UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

BAXTER INTERNATIONAL INC.
Petitioner

v.

BECTON, DICKINSON AND COMPANY
Patent Owner

CASE: IPR2020-00025
U.S. PATENT NO. 9,283,367

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
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

Petitioner is unaware of any presently pending matters related to U.S. Patent No. 9,283,367 ("the '367 Patent") (Ex. 1001).

Petitioner has filed concurrently petitions requesting institution of *Inter Partes* Review ("IPR") of claims 1-19 of U.S. Patent No. 8,740,864 ("the '864 Patent"), the parent patent to the '367 Patent, claims 1-18 of U.S. Patent No. 10,335,584, and claims 1-14 of U.S. Patent No. 10,159,828, and the subsequent cancellation of all of challenged claims in IPR2020-00024, IPR2020-00027, and IPR2020-00026 respectively.

Petitioner is unaware of any prior litigations or IPRs involving the '367 Patent.

The parent, the '864 Patent, 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).

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

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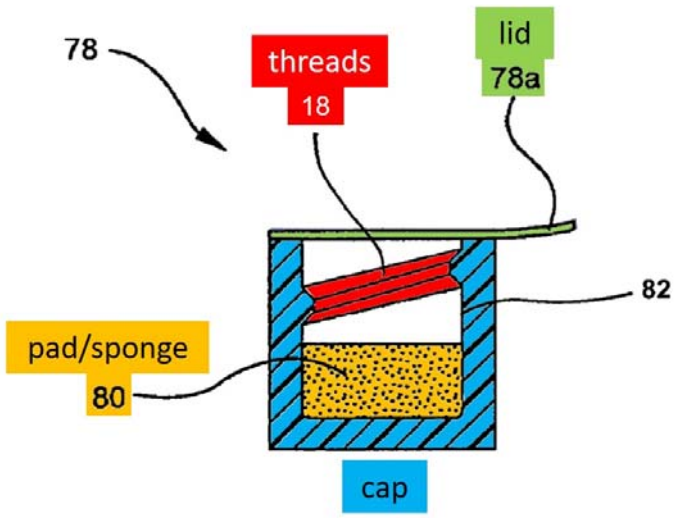
Petitioner consents to electronic service by email.

I. INTRODUCTION

Baxter requests institution of *Inter Partes* Review ("IPR") of claims 1-20 ("Challenged Claims") of the '367 Patent and the subsequent cancellation of the Challenged Claims in view of the Grounds described below. The purported invention of the '367 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 '367 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]

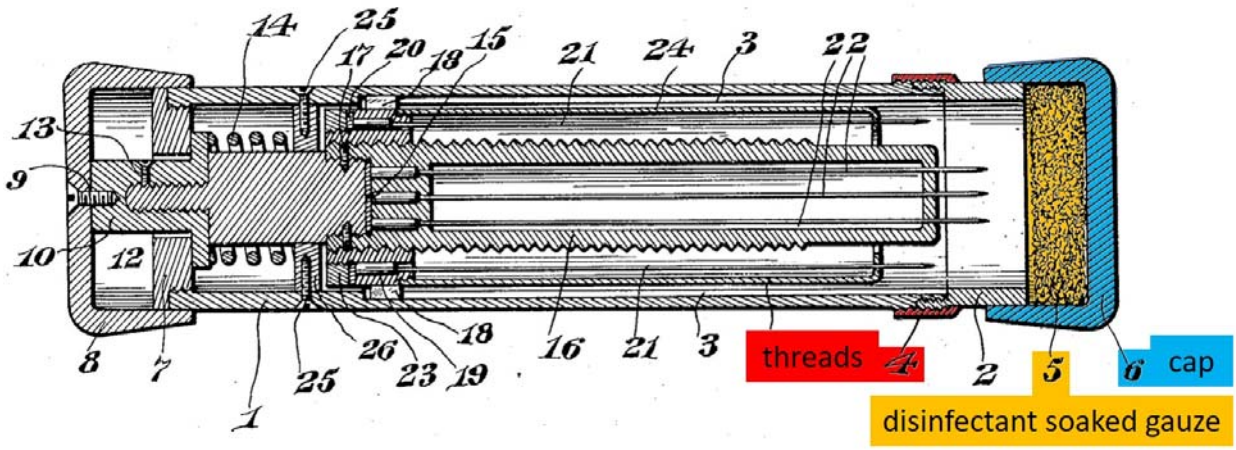
[1] The Parties in that prior proceeding stipulated to dismissal before the PTAB reached a final adjudication of the claims.

Figure 10b of the '367 Patent depicts an example embodiment of the Challenged Claims, with the cap (blue), threads (red), pad/sponge (orange), and lid (green):



(Ex. 1001, Fig. 10b, 5:9-13).

As shown herein, the '367 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 '367 Patent does not add anything to the state of the art. Thus, Petitioner hereby requests *inter partes* review of the Challenged Claims of the '367 Patent in light of the prior art identified herein.

II. TECHNOLOGY OF THE '367 PATENT

A. Overview of Patient Fluid Lines, Cleaning Capps, 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 for disinfection. (Ex. 1002, ¶20). One well-known way to disinfect these connectors is to provide a

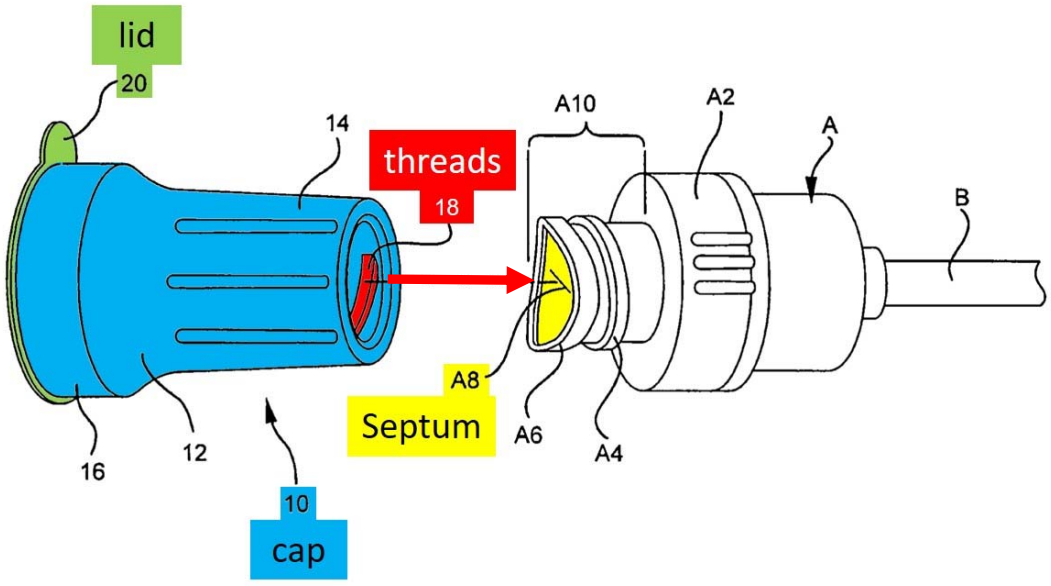
disinfectant cap that screws on to the connector, thereby applying a disinfectant via a sponge contained within the cap. (Ex. 1002, ¶¶20-23).

B. '367 Patent Overview

The '367 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, 1:49-50).

