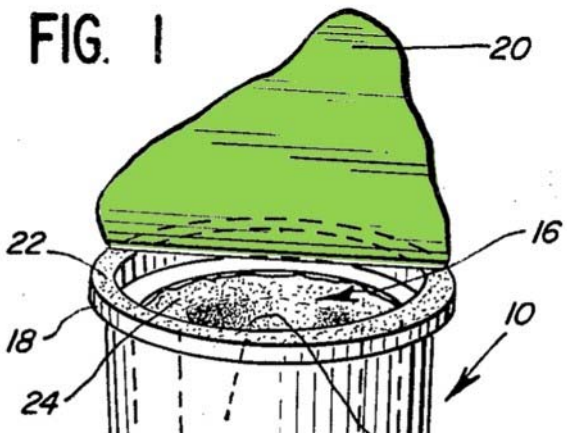
Part [d] recites "wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad." *Menyhay* discloses that the engagement between threads 17 and 15 cause the septum 18 to contact sponge 12, as shown in purple below. (Ex. 1007, 6:54-7:3, Figs. 2-3; Ex. 1002, ¶¶31, 79).




### viii. Part [e]

Part [e] recites "a removable lid attached to the opening of the housing enclosing the inner cavity to seal [the] inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve."

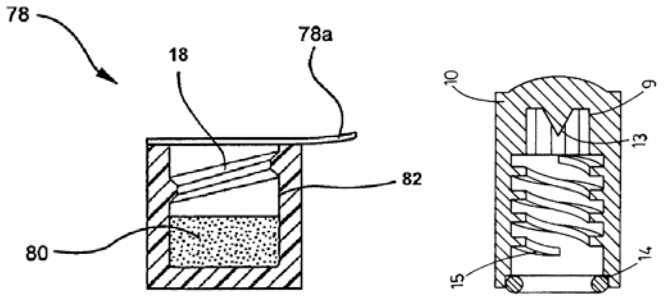
*Genatempo* discloses a peelable lid. (Ex. 1006, 2:63-66, Fig. 1). When the lid is completely closed, it seals the cap and prevents evaporation of the antibacterial agent until time for use. (Ex. 1006, 3:1-8; Ex. 1002, ¶¶36, 79).




**c. Claim 2**

Claim 2 adds the limitation "wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less than the inner circumference." The '864 Patent identifies no benefit from fixing the threading at "a length that is less than the inner circumference" of the inner cavity.

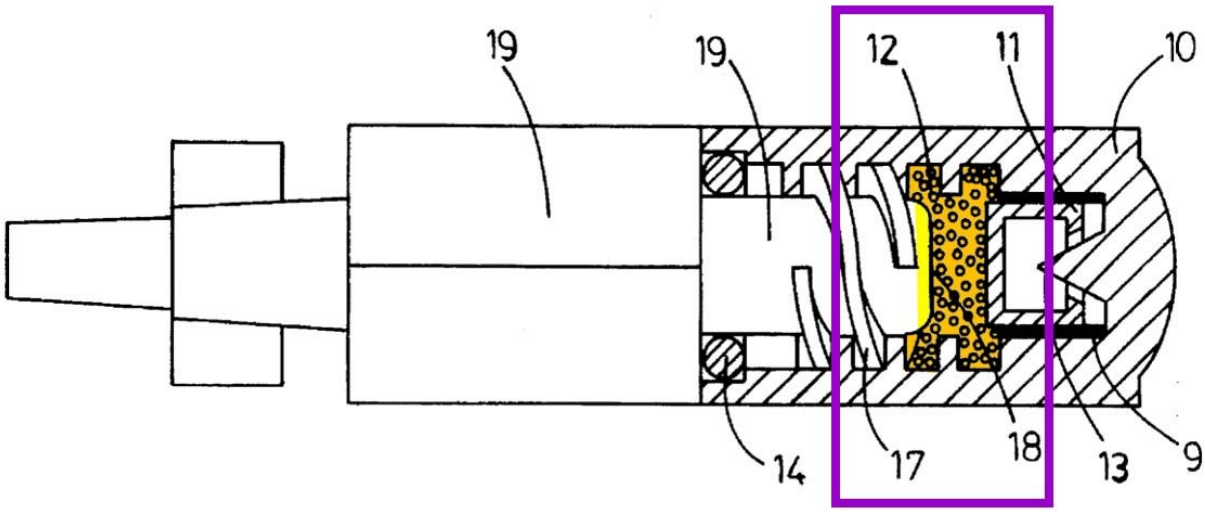
The claimed threading length, as depicted in the figures, closely mirrors that of the prior art references used herein. For example, the threading of Figure 10b of the '864 Patent completes one rotation, whereas the threading 15 of *Menyhay's* Figure 4 similarly completes 4 rotations. (*Compare* Ex. 1001, Fig. 10b *with* Ex. 1007, Fig. 4).




This election of size of the threading is only an unpatentable design choice. *See* MPEP 2144.04(IV)(A); *Gardner v. TEC Syst., Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830 (1984) (holding where the only difference between the prior art and the claims is a change in relative dimension, the claimed device with the change in relative dimension would not perform differently than the prior art and the claimed device is therefore not patentably distinct); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1570 (Fed. Cir. 1997) (the prior art cannot be held to a higher level of disclosure than the patent's specification). (Ex. 1002, ¶80).

**d. Claim 3**

Claim 3 adds the limitation "wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity." *Menyhay* states that cover 10 and port 19 threadingly engage. (Ex. 1007, 6:38-56, Figs. 2-3).




When tightened, the cap causes sponge 12 to contact septum 18 of the port. (Ex. 1007, 6:67-7:3). The threading of *Menyhay* provides for the advancement of septum 18 into cover 10, such that its position is based the engagement of the threading. (Ex. 1002, ¶¶32, 79).

**e. Claim 4**

Claim 4 adds the limitation to claim 3 "wherein adjustable positioning of the septum within the inner cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity." As set forth with regard to Part [b] of Claim 1 and Claim 3 above, *Menyhay* renders obvious the functionality of Claim 4. (Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1002, ¶¶32, 79).

**f. Claim 5**

Claim 5 adds the limitation "wherein the wet pad is a sponge." *Menyhay* discloses sponge 12 that is impregnated with antiseptic agents from capsule 11. (Ex. 1007, 6:64-7:3). As noted above, a POSA would have been motivated to preload *Menyhay's* sponge with *Genatempo's* liquid disinfectant. (Ex. 1002, ¶76).

**g. Claim 6**

Claim 6 adds the limitation "wherein the housing comprises a polyethylene or polypropylene material." *Genatempo* discloses the use of a thermoplastic in the production of its housing and *Menyhay* discloses the use of polynylon. (Ex. 1006, 3:19-21; Ex. 1007, 7:37-39; Ex. 1002, ¶36).

The '864 Patent identifies no specific benefit obtained by using "polyethylene or polypropylene," and indeed states that "Housing 12 is made from any of a number of types of plastic materials such as polycarbonate, polypropylene, polyethylene, glycol-modified polyethylene terephthalate, acrylonitrile butadiene styrene ***or any other moldable plastic material used in medical devices.***" (Ex. 1001, 2:12-17 (emphasis added)). The '864 Patent acknowledges that these plastics are known materials for manufacturing medical devices. (Ex. 1001, 2:12-17; Ex. 1002, ¶22). The known plastics of *Menyhay* and *Genatempo* render obvious the known plastics of the '864 Patent. The use of any of these materials does not render an otherwise unpatentable claim somehow patentable. *See KSR*, 550 U.S. at 420-21.

**h. Claim 7**

Claim 7 adds the limitation "wherein the cleaning solution comprises an antimicrobial agent." *Menyhay* and *Genatempo* both describe the use of antiseptics. (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23). A POSA would understand that an antiseptic is an antimicrobial. (Ex. 1002, ¶81; *Lockwood v. American Airlines, Inc.*, 107 F.3d at 1570).

**i. Claim 8**

Claim 8 adds the limitation to claim 7 "wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate." *Menyhay* and *Genatempo* both describe the use of povidone iodine. (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23). The '864 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad, including the claimed chlorhexidine and the povidone iodine of the prior art. (Ex. 1001, 2:49-54). A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents. (Ex. 1002, ¶¶81-84). As the '864 Patent confirms these were well known alternatives, a POSA would have found the selection of the claimed chlorhexidines to have been obvious. (Ex. 1002, ¶¶81-84, 87-91).

**j. Claim 9**

Claim 9 adds to claim 7 the limitation "wherein the cleaning solution is an alcohol-based cleaning solution." *Menyhay* teaches that the antiseptic solution

"contain[s] povidone iodine and isopropyl alcohol (an antiseptic, bactericidal and virucidal solution)." (Ex. 1007, 6:48-50).