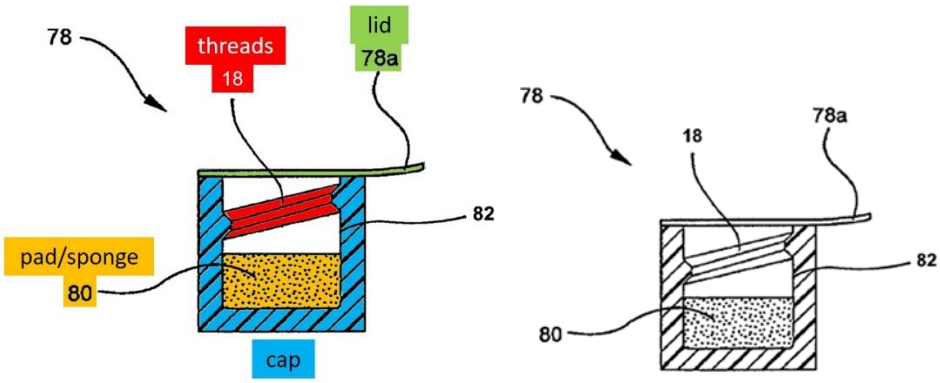
Figure 1 of the '367 Patent is an exploded view of the claimed cleaner cap (10) and access valve (A), along with a line (highlighted in red below) depicting the threading engagement of the connector by the cleaner cap. (Ex. 1001, 1:59-61; 2:15-18).

FIG. 1



Cap (10) includes a housing (12) having open cap end (14) and cleaning end (16). (Ex. 1001, 2:18-20). 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, 2:34-35, 39-43). 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, 2:26-28, 34-35, 3:8-11; Fig. 3). In alternative embodiments (depicted in Figure 7), the pad in the cap may be either dry or wet. (Ex. 1001, 5:14-16).

A different version of the claimed cap is illustrated in Figure 10b, with corresponding parts colored in the same manner as in Figure 1:



As shown above, the "invention" of the '367 Patent is simply a threaded cap with a sponge inside the cap. (Ex. 1002, ¶24). This Petition explains that the

Patentee did not invent such a device. The '367 Patent does not represent any improvement over the then-existing state of the art.

C. Prosecution History of the '367 Patent

The application leading to the '367 Patent was filed on November 21, 2014, as Application No. 14/159,959 ("the '959 Application"). (Ex. 1001, Cover). The '959 Application claims priority to U.S. application Ser. No. 11/281,711 ("the'711 Application"), which led to the '864 Patent and was filed on November 17, 2005. (*Id*. at Cover, 1:6-10).

The'959 Application received just one substantive rejection. On July 28, 2015, the Examiner issued a non-statutory double patenting rejection of all claims in the application, concluding that they were patentably indistinct from claims 1-19 of the '864 Patent. (Ex. 1003, 355-356). The Applicant filed a Terminal Disclaimer. On November 17, 2015, the Examiner issued a notice of allowance.

The '711 Application received five substantive rejections. In the notice of allowance, the Examiner stated that the prior art of record failed, in the Examiner's mind, to disclose the claimed arrangement. (Ex. 1021, 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). Such prior art addresses the Examiner's concerns regarding *Genatempo* alone and renders the claims of the '367 Patent obvious.

D. Prior IPR Proceedings

1. Prior IPR

The Board instituted review of claims 10, 12 and 14[2] of the '864 Patent as obvious over *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 claims 11 and 13 based on purportedly deficient evidence. 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)

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

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 '367 Patent is available for IPR; (2) Petitioner is not barred or estopped from requesting an IPR on the Grounds identified herein; and (3) Petitioner has not filed a complaint relating the '367 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 (PTAB June 20, 2014). A POSA 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 '367 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; Ex. 1005, 150). Such a person would have had knowledge of design considerations known in the fluid line industry, including patient safety considerations and 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). None of Petitioner's challenge grounds turn on these 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. "length"

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

B. "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. 1020, 2:3-7).

C. Remaining Terms

Petitioner submits that the remaining claim elements are to be given their plain and ordinary meaning as 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*	1-20
2	§ 103	*Menyhay*, *Genatempo*, and *Raad*	7, 12, and 20
3	§ 103	*Menyhay*, *Genatempo*, and *Miyahara*	10, 15
4	§ 103	*Connell*, *Raulerson*, and *Genatempo*	1-20
5	§ 103	*Connell*, *Raulerson*, *Genatempo*, and *Raad*	7, 12, and 20
6	§ 103	*Connell*, *Raulerson*, *Genatempo*, and *Miyahara*	10, 15

Petitioner also provides the declaration of Mr. Richard Meyst, an expert in the field of the '367 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

The Challenged Claims have not been challenged in a prior IPR.

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 under at least 35 U.S.C. §102(b). (Ex. 1007, Cover).[3]

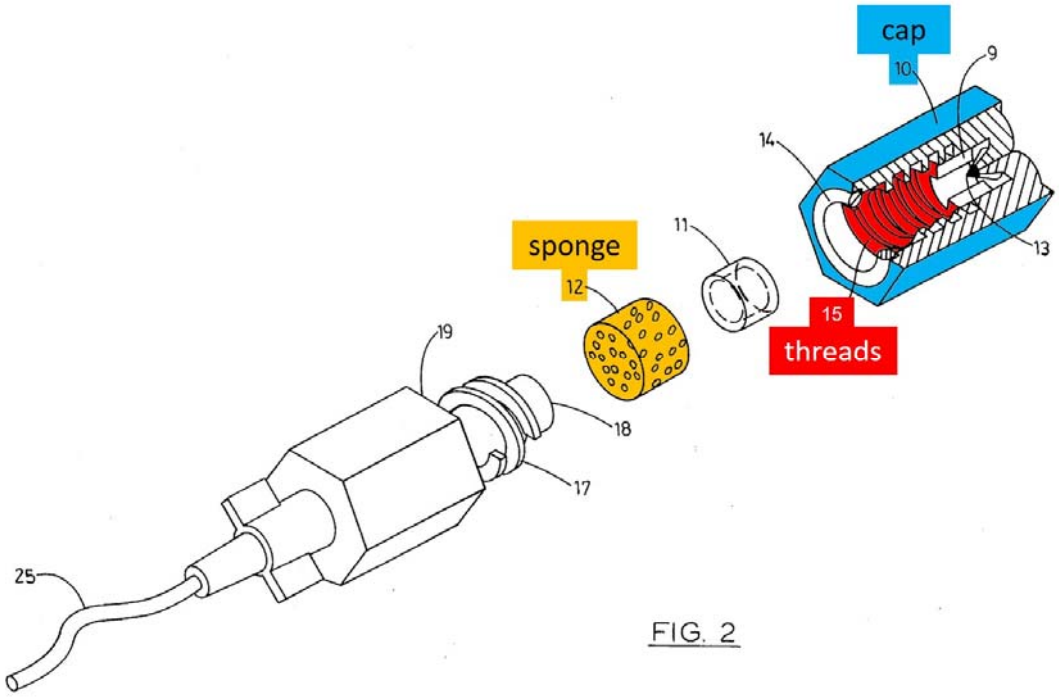


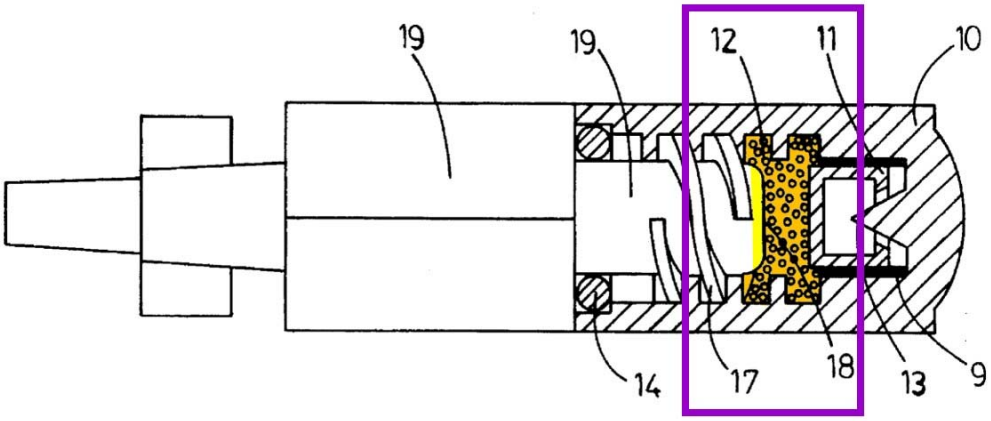
FIG. 2

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). Cylinder or cap 10 (in blue) is closed

[3] The '367 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

on one end that can be threadingly attached to port 19 via threads 17 of the port and threads 15 of the cap (in red). (Ex. 1007, 6:40-55; Ex. 1002, ¶30). Sponge 12 (in orange) and an antiseptic solution are located within cylinder 10 (which can be a solution of povidone iodine and isopropyl alcohol). (*Id.*).