**k. The Remaining Claims**

The following claim charts show how the combination of the *Menyhay* and *Genatempo* render the challenged claims obvious in the same manner as claim 1 and the claims depending therefrom.

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| 10 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum. | 1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising: | *See* Claim 1 [Preamble].<br><br>(Ex. 1007, 4:13-22, 6:53-57; Ex. 1006, 1:9-11; Ex. 1002, ¶¶30-31) |
| 10[a] a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity,<br><br>the housing including a thread on an inner wall of the cavity for engaging the external threads on the access | 1[a] a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve<br><br>1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, | *See* Claim 1[a], [c] & [d].<br><br>(Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1006, 1:21-24, 3:37-39, Fig. 3; Ex. 1002, ¶¶31-32, 34-35, 79) |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| portion of the patient fluid line access valve. | 1[d] wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad | |
| 10[b][4] a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve,<br><br>the wet pad being positioned within the cavity for contacting the end face to disinfect the end face | 1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve<br><br>1[c.i] the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion | *See* Claim 1[b], [c.i] & [c.ii].<br><br>(Ex. 1007, 6:38-56, Figs. 2-3, 6:64-7:3; Ex. 1006, 1:44-52, 2:64-68, 3:22-23, 3:42-45; Ex. 1002, ¶¶30-32, 35-36, 75-76) |

[4] Claim 10 states that "the wet pad...contact[]...at least a portion of the external threads" whereas claim 1 states the pad "contact...the end face of the access portion...to disinfect...at least a portion of the external threads." (Ex. 1001, Claims 1 and 10). As this ground has already been instituted for claim 10, the preliminary determination has been made that in the proposed combination of *Genatempo* and *Menyhay*, not only would the wet pad assist in disinfecting the external threads, but it would also contact at least a portion of those threads.

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| and at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion | of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve<br><br>1[c.ii] to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad | |
| 10[c] a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity so that the end face of the access portion contacts the wet pad | 1[e] a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve | *See* Claim 1[e].<br><br>(Ex. 1006, 2:63-66, 3:1-8, Fig. 1; Ex. 1002, ¶¶36, 79) |
| 11 The device of claim 10, wherein the cavity comprises an inner circumference and the thread | [2] wherein the inner cavity comprises an inner circumference and the threading comprises | *See* Claim 2.<br><br>(Ex. 1007, Fig. 4; Ex. 1002, ¶80) |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| comprises a length that is less than the inner circumference | a length that is less than the inner circumference. | |
| 12 The device of Claim 10, wherein the cleaning solution comprises an antimicrobial agent. | [7] wherein the cleaning solution comprises an antimicrobial agent | *See* Claim 7.<br><br>(Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23; Ex. 1002, ¶81) |
| 13 The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate. | [8] wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate | *See* Claim 8.<br><br>(Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23; Ex. 1002, ¶¶81-84, 87-91) |
| 14 The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution. | [9] wherein the cleaning solution is an alcohol-based cleaning solution | *See* Claim 9.<br><br>(Ex. 1007, 6:48-50). |
| 15 [Preamble] A device for maintaining a threaded patient fluid line access valve | 1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising: | *See* Claim 1 [Preamble].<br><br>(Ex. 1007, 4:13-22, 6:53-57; Ex. 1006, 1:9-11; Ex. 1002, ¶¶30-31) |
| 15[a] a housing having an inner cavity for covering an end face of the threaded | 1[a] a housing having an opening to an inner cavity for receiving the access portion of the | *See* Claim 1[a].<br><br>(Ex. 1007, 6:38-56, Fig. 2; Ex. 1006, 3:37-39, Fig. 3). |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| patient fluid line access valve | patient fluid line access valve | |
| 15[b] a wet pad within the housing and impregnated with a cleaning solution prior to contacting the threaded patient fluid line access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the threaded patient fluid line access valve to disinfect the end face and at least a portion of an external thread of the threaded patient fluid line access valve | 1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve<br><br>1[c.i] the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve<br><br>1[c.ii] to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad | *See* Claim 1[b], [c.i] & [c.ii].<br><br>(Ex. 1007, 6:38-56, Figs. 2-3, 6:64-7:3; Ex. 1006, 1:44-52, 2:64-68, 3:22-23, 3:42-45; Ex. 1002, ¶¶30-32, 35-36, 75-76) |
| 15[c] an internal thread within the inner cavity of the housing and positioned close to the wet pad for | 1[a] a housing having an opening to an inner cavity for receiving the access portion of the | *See* Claim 1[a], [c] & [d].<br><br>(Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1006, 1:21-24, 3:37-39, |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| engaging the external thread of the threaded patient fluid line access valve, whereby rotational movement of the external thread with respect to the internal thread causes the end face to advance into the inner cavity such that a septum of the end face contacts the wet pad. | patient fluid line access valve<br><br>1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening,<br><br>1[d] wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad | Fig. 3; Ex. 1002, ¶¶31-32, 34-35, 79) |
| 15[d] a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the threaded patient fluid line access valve, the lid being removable to allow the end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad. | 1[e] a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve | *See* Claim 1[e].<br><br>(Ex. 1006, 2:63-66, 3:1-8, Fig. 1; Ex. 1002, ¶¶36, 79) |
| 16 The device of claim 15, wherein the inner cavity comprises an inner circumference | [2] wherein the inner cavity comprises an inner circumference and the threading comprises | *See* Claim 2.<br><br>(Ex. 1002, ¶80) |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| and the internal thread comprises a length that is less than the inner circumference. | a length that is less than the inner circumference. | |
| 17 The device of claim 15, wherein the wet pad is a sponge. | [5] wherein the wet pad is a sponge. | *See* Claim 5.<br><br>(Ex. 1007, 6:64-7:3) |
| 18 The device of claim 15, wherein the housing comprises a polyethylene or polypropylene material. | [6] wherein the housing comprises a polyethylene or polypropylene material | *See* Claim 6.<br><br>(Ex. 1006, 3:19-21; Ex. 1007, 7:37-39; Ex. 1002, ¶36) |
| 19 The device of claim 15, wherein the cleaning solution is an alcohol-based cleaning solution. | [9] wherein the cleaning solution is an alcohol-based cleaning solution. | *See* Claim 9.<br><br>(Ex. 1007, 6:48-50). |

### D. Ground 2: Claims 8 and 13 are Obvious in Light of *Menyhay*, *Genatempo* and *Raad*

To the extent the Board finds that claims 8 and 13 would not have been obvious in view of *Menyhay* and *Genatempo* alone, the disclosure of *Raad* explicitly confirms that a POSA would have understood that the additional limitations of claims 8 and 13 are taught by that reference.

#### 1. Basis for Combination

A POSA would have known that povidone iodine (the antiseptic solution of the *Menyhay/Genatempo* combination described above) is a known alternative for chlorhexidine gluconate, such that they are interchangeable. (Ex. 1002, ¶¶86-91).

*Raad* discloses that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28). *Raad* also confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27). A POSA would understand that the povidone iodine of the *Menyhay/Genatempo* combination would be readily replaced with the chlorhexidine gluconate[5] solution of *Raad* with an expectation of success. (Ex. 1002, ¶¶88, 91).

*Genatempo* explains that the disclosed absorbent material retains an antiseptic and gives povidone iodine as an example. (Ex. 1006, 2:14-15). *Menyhay* also discloses the use of povidone iodine and isopropyl alcohol as an antiseptic. (Ex. 1007, 6:47-49). Each of *Menyhay* and *Genatempo* states that modifications to the disclosed invention (which a POSA would understand to include the selection of other, equally applicable antiseptic solutions (Ex. 1002, ¶¶87-91)), may be made

[5] A POSA would understand that chlorhexidine, the term used in *Raad*, is the active component of chlorhexidine gluconate and is a common way of referring to commercial antiseptic products containing chlorhexidine gluconate. (Ex. 1002, ¶87).

without deviating from the scope and spirit of the disclosure. (Ex. 1006, 8:4-9; Ex. 1007, 3:57-59).

Moreover, Exhibit 1015, which relates to cleaning medical devices that are likely to—or have already—become contaminated with microorganisms, confirms that those of skill in the art understood, in the prior art time frame, that one way of cleaning these devices' surfaces is with "antimicrobial agents or antimicrobial compositions." (Ex. 1015, 17:47-49). Ex. 1015 further lists povidone iodine and chlorhexidine as suitable alternatives for each other. (Ex. 1015, 17:47-67). These two antiseptic solutions are equally applicable as antimicrobials for medical devices. (Ex. 1002, ¶89).

Additionally, U.S. Patent No. 9,028,852 to Scholz ("*Scholz*"), filed on September 7, 2004 (over a year before the application leading to the '864 Patent was filed), confirms that *Raad* taught "chlorhexidine and its various salts including…diacetate" and gluconate, are an improvement over povidone-iodine. (Ex. 1012, 3:55-67, 15:35-41; Ex. 1002, ¶¶59-60).