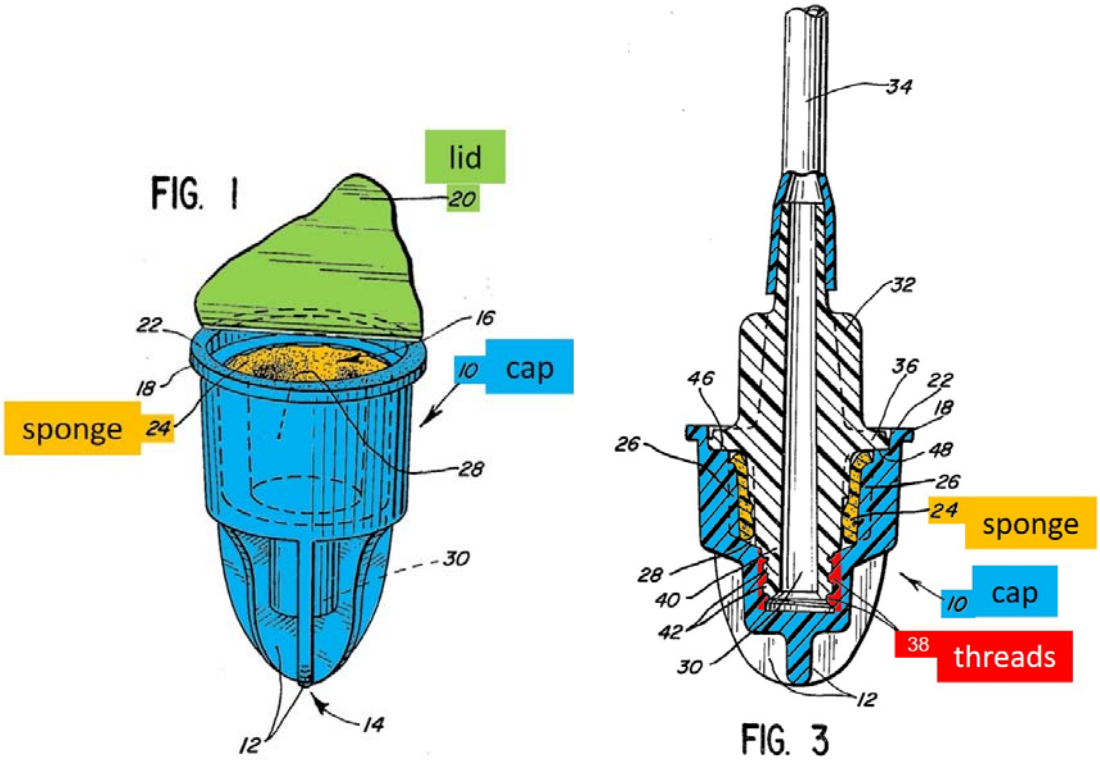
As the cylinder and connector port are screwed together, the wetted sponge contacts the septum 18 (in yellow), as shown below in the purple box. (*Id.* at 6:59-7:3).



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; threading the cap and port together causes the projection 13 to break the capsule 11, releasing the 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 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). Threading 38 on the internal wall of the cap engages with external threads 42 of connector 32. (Ex. 1006, 3:37-39, Fig. 3).

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* 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 the solution for cleaning a surface. (Ex. 1016, claims 10, 20; Ex. 1002, ¶39). These surfaces may include a catheter and using the solution to clean a surface of that catheter. (Ex. 1016, ¶¶26-27). 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* discloses rotational advancement of the connector into the cap using a protrusion 21 and guide groove 13 to facilitate the cleaning of the connector. (Ex. 1009, ¶¶41, 50, 55-57; Ex. 1002, ¶44).

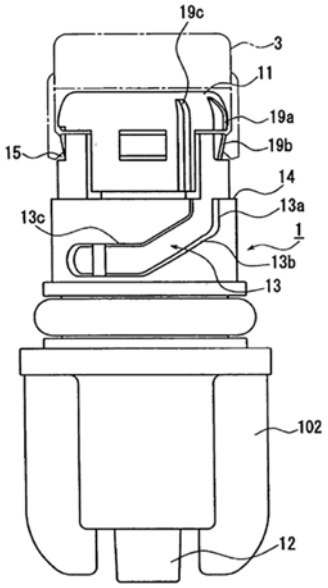


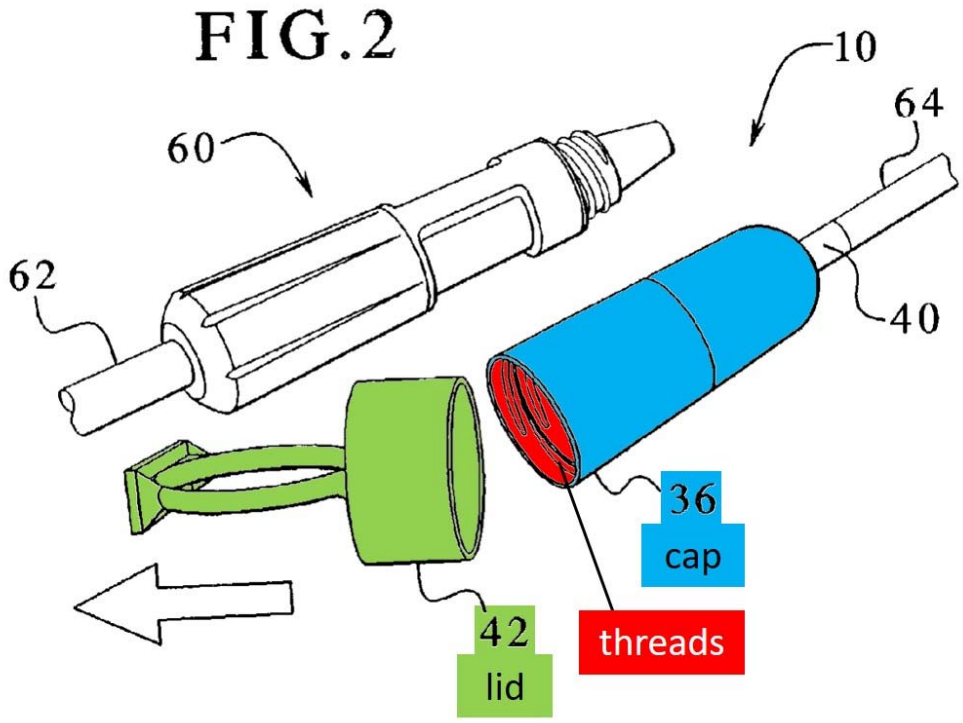
FIG. 3

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

5. Connell

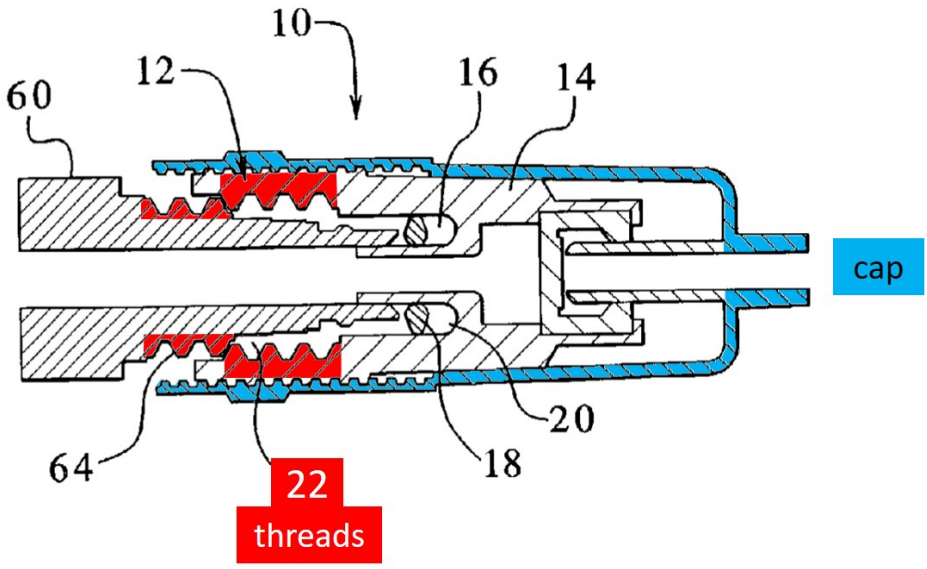
U.S. Patent Publication No. 2003/0153865 to Connell et al. ("*Connell*") published August 14, 2003. (Ex. 1010, Cover) and is prior art under at least 35 U.S.C. §102(b).