Finally, Exhibit 1017 further confirms that POSAs knew that chlorhexidine gluconate solutions may be used to clean needle-less connectors. (Ex. 1017, 1; Ex. 1002, ¶90). Exhibit 1017 is particularly relevant as it describes work funded by an affiliate of the Patent Owner in the prior art time frame, yet was not disclosed during examination of the '864 Patent. (Ex. 1017, 2 ("this work was supported by an

education grant from Becton Dickinson, UK")). A POSA would know that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions. (Ex. 1002, ¶90).

A POSA would have understood that the known antiseptic solution of *Raad*, which constitutes well-studied ingredients and combinations in the medical field, would have been readily used as a known replacement in *Menyhay* and *Genatempo* individually, as well as in the combination resulting from the two. (Ex. 1002, ¶91). The composition of *Raad* would perform in a predictable manner to yield predictable results when incorporated, confirms that this claim litigation is the substitution of known components performing the same benefit as in *Raad*. (Ex. 1002, ¶¶87-91; *KSR*, 550 U.S. at 416-17 (2007)).

**2. Claim 8**

As discussed above, the combination of *Menyhay* and *Genatempo* by itself renders claim 7 obvious. *Raad* further confirms that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28; Ex. 1002, ¶87). Moreover, *Raad* confirms that chlorhexidine and povidone iodine (the additional limitations of claim 8) are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as a medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶88, 91).

#### 3. Claim 13

For at least the reasons set forth with regard to claim 8, the combination of *Menyhay*, *Genatempo*, and *Raad* render this claim obvious. (Ex. 1016, ¶¶26-28, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶88, 91).

### E. Ground 3: Claims 2, 11, and 16 are Obvious in Light of *Menyhay*, *Genatempo* and *Miyahara*.

#### 1. Basis for Combination

A POSA would have been motivated to modify the afore-described *Menyhay/Genatempo* combination in view of the disclosure of *Miyahara* in recognition of the fact that a single-turn threading arrangement is within the knowledge of a POSA. (Ex. 1002, ¶¶92-95). *Miyahara* discloses that a disinfecting and protective cap may be securely adhered to a connector with a rotation that is less than one full rotation of the cap, confirming that the threading in the aforementioned combinations may be sized to have a length less than the internal circumference of the cap. (Ex. 1009, ¶¶55-56, Fig. 3).

A POSA would understand that the length of the threads of the *Menyhay*/*Genatempo* combination would be modifiable to a variety of lengths as dictated by the specific circumstances of an application. (Ex. 1002, ¶¶92-95). In particular, because of the seal in that combination, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal already provides this

function. (Ex. 1002, ¶94). A POSA would also understand that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector. (Ex. 1002, ¶04). A reduced number of rotations makes the product easier to use for patients and health care providers. (Ex. 1002, ¶94).

*Miyahara* depicts guide protrusion 42, which mates with guide groove 13, and the screw action generated between the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶¶55-56, Fig. 3). *Miyahara* confirms that a rotational distance greater than the inner circumference of the inner cavity is not necessary for advancement, and that sufficient cleaning can occur with threading that is shorter (and therefore requiring less rotational movement) than the internal circumference. (Ex. 1002, ¶95).

The rotational distance required by *Miyahara* would suggest to a POSA that shorter threads should be used in the combination of *Menyhay*/*Genatempo* to reduce the number of rotations necessary to fully adhere the cap to the patient access line. (Ex. 1002, ¶95).

**2. Claim 2**

As discussed above, claim 1 is obvious in view of *Menyhay* and *Genatempo*. *Miyahara* depicts guide protrusion 42 which mates with guide groove 13, and the screw action generated between the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶¶55-56). *Miyahara* confirms that a rotational

distance greater than the inner circumference of the inner cavity is not necessary for advancement or for coupling, and that sufficient cleaning can occur with threading that is shorter (and therefore requiring less rotational movement) than the internal circumference. (Ex. 1002, ¶¶44, 95). As such, the selection of the length of threading in the combination of *Menyhay* and *Genatempo* is a design choice, as evidenced by *Miyahara*.

#### 3. Claim 11

As discussed above with regard to claim 2, *Menyhay*, *Genatempo* and *Miyahara* render obvious this limitation. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 95).

#### 4. Claim 16

As discussed above with regard to claim 2, *Menyhay*, *Genatempo* and *Miyahara* render obvious this limitation. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 95).

### F. Ground 4: Challenged Claims are Obvious in Light of *Connell*, *Raulerson,* and *Genatempo*.

*Connell* and *Raulerson* were not considered during prosecution, and, while *Genatempo* was considered, it was not considered in view of *Connell* and *Raulerson,* or in the context of the testimony of Mr. Meyst.

#### 1. Basis for Combination

The controlling case law on combination is set forth above in Section VII.C.1. *Connell* identifies the same problem and solution as that of the '864 Patent, noting

that disinfecting connectors is essential, but contamination occurred with the then-existing methods and proposes the use of a cap. (Ex. 1010, ¶¶10-11, 15-25; Ex. 1002, ¶¶49, 53). This is precisely the same solution to the same problem addressed by the '864 Patent—an "effective and inexpensive way to reduce catheter-related infections" taking the form of "a housing for covering the access portion of the access valve," (e.g., a cap). (Ex. 1001, 1:25-40).

*Connell* provides a fluid connector cleaner that provides sealed disinfectant to clean the threading of the connector. (Ex. 1010, ¶¶101-103; Ex. 1002, ¶97). *Connell* confirms that it was known to use a cap that threadingly mates with a connector to protect and clean a patient tube. (Ex. 1010, ¶100; Ex. 1002, ¶97). *Connell* further discusses the threading advancement of the cap onto the connector. (Ex. 1010, ¶¶77-80; Ex. 1002, ¶97).

*Raulerson* teaches a scrubbing mechanism that uses rotational energy (such as that produced by a threading engagement or other twisting motion) to clean the threading of a connector. (Ex. 1011, ¶4; Ex. 1002, ¶¶97-98). A POSA would have understood the value of a contact cleaning device (such as a sponge or bristles), as it ensures sufficient distribution of a liquid cleaner on all surfaces. (Ex. 1002, ¶¶97-98).

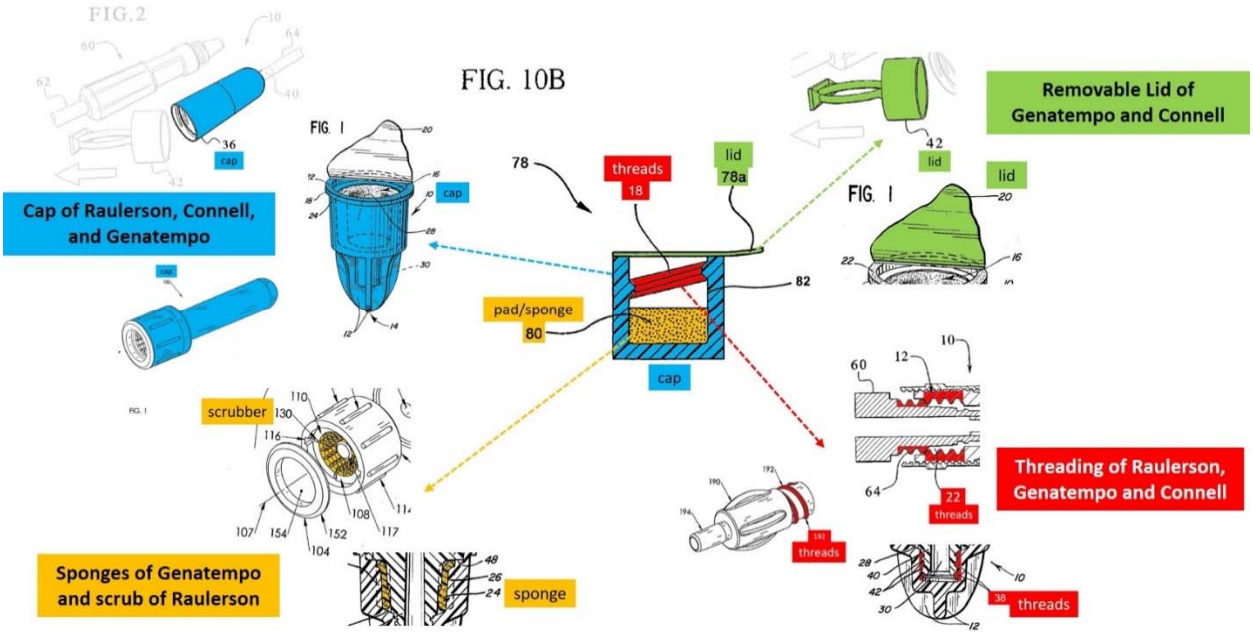
*Connell* and *Raulerson* disclose either a small sealed portion with disinfectant (Ex. 1010, ¶100), or a separate squeezable body for the release of cleaning solution

(Ex. 1011, ¶31). A POSA would understand that the use of a pre-impregnated absorbent material, such as that of *Genatempo* (Ex. 1006, Abstract), would provide the added benefit of ensuring sufficient wetting of the sponge in advance. (Ex. 1002, ¶99). As discussed above, in such a combination, there would be no dry spots or other infirmities associated with a failure to break the seal. (Ex. 1002, ¶99).