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, 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).

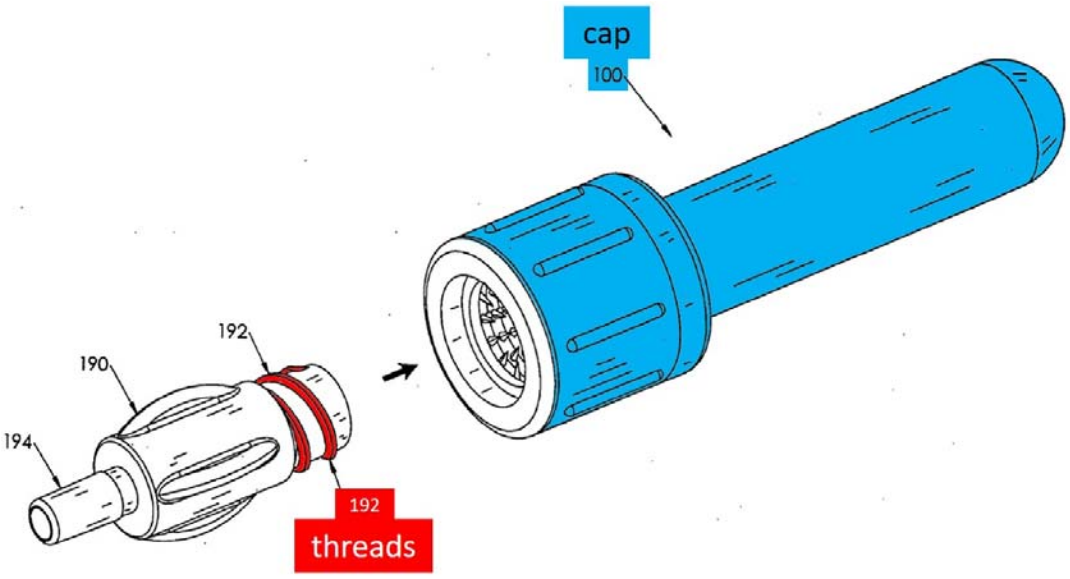


FIG. 1

Luer cleaner 100 is insertable over a luer connector 190 and axially rotatable 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).

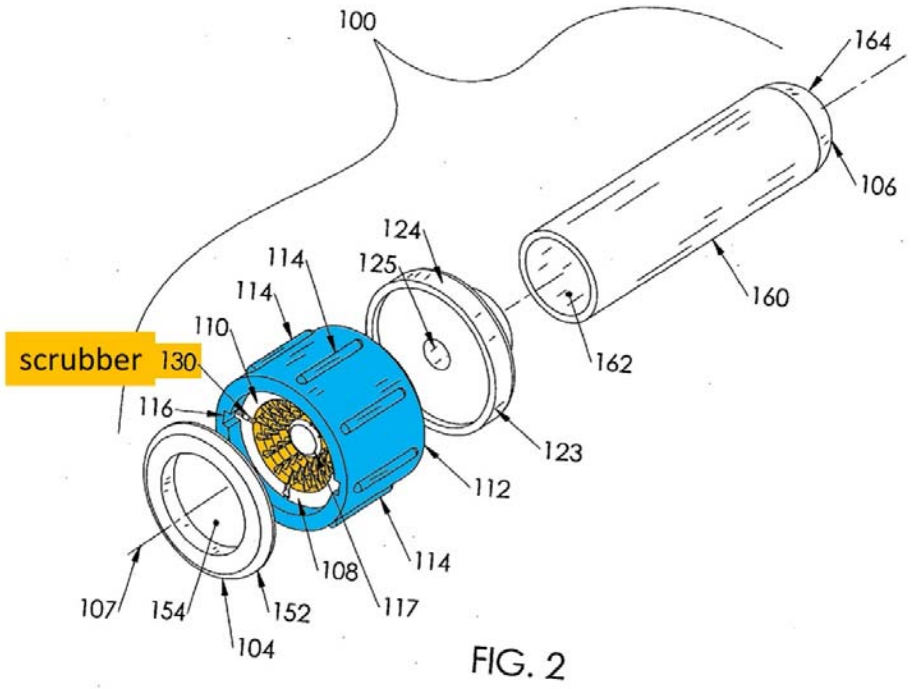


FIG. 2

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 Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over Genatempo and Menyhay.

Independent claims 1, 9, and 14, and claims 2-8, 10-13, and 15-20 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. As such, Ground 1 should not be

denied under 35 U.S.C. § 325(d). Additionally, the Board has previously instituted a review of a subset of the Challenged Claims in view of this same combination. *See SAS Institute*, 138 S. Ct. at 1359-60.

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 of the '864 Patent (which in view of the terminal disclaimer is patentably indistinct from the claims of the '367 Patent). (*See* Ex. 1005, 99-103, 105-108, 168). *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 the '367 Patent (using "a housing for covering the access portion of the access valve" to "reduce the number of catheter-related infections.") (Ex. 1001, 1:39-55).

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 avoid dry spots in the event that the capsule of *Menyhay* fails to break and wet sponge 12. (Ex. 1002, ¶¶75-76). A POSA would have also understood that preloading *Menyhay's* sponge as suggested

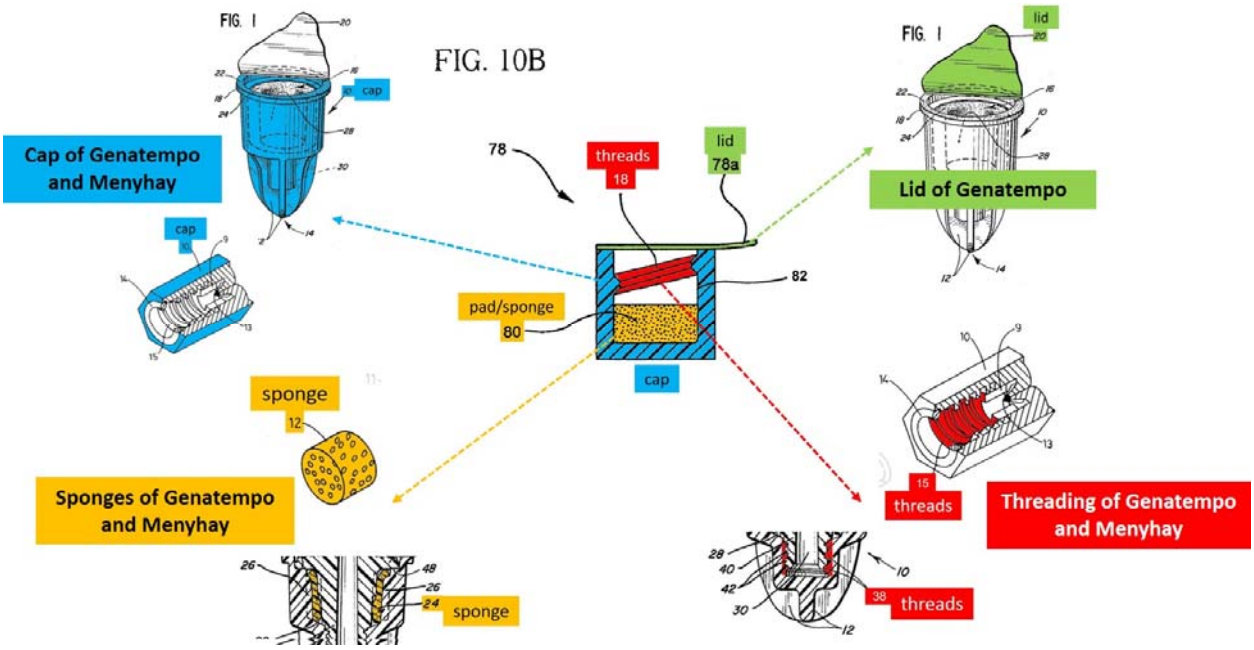
by *Genatempo*, along with the additional sponge location of *Genatempo* would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety. (Ex. 1002, ¶¶75-78). The compression of these pre-wetted sponges would allow the stored antiseptic liquids to flow across exposed surfaces. (Ex. 1002, ¶77).

Having combined *Menyhay* with *Genatempo* in the manner described above, a POSA would have also needed 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 the solution does not evaporate. (Ex. 1006, 2:62-3:8). The combination would have been made 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 v. Teleflex*, 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. "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

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 as long as a POSA would have a reasonable expectation of success. *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017); *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 the *Menyhay*/*Genatempo* combination. As supported by Mr. Meyst, the 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 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). 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 cleans 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). The cap includes a peelable lid to ensure that the solution does not 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. (Ex. 1002, ¶85).

2. The Challenged Claims of the '367 Patent are Obvious

a. Representative Independent Claim 1 and the Claims Depending Therefrom

The '367 Patent has three independent claims: claims 1, 9, and 14. 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 (in red), a sponge within the cap to assist in cleaning of the inserted access portion (in orange), and a peelable lid (in green). The combination of the cited art renders obvious the Challenged Claims of the '367 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 a distalmost end face that includes a

septum and external threads on the access portion proximate the distalmost end face." *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* discloses threaded mating between a cover and a port. (Ex. 1007, 6:52-53). The port of *Menyhay* is consistent with the claimed "patient fluid line access valve" and cover 10 of *Menyhay* is consistent with the claimed "device." (Ex. 1002, ¶31; Ex. 1007, 6:56-57). Port 19 of *Menyhay* includes a rubber septum 18. (Ex. 1007, 6:52-53). *Genatempo* also discloses a threaded 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 threaded cap 10 that mates with threads 17 of a connector. (Ex. 1007, 6:38-56, Fig. 2; Ex. 1002, ¶¶31-32).

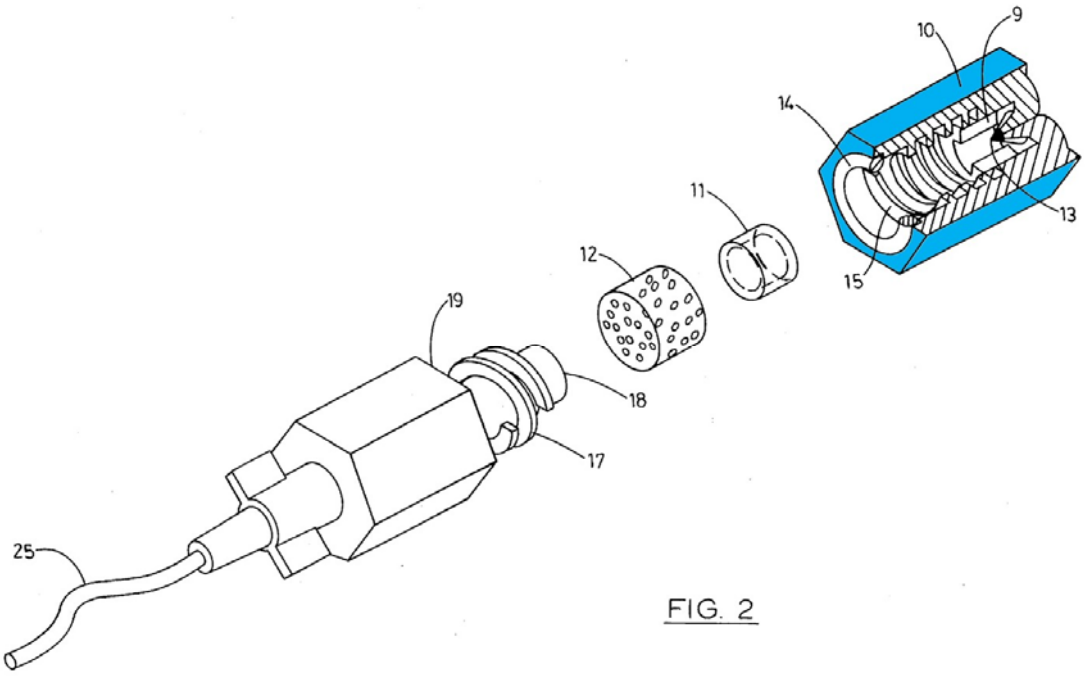


FIG. 2

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

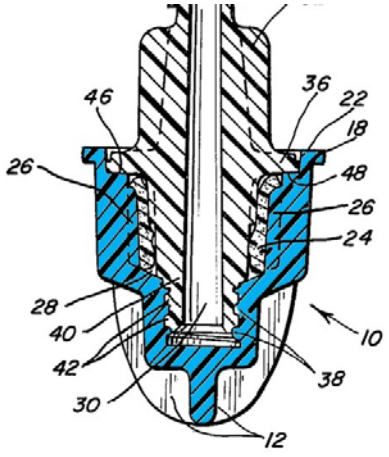


FIG. 3

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).

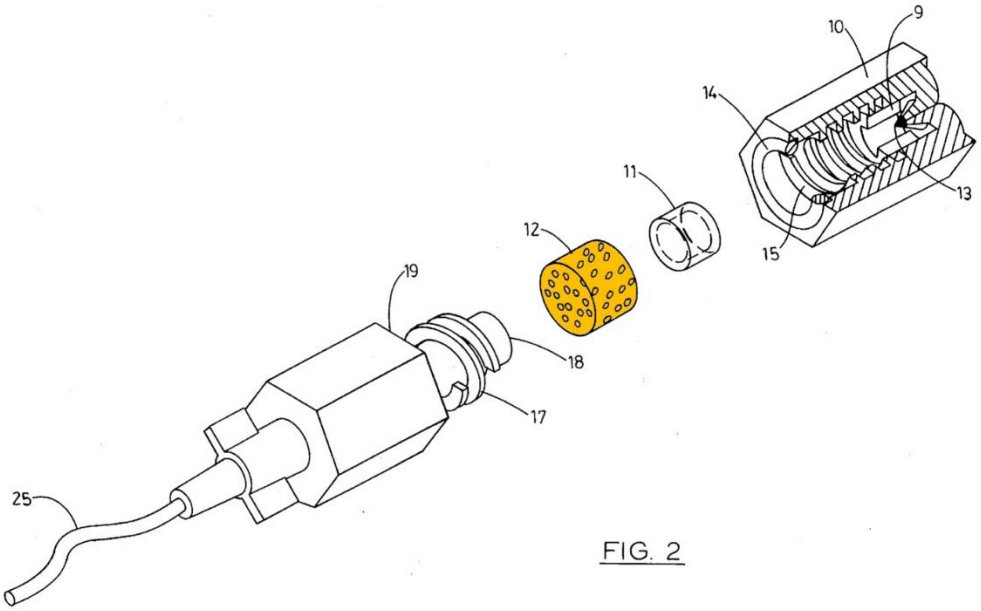


FIG. 2

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).