*Genatempo* also confirms that additional cleaning due to the migration of the antiseptic fluid can be achieved. (Ex. 1006, 3:43-45; Ex. 1002, ¶99). By adopting the pre-impregnated sponge of *Genatempo*, as previously discussed, a POSA would understand that additional liquid can be provided, sufficient to, when the sponge is compressed, release liquid to flow throughout the threading portions of the coupling. (Ex. 1002, ¶99). Relatedly, *Genatempo* describes the use of a removable lid, which a POSA would recognize as necessary to ensure that *Genatempo's* pre-impregnated sponge does not dry out or expel its liquid prematurely. (Ex. 1002, ¶99).

In short, the Challenged Claims are nothing more than an arrangement of old elements, "with each [element] performing the same function it had been known to perform" and yield "no more than one would expect from such an arrangement." *KSR*, 550 U.S. at 417. Because the claimed components in the '864 Patent are mechanical in nature, and each performs a similar function in the claimed combination as it did in the subject prior art references, a POSA would have made

the prior art combination in this challenge ground with an expectation of success. (Ex. 1002, ¶105).




(Ex. 1002, ¶100).

In the above exemplary illustrative representation of the subject prior art combination, a connector includes external threads (annotated in red) to, *inter alia*, permit threading engagement between an access end of the connector and a disinfectant cap (annotated in blue), and that the cap would include a wetted-sponge (annotated in orange) and a sealable peelable lid (annotated in green). (*See e.g.*, Ex. 1010, ¶¶77-78; Ex. 1002, ¶100).

The sponge of this combination would be impregnated with an antiseptic cleaning solution. (*See e.g.*, Ex. 1006, 3:22-23, Fig. 3; Ex. 1011, ¶4, Fig. 3; Ex. 1002, ¶100). Additionally, in the resulting combination, the cap would include

threading to engage with the threading of the connector. (*See e.g.*, Ex. 1010, ¶¶77-78; Ex. 1002, ¶100). The threading causes the advancement of the connector into the cap when rotated, and the rotation causes cleaning of the threads and septum at the end of the connector cap through the advancement of the face into the wetted sponge. (*See e.g.*, Ex. 1010, ¶¶77-78, 80, 101-103, Fig. 5; Ex. 1002, ¶100). Additionally, the cap would include a peelable lid to ensure that the solution did not prematurely evaporate or become contaminated prior to use. (*See e.g.*, Ex. 1006, 2:63-66, Fig. 1; Ex. 1010, ¶¶14-15, 68, Fig. 2; Ex. 1002, ¶100).

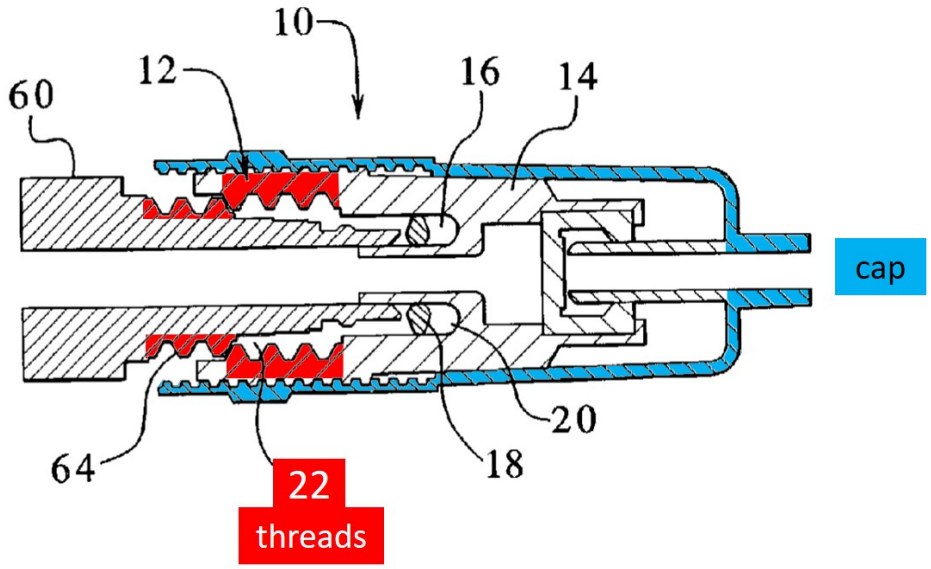
**2. The Challenged Claims are Obvious**

**a. Claim 1 and the Claims Depending Therefrom**

**i. Preamble**

*Connell* describes a connector and a cap for disinfecting the system. (Ex. 1010, ¶66; Ex. 1002, ¶46). Cap 12 includes a body 14 that defines a receptacle 16. (Ex. 1010, ¶71). Seal 18 encloses receptacle 16 and can be made of solid or sponge rubber impregnated with disinfectant. (Ex. 1010, ¶¶71-72). Seal 18 may be a thin or frangible barrier that is designed to rupture. (Ex. 1010, ¶74). Body 14 further defines housing 28, which is sized to hold septum 30. (Ex. 1010, ¶80). Additionally, the two separate members move relative each other by engaging threads of the other member (e.g., threads 22 and 24). (Ex. 1010, ¶77).

FIG.4



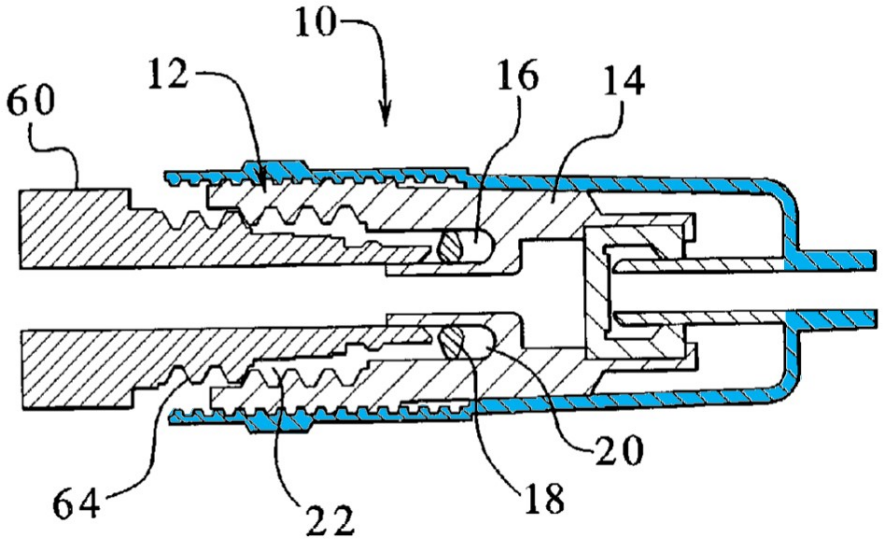

(Ex. 1010, Fig. 4, ¶100).

*Genatempo* also discloses "a protective cap for a medical connector…which provides an antibacterial effect." (Ex. 1006, 1:9-11). *Raulerson* describes a luer cleaner that engages with and scrubs the outer surface of a luer connector, including the threading. (Ex. 1011, ¶4).

**ii. Part [a]**

As depicted in Figure 4, *Connell* discloses a cleaning cap that can be used to disinfect connector 60. (Ex. 1010, ¶¶101-104, Fig. 4; Ex. 1002, ¶53).

FIG.4




Similarly, *Raulerson* discloses a luer cleaner 100 that is to be inserted over an end of a luer connector 190. (Ex. 1011, ¶14, Fig. 1; Ex. 1002, ¶56).