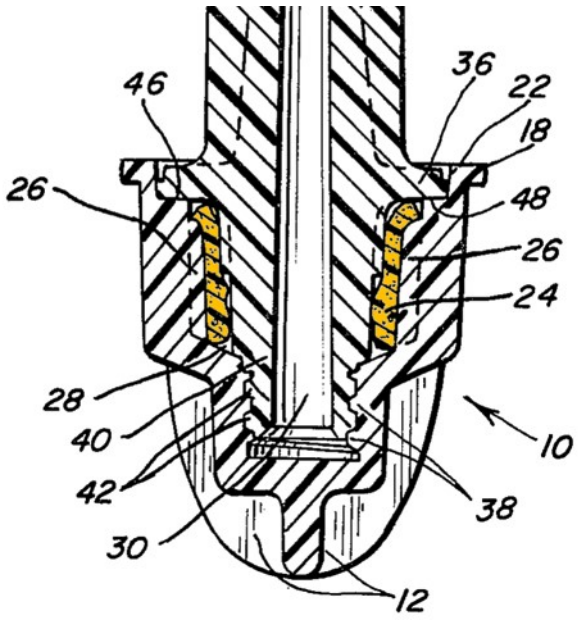


FIG. 3

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*, the sponge not become wetted in the time between breaking the seal and the disinfecting process. (Ex. 1002, ¶¶75-76; Ex. 1006, 1:44-52). 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).

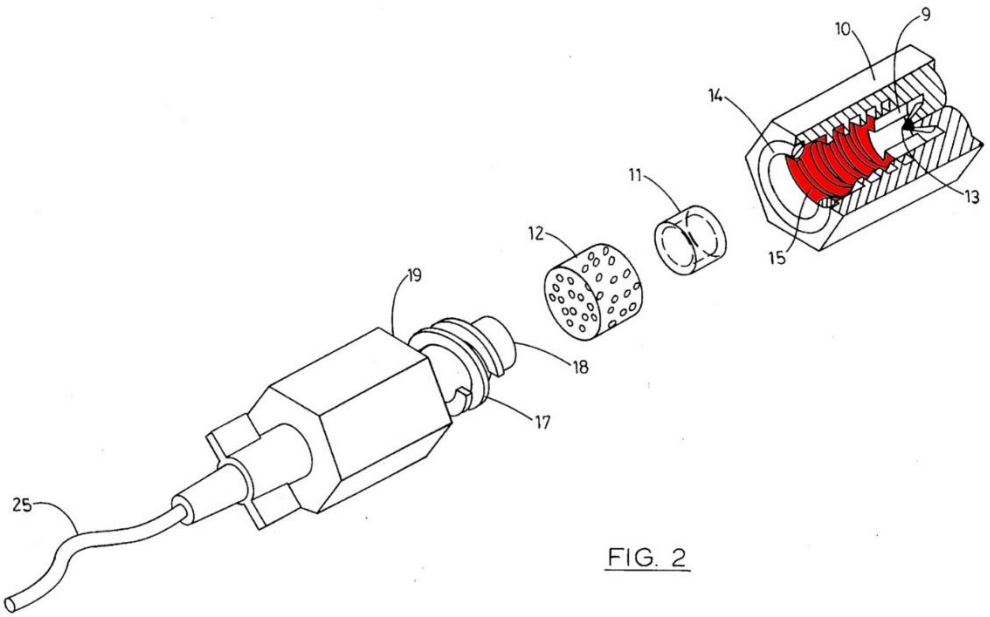


FIG. 2

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

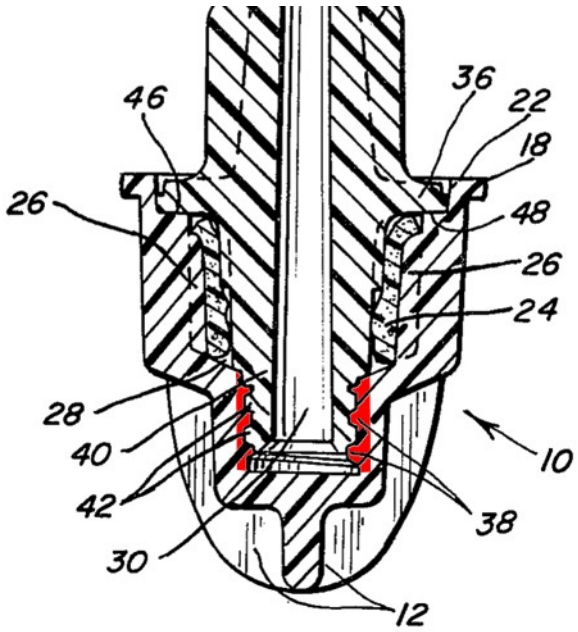
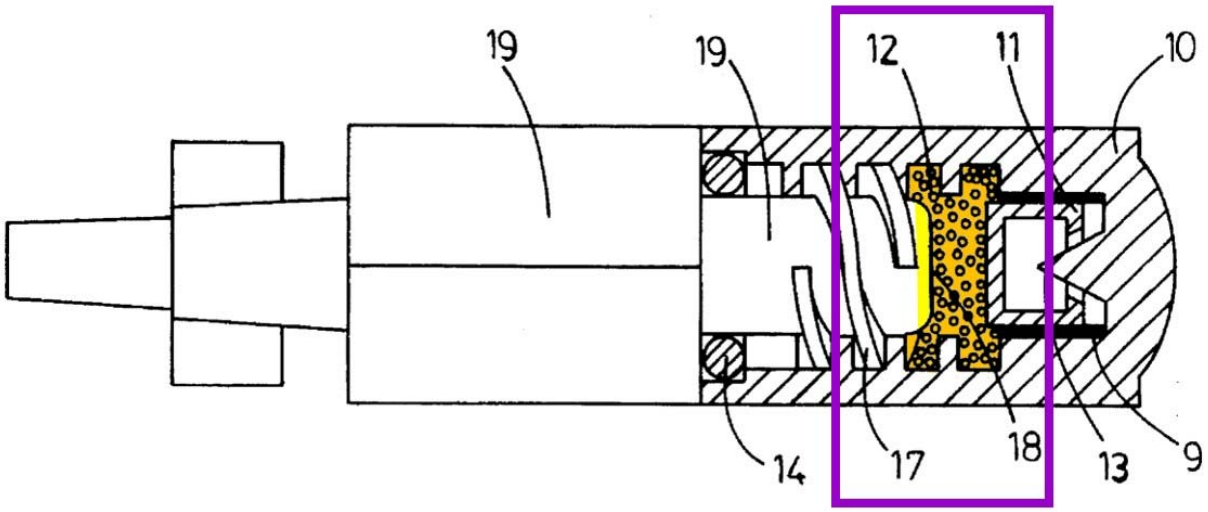


FIG. 3

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 distalmost 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).



When attached, sponge 12 (orange above) contacts septum 18 (yellow), "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]

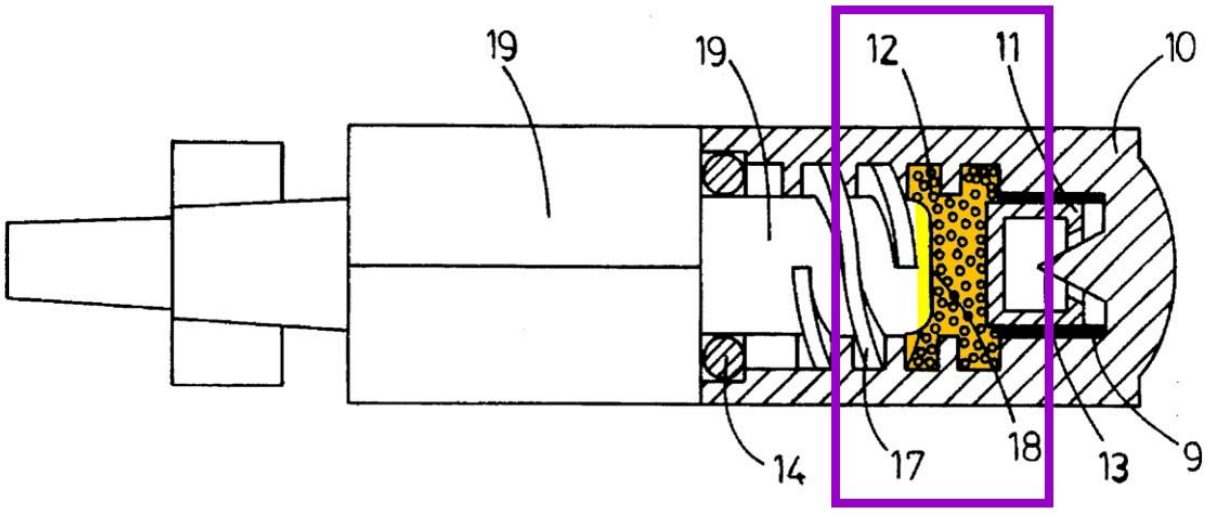
Part [c.ii] recites "to disinfect the distalmost end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad."

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 of the access portion of the patient fluid line access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad."

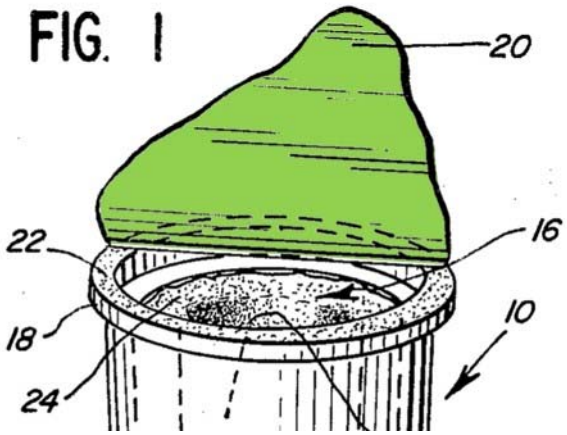
Menyhay discloses that the engagement between threads 17 and 15 cause the septum 18 to contact sponge 12, as shown in purple below. (Ex. 1007, 6:54-7:3, Figs. 2-3; Ex. 1002, ¶¶31, 79).



viii. Part [e]

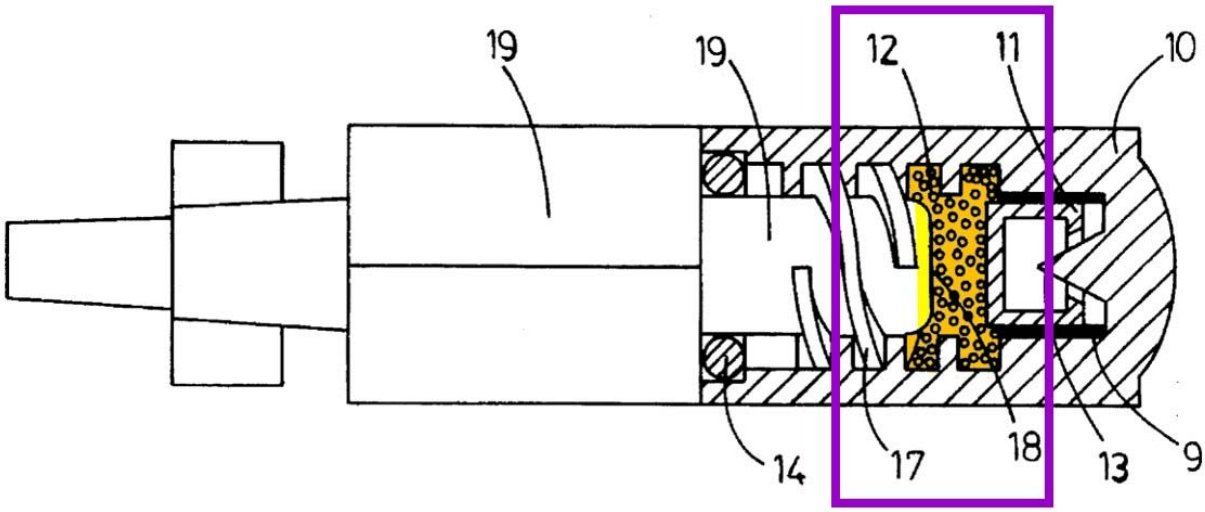
Part [e] recites "a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve."

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. (Ex. 1006, 3:1-8; Ex. 1002, ¶¶36, 79).



c. Claim 2

Claim 2 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). *Menyhay's* threading 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).

d. Claim 3

Claim 3 adds the limitation to claim 2 "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 2 above, *Menyhay* renders obvious the functionality of claim 3. (Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1002, ¶¶32, 79).

e. Claim 4

Claim 4 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, one of ordinary skill would have been motivated to preload *Menyhay's* sponge with *Genatempo's* liquid disinfectant. (Ex. 1002, ¶76).

f. Claim 5

Claim 5 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 '367 Patent identifies no specific benefit obtained by using "polyethylene or polypropylene" and 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, 2:26-32 (emphasis added)). The '367 Patent acknowledges that these plastics are known materials for manufacturing medical devices. (*Id.*; Ex. 1002, ¶22). The known plastics of *Menyhay* and *Genatempo* render obvious the known plastics of the '367

Patent. The use of any of these materials does not render an otherwise unpatentable claim patentable. *See KSR*, 550 U.S. at 420-21.

g. Claim 6

Claim 6 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).

h. Claim 7

Claim 7 adds the limitation to claim 6 "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 '367 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, 2:64-3:2). A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents. (Ex. 1002, ¶¶81-84). A POSA would have found the selection of the claimed chlorhexidines to have been obvious. (Ex. 1002, ¶¶81-84, 87-91).

i. Claim 8

Claim 8 adds the limitation to claim 6 "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).

j. Claim 9

The following claim chart shows how the combination of *Menyay* and *Genatempo* renders claim 9 obvious in the same manner as claim 1.

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
9 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face	1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face	*See* Claim 1 [Preamble]. (Ex. 1006, 1:9-11; Ex. 1007, 4:13-22, 6:52-53, 6:56-57; Ex. 1002, ¶¶30-31).
9[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	1[a] a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve 1[c] threading protruding inwardly into the inner cavity from an inner wall	*See* Claim 1[a], [c], and [c.i]. (Ex. 1006, 1:21-24, 3:37-39; Ex. 1007, 6:38-56, 6:67-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 34-35).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
proximate the open end for engaging the external threads on the access portion of the patient fluid line access valve	of the housing near the opening 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 distalmost end face of the access portion of the patient fluid line access valve	
9[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 distalmost end face of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion	1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve 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 distalmost end face of the access	*See* Claim 1[b], 1[c.i], and 1[c.ii]. (Ex. 1006, 2:64-68, 1:44-52, 2:62-3:8, 3:22-23, 3:42-45, Fig. 3; Ex. 1007, 6:38-56, 6:64-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 75-76, 79).

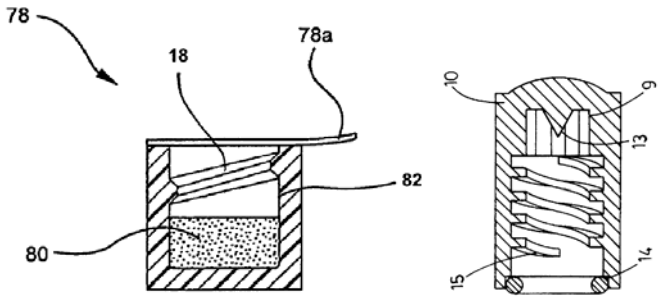
Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
	portion of the patient fluid line access valve 1[c.ii] to disinfect the distalmost end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad	
9[c] a lid over the open end of the housing to close 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 such that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 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 distalmost end face of the access portion of the patient fluid line access valve 1[d] wherein the threading threadedly receives the external threads thereby causing	*See* Claim 1[c], 1[c.i], 1[d], and 1[e]. (Ex. 1006, 1:21-24, 2:63-66, 3:1-8, Fig. 1; Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 79).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
portion of the external threads	the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad 1[e] a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve	

k. Claim 10

Claim 10 adds the limitation "wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference." The '367 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, mirrors that of the prior art references. For example, the threading of Figure 10b of the '367 Patent completes one rotation, whereas the threading 15 of *Menyhay's* Figure 4 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).

l. The Remaining Claims

The following claim charts show how the combination of *Menyhay* and *Genatempo* renders the remaining claims obvious in the same manner as the claims discussed above.