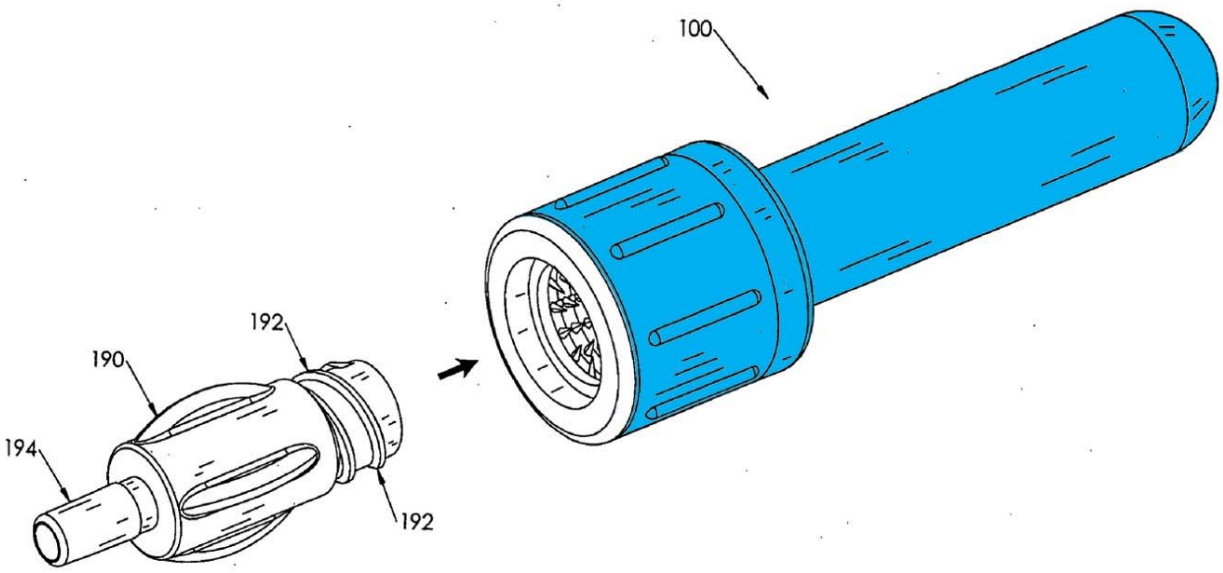



FIG. 1

(*Id.*)

The relevant disclosure of *Genatempo* is described in connection with claim 1[a] in the first challenge ground. (Ex. 1006, 3:37-39, Fig. 3).

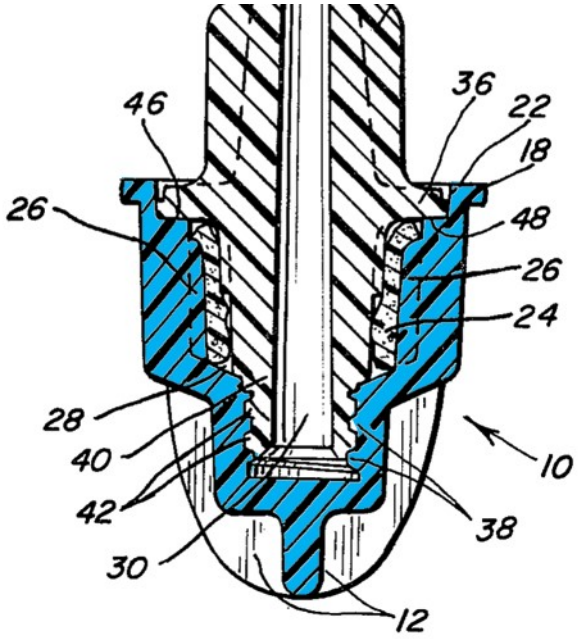



FIG. 3

**iii. Part [b]**

*Connell* discloses that seal 18 may seal disinfectant in receptacle 16. (Ex. 1010, ¶72, Fig. 4; Ex. 1002, ¶53). *Raulerson* discloses a plurality of brushes long enough to engage with the luer connector inserted therein. (Ex. 1011, ¶¶4, 21, 31, Fig. 2; Ex. 1002, ¶57). The antiseptic liquid of *Raulerson* is contained within bulb 160 until after luer 190 is fully inserted. (Ex. 1011, ¶31).

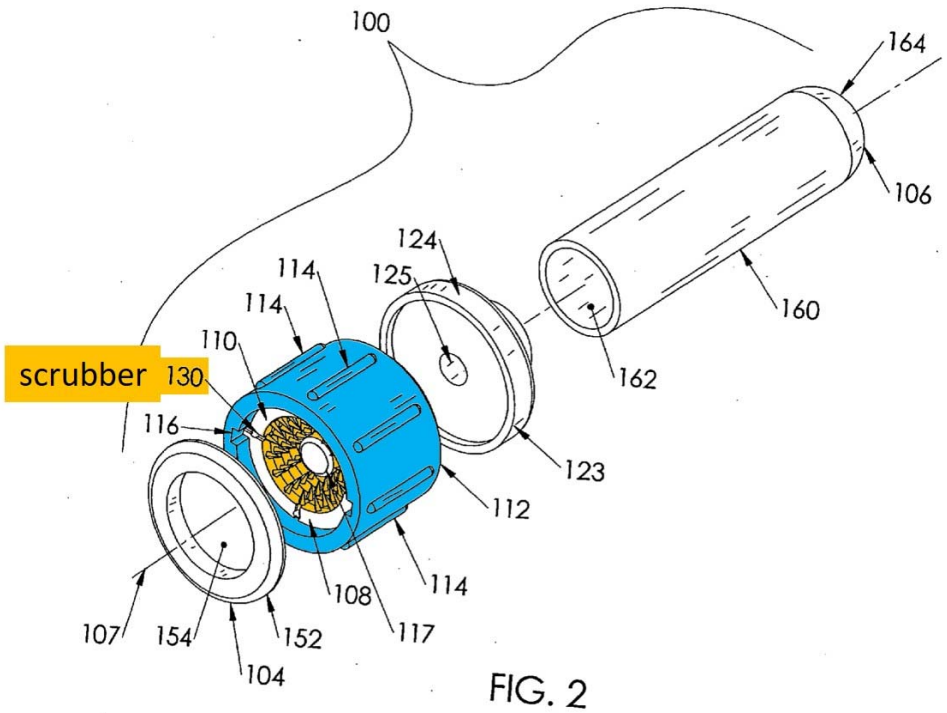



FIG. 2

(Ex. 1011, Fig. 2).

*Genatempo* states that during the manufacture of cap 10, sponge 24 (in orange below) is wetted such that the pad is impregnated with the antiseptic before receiving connector 32. (Ex. 1006, 3:22-23).

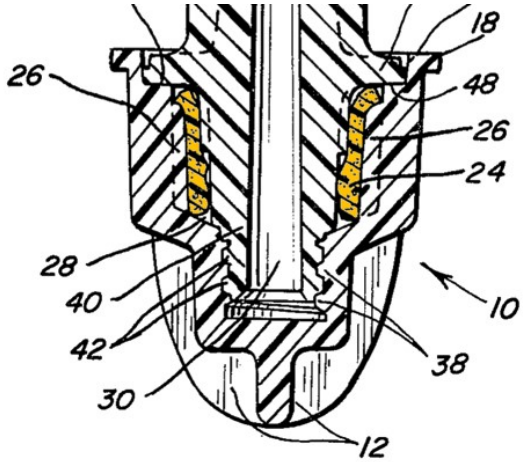


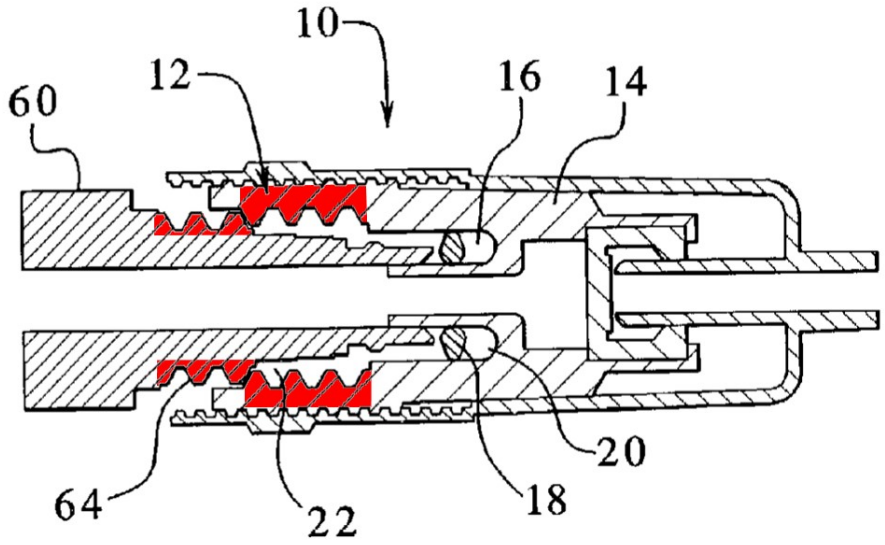

FIG. 3

Before using protective cap 10 of *Genatempo*, removable lid 20 is removed, exposing the wet pad and antiseptic solution. (Ex. 1006, 2:64-68). *Genatempo* suggests that a POSA would have been motivated to adopt a sealed cap structure which would have provided for a full wetting of the sponge within the cap at manufacture as opposed to hoping that the sponge became fully wetted in the time between breaking and the cleaning process as well as ensuring that no liquid is accidentally spilled. (Ex. 1002, ¶¶99-100; Ex. 1006, 1:44-52).

**iv. Part [c]**

*Connell* discloses threading 22 that extends inward from the housing 10 that engages with external threading 64 of connector 60. (Ex. 1010, ¶¶101-103, Figs. 4-7).

FIG.4



The relevant portions of *Genatempo* are set forth in connection with Claim 1[c] in the first challenge ground, and specifically describing the threading 38 of cleaning cap 10. (Ex. 1006, 2:21-24; Ex. 1002, ¶35).

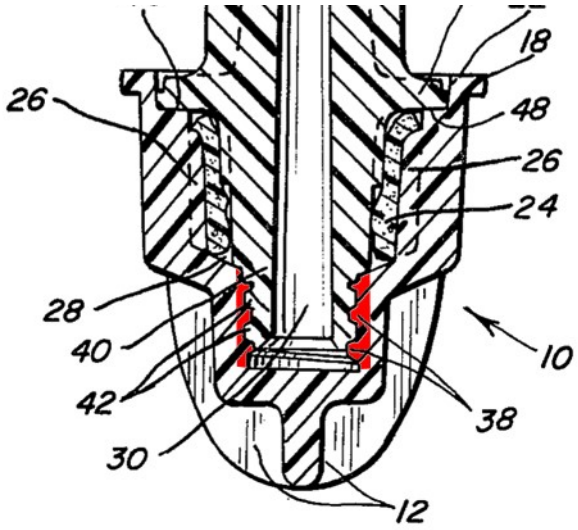



FIG. 3

**v. Part [c.i]**

The threading of *Genatempo*, as set forth in connection with claim 1[c], and *Connell* are each configured to engage with threading of a patient line connector. (Ex. 1006, 2:21-24; Ex. 1002, ¶35; Ex. 1010, ¶¶77-78, 115, Figs. 4-7). When the resulting combination is connected, the cleaning action of *Raulerson*—rotation to clean and scrub the connector—cleans the end face (the proximal end of the luer where the septum in the combination would reside). (Ex. 1011, ¶¶4, 31; Ex. 1002, ¶100).

**vi. Part [c.ii]**

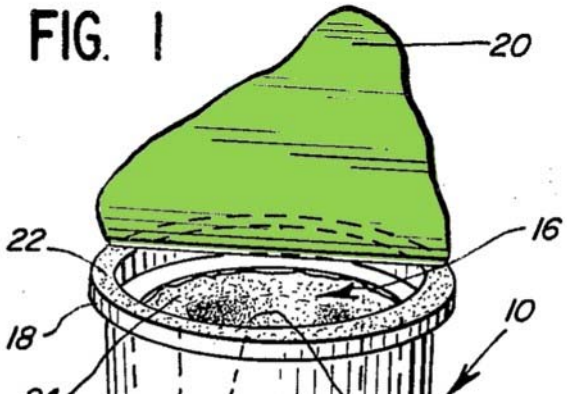
The relevant portions of *Genatempo* are set forth in connection with Claim 1[c.ii] in the first challenge ground. (Ex. 1006, 3:42-45; Ex. 1002, ¶35). *Raulerson* similarly discloses the scrubbing is to clean the luer, and provides examples of known disinfectants as the cleaning solution. (Ex. 1011, ¶¶29, 31).

**vii. Part [d]**

*Connell* states that the connector and cap are threadingly connected. (Ex. 1010, ¶101, Figs. 4-7). The resulting combination would include this threading advancement of *Connell* that causes the septum to contact the wetted sponge of the resulting combination. (Ex. 1002, ¶102).

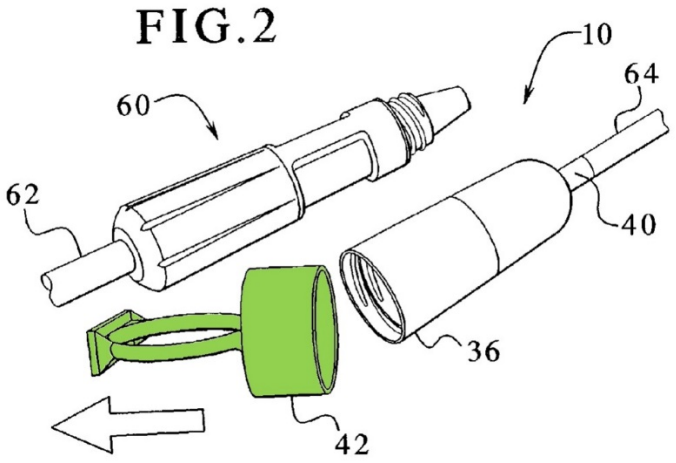
**viii. Part [e]**

*Genatempo* discloses a peelable lid. (Ex. 1006, 2:63-66, Fig. 1).



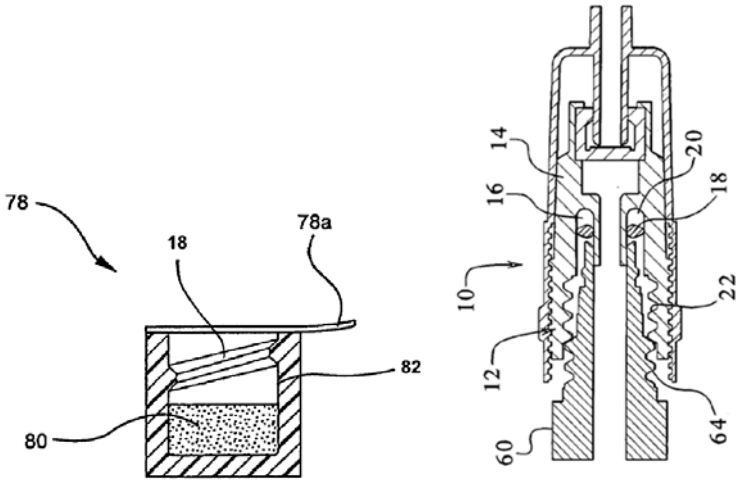

*Raulerson* describes removable cap 152 that seals luer cleaner 100 before use. (Ex. 1011, ¶27). Similarly, *Connell* describes a lid to seal the cleaning solution

within a portion of the inner cavity. (Ex. 1010, ¶74). Additionally, *Connell* discloses tip protector 42, a removable cover for connector 10. (Ex. 1010, ¶¶87-88, Fig 2).




**b. Claim 2**

The '864 Patent teaches no benefit from fixing the threading at "a length that is less than the inner circumference" of the inner cavity. The claimed threading length, as depicted in the figures, closely mirrors that of the prior art references used herein. For example, the threading of Figure 10b of the '864 Patent completes one rotation, whereas the threading 22 of *Connell's* Figure 4 similarly completes 4 rotations. (*Compare* Ex. 1001, Fig. 10b *with* Ex. 1010, Fig. 4).




A POSA would recognize that the selection of the threading distance does not provide a patentable distinction and the modification of the prior art to arrive at the claimed length is nothing more than routine optimization. (Ex. 1002, ¶101; *See* MPEP 2144.04(IV)(A); *Gardner v. TEC Syst., Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830 (1984)).

**c. Claim 3**

*Connell* describes the claimed threaded advancement of Claim 3. (Ex. 1010, ¶101, Figs. 4-7; Ex. 1002, ¶97).

**d. Claim 4**

The advancement of *Connell* (Ex. 1010, ¶101, Figs. 4-7), in combination with the wet pad of *Genatempo* (absorbent material 24) and the scrubbing/septum arrangement of *Raulerson* (Ex. 1011, ¶¶94, 115-118), render this claim obvious. (Ex. 1002, ¶100).

**e. Claim 5**

*Genatempo* teaches the use of absorbent materials and sponges in connector cleaners. (Ex. 1007, Claim 11, 3:41-45).

**f. Claim 6**

*Connell* teaches that device components may be made of known medical device grade plastics including polyethylene or polypropylene. (Ex. 1010, ¶68).

**g. Claim 7**

*Connell* discloses the use of iodine-containing antimicrobials as a disinfectant. (Ex. 1010, ¶76). *Raulerson* discloses antiseptic fluids, for example an isopropyl alcohol, povidone iodine, or hydrogen peroxide, but recognizes any suitable fluid may be used. (Ex. 1011, ¶29). The relevant portions of *Genatempo* are set forth in connection with claim 7 in the first challenge ground. (*See* Section VII.C.2.h). A POSA would understand that an antiseptic is an antimicrobial. (Ex. 1002, ¶102).

**h. Claim 8**

*Genatempo* describes the use of povidone iodine. (Ex. 1006, 3:22-23). *Raulerson* discloses the use of alcohols, povidone iodine, or hydrogen peroxide, but recognizes any suitable fluid may be used. (Ex. 1011, ¶29). *Connell* similarly discloses the use of povidone iodine as a disinfectant. (Ex. 1010, ¶¶75-76). The '864 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad, including the claimed chlorhexidine and the povidone iodine of the prior art.

(Ex. 1001, 2:49-54) A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents. (Ex. 1002, ¶¶102-104). As the '864 Patent confirms these were well known alternatives, a POSA would have found the selection of the claimed chlorhexidines to have been obvious. (Ex. 1002, ¶¶102-104, 107-111).

**i. Claim 9**

*Raulerson* discloses antiseptic fluids, for example an isopropyl alcohol, but recognizes any suitable fluid may be used. (Ex. 1011, ¶29).

**j. The Remaining Claims**

The following claim charts show how this prior art combination renders the challenged claims obvious in the same manner as claim 1 and the claims depending therefrom.

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| 10 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum. | 1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising: | *See* Claim 1 [Preamble].<br><br>(Ex. 1010, ¶¶66, 71, 74, 77, 80, 100, Fig. 4; Ex. 1006, 1:9-11; Ex. 1011, ¶4; Ex. 1002, ¶46). |
| 10[a] a housing for covering the access | 1[a] a housing having an opening to an inner | *See* Claim 1[a], [c] & [d]. |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity,<br><br>the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the patient fluid line access valve. | cavity for receiving the access portion of the patient fluid line access valve<br><br>1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening,<br><br>1[d] wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad | (Ex. 1010, ¶¶101-104, Figs. 4-7; Ex. 1011, ¶14, Fig. 1; Ex. 1006, 3:37-39, Fig. 3; Ex. 1002, ¶¶35, 53, 56-57, 99-102). |
| 10[b] a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve,<br><br>the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line | 1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve<br><br>1[c.i] the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access | *See* Claim 1[b], [c.i] & [c.ii].<br><br>(Ex. 1010, ¶72; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 3:22-23; Ex. 1002, ¶¶35, 53, 57, 99-100) |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| access valve when the housing is positioned over and covers the access portion | portion of the patient fluid line access valve<br><br>1[c.ii] to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad | |
| 10[c] a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity so that the end face of the access portion contacts the wet pad | 1[e] a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve | *See* Claim 1[e].<br><br>(Ex. 1006, 2:63-66, Fig. 1; Ex. 1011, ¶27; Ex. 1010, ¶¶74, 87-88, Fig 2). |
| 11 The device of claim 10, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference | [2] wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less than the inner circumference. | *See* Claim 2.<br><br>(Ex. 1002, ¶101). |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| 12 The device of Claim 10, wherein the cleaning solution comprises an antimicrobial agent. | [7] wherein the cleaning solution comprises an antimicrobial agent | *See* Claim 7.<br><br>(Ex. 1010, ¶76; Ex. 1011, ¶29; Ex. 1002, ¶102). |
| 13 The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate. | [8] wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate | *See* Claim 8.<br><br>(Ex. 1006, 3:22-23; Ex. 1011, ¶29; Ex. 1010, ¶¶75-76; Ex. 1002, ¶¶102-104, 107-111). |
| 14 The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution. | [9] wherein the cleaning solution is an alcohol-based cleaning solution | *See* Claim 9.<br><br>(Ex. 1011, ¶29). |
| 15 [Preamble] A device for maintaining a threaded patient fluid line access valve | 1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising: | *See* Claim 1 [Preamble].<br><br>(Ex. 1010, ¶¶66, 71, 74, 77, 80, 100, Fig. 4; Ex. 1006, 1:9-11; Ex. 1011, ¶4; Ex. 1002, ¶46). |
| 15[a] a housing having an inner cavity for covering an end face of the threaded patient fluid line access valve | 1[a] a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve | *See* Claim 1[a].<br><br>(Ex. 1010, ¶¶101-104, Figs. 4-7; Ex. 1011, ¶14, Fig. 1; Ex. 1006, 3:37-39, Fig. 3; Ex. 1002, ¶¶35, 53, 56-57, 99-102). |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| 15[b] a wet pad within the housing and impregnated with a cleaning solution prior to contacting the threaded patient fluid line access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the threaded patient fluid line access valve to disinfect the end face and at least a portion of an external thread of the threaded patient fluid line access valve | 1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve<br><br>1[c.i] the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve<br><br>1[c.ii] to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad | *See* Claim 1[b], [c.i] & [c.ii].<br><br>(Ex. 1010, ¶72; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 3:22-23; Ex. 1002, ¶¶35, 53, 57, 99-100) |
| 15[c] an internal thread within the inner cavity of the housing and positioned close to the wet pad for engaging the external thread of the threaded patient fluid line | 1[a] a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve | *See* Claim 1[a], [c] & [d].<br><br>(Ex. 1010, ¶¶101-104, Figs. 4-7; Ex. 1011, ¶14, Fig. 1; Ex. 1006, 3:37-39, Fig. 3; Ex. 1002, ¶¶35, 53, 56-57, 99-102). |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| access valve, whereby rotational movement of the external thread with respect to the internal thread causes the end face to advance into the inner cavity such that a septum of the end face contacts the wet pad. | 1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening,<br><br>1[d] wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad | |
| 15[d] a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the threaded patient fluid line access valve, the lid being removable to allow the end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad. | 1[e] a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve | *See* Claim 1[e].<br><br>(Ex. 1006, 2:63-66, Fig. 1; Ex. 1011, ¶27; Ex. 1010, ¶¶74, 87-88, Fig 2). |
| 16 The device of claim 15, wherein the inner cavity comprises an inner circumference and the internal thread comprises a length that | [2] wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less than the inner circumference. | *See* Claim 2.<br><br>(Ex. 1002, ¶101). |

| Claim Limitation | Already Discussed Claim Language | Prior Art Teaching |
|---|---|---|
| is less than the inner circumference. | | |
| 17 The device of claim 15, wherein the wet pad is a sponge. | [5] wherein the wet pad is a sponge. | *See* Claim 5.<br><br>(Ex. 1007, Claim 11, 3:41-45). |
| 18 The device of claim 15, wherein the housing comprises a polyethylene or polypropylene material. | [6] wherein the housing comprises a polyethylene or polypropylene material | *See* Claim 6.<br><br>(Ex. 1010, ¶68). |
| 19 The device of claim 15, wherein the cleaning solution is an alcohol-based cleaning solution. | [9] wherein the cleaning solution is an alcohol-based cleaning solution. | *See* Claim 9.<br><br>(Ex. 1011, ¶29). |

### G. Ground 5: Claims 8 and 13 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Connell*, *Raulerson*, *Genatempo,* and *Raad*.

To the extent the Board finds that claims 8 and 13 would not have been obvious in view of *Connell*, *Raulerson*, and *Genatempo*, the disclosure of *Raad* explicitly teaches the additional limitations of claims 8 and 13.

#### 1. Basis for Combination

A POSA would have understood that the antiseptic solution of the *Connell*, *Raulerson*, and *Genatempo*, the povidone iodine described above, was a well-known alternative to chlorhexidine gluconate. (Ex. 1002, ¶¶107-108). *Raad* discloses that then-known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28). *Raad* also confirms that chlorhexidine and povidone iodine are known

alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as a medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27). A POSA would understand that the povidone iodine of the *Connell*/ *Raulerson/Genatempo* combination would be readily replaced with the chlorhexidine gluconate[6] solution of *Raad* with an expectation of success. (Ex. 1002, ¶¶106-108).

*Raulerson* states that, while certain solutions were explicitly identified, other fluids may be used. (Ex. 1011, ¶29). Similarly, *Connell* discloses that other disinfectants may be used. (Ex. 1010, ¶¶75-76). *Genatempo* explains that the disclosed absorbent material retains an antiseptic and gives an example as povidone iodine. (Ex. 1006, 2:14-15). Each of *Connell*, *Raulerson* and *Genatempo* states that modifications to their respective disclosed inventions may be made without deviating from the scope and spirit thereof. (Ex. 1006, 8:4-9; Ex. 1010, ¶109; Ex. 1011, ¶36).

Moreover, Exhibit 1015, which relates to cleaning medical devices that are likely to—or have already—become contaminated with microorganisms, confirms that one way of cleaning these devices surfaces is with "antimicrobial agents or

[6] A POSA would understand that chlorhexidine, the term used in *Raad*, is a common way of referring to chlorhexidine gluconate. (Ex. 1002, ¶107).

antimicrobial compositions." (Ex. 1015, 17:47-49). Exhibit 1015 further lists povidone iodine and chlorhexidine as suitable alternatives for each other. (Ex. 1015, 17:47-67). These two antiseptic solutions are equally applicable as antimicrobials for medical devices. (Ex. 1002, ¶109).

Additionally, *Scholz* confirms that chlorhexidine diacetate and gluconate are an improvement over povidone-iodine. (Ex. 1012, 3:55-67, 15:35-41). Finally, Exhibit 1017 confirms that chlorhexidine gluconate solutions may be used to clean needleless connectors. (Ex. 1017, 1). Exhibit 1017 further describes work funded by the Patent Owner (or related affiliate) dating back to 2002. (Ex. 1017, 2 ("this work was supported by an education grant from Becton Dickinson, UK")). A POSA would know that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions. (Ex. 1002, ¶110).

A POSA would also have understood that the known antiseptic solution of *Raad*, which constitutes well studied ingredients and combinations in the medical field, would have been readily used as a known replacement in each of *Connell*, *Raulerson*, and *Genatempo*, as well as in the combination resulting from the three. (Ex. 1002, ¶111). The composition of *Raad* would perform in a predictable manner to yield predictable results when incorporated. (Ex. 1002, ¶¶107-111; *KSR*, 550 U.S. at 416-17 (2007)).

**2. Claim 8**

For at least the reasons set forth in the fourth challenge ground, claim 7, from which Claim 8 depends, is obvious. *Raad* additionally teaches that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28; Ex. 1002, ¶107). Moreover, *Raad* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as a medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27).

A POSA would have understood that the known antiseptic solutions of *Raad*, which constitute well-studied ingredients and combinations in the medical field and medical device field, would have been readily used as a known replacement for the povidone iodine explicitly disclosed by *Connell*, *Raulerson*, and *Genatempo*. (Ex. 1002, ¶¶107-108).

**3. Claim 13**

For at least the reasons set forth above in connection with Claim 8, the combination of *Connell*, *Raulerson*, *Genatempo*, and *Raad* render obvious this limitation. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶107-108).

### H. Ground 6: Claims 2, 11, and 16 are Obvious in Light of *Connell*, *Raulerson*, *Genatempo*, and *Miyahara*.

#### 1. Basis for Combination

A POSA would have been motivated to modify the *Connell*/*Raulerson*/*Genatempo* combination, described above, in view of the disclosure of *Miyahara* to specify the length of the threading that is used for the engagement between the cap and the connector. (Ex. 1002, ¶¶112-115). To the extent the *Connell*/*Raulerson*/*Genatempo* combination does not expressly disclose the length of the threading, a POSA would understand that this length could be easily modifiable to a variety of lengths. In particular, because of the sealing flange of *Genatempo*, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal of the resulting combination provides this function. (Ex. 1002, ¶115). Flange 46 of *Genatempo* ensures that the antiseptic solution is retained within the cap during the cleaning process. (Ex. 1006, 3:46-47; Ex. 1002, ¶114). A POSA would understand that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector. (Ex. 1002, ¶¶114-115). A reduced number of rotations makes the product easier to use for patients and health care providers. (Ex. 1002, ¶¶114-115).

Further, *Miyahara* discloses that a cleaning and protective cap may be securely adhered to a connector with a rotation that is less than one full rotation of

the cap, confirming that the threading in the aforementioned combinations may be sized to have a length less than the internal circumference of the cap. (Ex. 1009, ¶¶55-56, Fig. 3). Specifically, *Miyahara* depicts guide protrusion 42 which mates with guide groove 13, and the screw action generated between the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶¶55-56, Fig. 3).

The rotational distance required by *Miyahara* would suggest to a POSA that shorter threads would be used in the combination of *Connell*/*Raulerson*/*Genatempo* to reduce the number of rotations necessary to adhere the cap to the patient access line. (Ex. 1002, ¶¶114-115).

**2. Claim 2**

As set forth above, claim 1 is obvious in view of *Connell*, *Raulerson*, and *Genatempo*. *Miyahara* further depicts guide protrusion 42 which mates with guide groove 13, and the screw action generated between the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶¶55-56). *Miyahara* confirms that a rotational distance greater than the inner circumference of the inner cavity is not necessary and sufficient cleaning can occur with threading that is shorter (and therefore less rotational movement). (Ex. 1002, ¶¶44, 115). As such, the selection of the length of threading in the combination of *Connell*, *Raulerson*, and *Genatempo* is a design choice.

### 3. Claim 11

As set forth with regard to claim 2, *Connell*, *Raulerson*, *Genatempo*, and *Miyahara* render obvious this limitation. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 115).

### d. Claim 16

As set forth with regard to claim 2, *Connell*, *Raulerson*, *Genatempo*, and *Miyahara* render obvious this limitation. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 115).

## VIII. CONCLUSION

This Petition demonstrates a reasonable likelihood that at least one claim of the '864 Patent is unpatentable under 37 C.F.R. § 42.108(c). Accordingly, all grounds in this Petition should be instituted. *See SAS Institute Inc. v. Iancu*, 138 S.Ct. at 1359-60; Trial Practice Guide Update, 31 (July 2019).

Respectfully submitted by

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## CLAIM APPENDIX OF THE CHALLENGED CLAIMS

1. **[pre]** A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

**[a]** a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve;

**[b]** a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve;

**[c]** threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening,

**[c.i]** the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the wet pad with the end face of the access portion of the patient fluid line access valve, and

**[c.ii]** to disinfect the end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad,

**[d]** wherein the threading threadedly receives the external threads thereby causing the end face to advance into the inner cavity such that the septum contacts the wet pad; and

**[e]** a removable lid attached to the opening of the housing enclosing the inner cavity to seal inner cavity and to maintain the wet pad and cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve.

2. The device of claim 1, wherein the inner cavity comprises an inner circumference and the threading comprises a length that is less than the inner circumference.

3. The device of claim 1, wherein a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity.

4. The device of claim 3, wherein adjustable positioning of the septum within the inner cavity allows the septum to contact the wet pad, and further allows the septum to contact and compress the wet pad between the septum and the inner cavity.

5. The device of claim 1, wherein the wet pad is a sponge.

6. The device of claim 1, wherein the housing comprises a polyethylene or polypropylene material.

7. The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.

8. The device of claim 7, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

9. The device of claim 7, wherein the cleaning solution is an alcohol-based cleaning solution.

10. A device for maintaining a patient fluid line access valve having an access portion with an end face that includes a septum and external threads on the access portion proximate the septum, the device comprising:

**[a]** a housing for covering the access portion of the patient fluid line access valve, the housing having an open end, a closed end, and a cavity, the housing including a thread on an inner wall of the cavity for engaging the external threads on the access portion of the patient fluid line access valve;

**[b]** a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve, the wet pad being positioned within the cavity for contacting the end face to disinfect the end face and

at least a portion of the external threads of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion; and

**[c]** a lid over the open end of the housing to seal the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity so that the end face of the access portion contacts the wet pad.

11. The device of claim 10, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

12. The device of claim 10, wherein the cleaning solution comprises an antimicrobial agent.

13. The device of claim 12, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

14. The device of claim 12, wherein the cleaning solution is an alcohol-based cleaning solution.

15. A device for maintaining a threaded patient fluid line access valve, the device comprising:

**[a]** a housing having an inner cavity for covering an end face of the threaded patient fluid line access valve;

**[b]** a wet pad within the housing and impregnated with a cleaning solution prior to contacting the threaded patient fluid line access valve, the wet pad being configured to contact at least a portion of the threaded patient fluid line access valve and the end face of the threaded patient fluid line access valve to disinfect the end face and at least a portion of an external thread of the threaded patient fluid line access valve;

**[c]** an internal thread within the inner cavity of the housing and positioned close to the wet pad for engaging the external thread of the threaded patient fluid line access valve, whereby rotational movement of the external thread with respect to the internal thread causes the end face to advance into the inner cavity such that a septum of the end face contacts the wet pad; and

**[d]** a lid providing a moisture barrier for the wet pad and the cleaning solution prior to contact between the wet pad and the threaded patient fluid line access valve, the lid being removable to allow the end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad.

16. The device of claim 15, wherein the inner cavity comprises an inner circumference and the internal thread comprises a length that is less than the inner circumference.

17. The device of claim 15, wherein the wet pad is a sponge.

18. The device of claim 15, wherein the housing comprises a polyethylene or polypropylene material.

19. The device of claim 15, wherein the cleaning solution is an alcohol-based cleaning solution.

**Certification of Service Under 37 C.F.R. § 42.6(e)(4)**

A copy of this Petition for *Inter Partes* Review and supporting materials has been served at the following correspondence address of record for the subject patent via Federal Express Priority Overnight® on this 18th day of October, 2019:

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**Certification of Word Count Under 37 C.F.R. § 42.24(d)**

The undersigned hereby certifies that the foregoing petition for *Inter Partes* Review contains **13,959** words, not including a table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits or appendix of claim listing as specified by 37 C.F.R. §42.24, according to the word count feature of the word-processing software used to prepare the petition.

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