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
11. The device of claim 9, wherein the cleaning solution comprises an antimicrobial agent.	6. The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.	*See* Claim 6. (Ex. 1006, 3:22-23; Ex. 1007, 6:64-7:3; Ex. 1002, ¶81).
12. The device of claim 11, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	7. The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	*See* Claim 7. (Ex. 1006, 3:22-23; Ex. 1007, 6:64-7:3; Ex. 1002, ¶¶81-84, 87-91).
13. The device of claim 11, wherein the cleaning solution is an alcohol-based cleaning solution.	8. The device of claim 6, wherein the cleaning solution is an alcohol-based cleaning solution.	*See* Claim 8. (Ex. 1007, 6:48-50).
14 [Preamble] A device for maintaining a threaded patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face	1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face	*See* Claim 1[Preamble] (Ex. 1006, 1:9-11; Ex. 1007, 4:13-22, 6:52-53, 6:56-57; Ex. 1002, ¶¶30-31).
14[a] a housing having an inner cavity for covering the access portion 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] and 1[c.i] (Ex. 1006, 3:37-39, Fig. 3; Ex. 1007, 6:38-56, 6:67-7:3; Figs. 2-3; Ex. 1002, ¶¶30-32, 34-35).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
	1[c.1] 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 distalmost end face of the access portion of the patient fluid line access valve	
14[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 distalmost end face of the threaded patient fluid line access valve to reduce the amount of microbes on 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 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 distalmost end face of the access portion of the patient fluid line access valve 1[c.ii] to disinfect the distalmost end face and at	*See* Claim 1[b], 1[c.i], and 1[c.ii]. (Ex. 1006, 1:44-52, 2:64-3:8, 3:22-23, 3:42-45; Fig. 3; Ex. 1007, 6:38-56, 6:64-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 75-76, 79).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
	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	
14[c] a thread within the inner cavity of the housing and positioned between the wet pad and an opening to the inner cavity, the thread for engaging the external threads of the threaded patient fluid line access valve to cause the wet pad to contact the distalmost end face of the threaded patient fluid line access valve	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 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 distalmost end face of the access portion of the patient fluid line access valve	*See* Claim 1[c], 1[c.i]. (Ex. 1006, 1:21-24; Ex. 1007, 6:38-56, 6:67-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35).
14[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 distalmost end face of	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 1[c.i] the threading to engage the external threads of the access	*See* Claim 1[c], 1[c.i], and 1[e] (Ex. 1006, 1:21-24, 2:63-66, 3:1-8, Fig. 1; Ex. 1007, 6:38-56, 6:67-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 79).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads	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 distalmost end face of the access portion of the patient fluid line access valve 1[e] a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve	
15. The device of claim 14, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.	10. The device of claim 9, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.	*See* Claim 10. (Ex. 1007, Fig. 4; Ex. 1002, ¶80).
16. The device of claim 14, wherein the wet pad is a sponge.	4. The device of claim 1, wherein the wet pad is a sponge.	*See* Claim 4. (Ex. 1007, 6:64-7:3; Ex. 1002, ¶76).
17. The device of claim 14, wherein the housing comprises a polyethylene	5. The device of claim 1, wherein the housing comprises a polyethylene	*See* Claim 5.

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
or polypropylene material.	or polypropylene material.	(Ex. 1006, 3:19-21; Ex. 1007, 7:37-39; Ex. 1002, ¶¶22, 36).
18. The device of claim 14, wherein the cleaning solution is an alcohol-based cleaning solution.	8. The device of claim 6, wherein the cleaning solution is an alcohol-based cleaning solution.	*See* Claim 8. (Ex. 1007, 6:48-50).
19. The device of claim 14, wherein the cleaning solution comprises an antimicrobial agent.	6. The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.	*See* Claim 6. (Ex. 1006, 3:22-23; Ex. 1007, 6:64-7:3; Ex. 1002, ¶81).
20. The device of claim 19, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	7. The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	*See* Claim 7. (Ex. 1006, 3:22-23; Ex. 1007, 6:64-7:3; Ex. 1002, ¶¶81-84, 87-91).

D. Ground 2: Claims 7, 12, and 20 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Menyhay*, *Genatempo* and *Raad*.

If the Board finds that claims 8 and 13 would not have been obvious in view of *Menyhay* and *Genatempo*, 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 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 could be replaced with the chlorhexidine gluconate[4] 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* discloses

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[4] 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).

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

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).

U.S. Patent No. 9,028,852 to Scholz ("*Scholz*"), filed on September 7, 2004 (over a year before the priority date of the '367 Patent), 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).

Exhibit 1017 confirms that POSAs knew that chlorhexidine gluconate solutions may be used to clean needle-less connectors. (Ex. 1017, 1; Ex. 1002, ¶90). Ex. 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 '367 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, could have been used as a known replacement in *Menyhay* and *Genatempo* individually, as well as in the combination of the two. (Ex. 1002, ¶91). The composition of *Raad* would perform in a predictable manner to yield predictable results when incorporated into the combination, confirming that this limitation 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 7

As discussed above, the combination of *Menyhay* and *Genatempo* renders claim 6 obvious. *Raad* teaches that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28; Ex. 1002, ¶87). *Raad* confirms that chlorhexidine and

povidone iodine (the additional limitations of claim 7) are known alternative anti-microbial solutions that are suitable for cleaning a medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶88, 91).

3. Claim 12

For at least the reasons set forth with regard to claim 7, the combination of *Menyhay*, *Genatempo*, and *Raad* renders this claim obvious. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶87-88, 91).

4. Claim 20

For at least the reasons set forth above in Section VII.D.2, the combination of *Menyhay*, *Genatempo*, and *Raad* renders this claim obvious. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶87-88, 91).

E. Ground 3: Claims 10 and 15 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Menyhay*, *Genatempo* and *Miyahara*.

1. Basis for Combination

A POSA would have been motivated to modify the *Menyhay/Genatempo* combination with *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 smaller 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 could be modified as dictated by the circumstances of an application. (Ex. 1002, ¶¶92-95). Because of the seal in that combination, the thread length need not 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. (*Id.*). A reduced number of rotations makes the product easier to use for patients and health care providers. (*Id.*).

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. (*Id.*).

2. Claim 10

As discussed above, Claim 9 is obvious in view of *Menyhay* and *Genatempo*. *Miyahara* depicts guide protrusion 42 which mates with guide grove 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 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 15

As discussed above with regard to claim 10, *Menyhay*, *Genatempo* and *Miyahara* render obvious this limitation. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 95).

F. Ground 4: Challenged Claims are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Connell*, *Raulerson,* and *Genatempo*.

The combination of *Connell*, *Raulerson*, and *Genatempo* was not considered during prosecution, nor was the testimony of Mr. Meyst. Ground 4 should be instituted. *See* 35 U.S.C. §325(d); Ex. 1002, ¶¶96-105.

1. Basis for Combination

Section VII.C.1 sets forth the controlling case law on combination. *Connell* identifies the same problem and solution as the '367 Patent, noting that disinfecting connectors is essential, but contamination occurred with then-existing methods. (Ex. 1010, ¶¶10-11; Ex. 1002, ¶49). *Connell* teaches use of a cap to enclose and disinfect the patient line. (Ex. 1010, ¶¶15-25; Ex. 1002, ¶53). This is the same solution to the same problem addressed by the '367 Patent—an "effective and inexpensive way to reduce catheter-related infections," *i.e.*, "a housing for covering the access portion of the access valve," (e.g., a cap). (Ex. 1001, 1:49-55).

Connell provides a fluid connector cleaner with sealed disinfectant to clean the connector threading. (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's* disinfectant is contained in a sealed chamber. (Ex. 1010, ¶100; Ex. 1002, ¶¶47-48). *Connell* further

discusses the threading advancement of the cap onto the connector. (Ex. 1010, ¶¶77-80; Ex. 1002, ¶97).

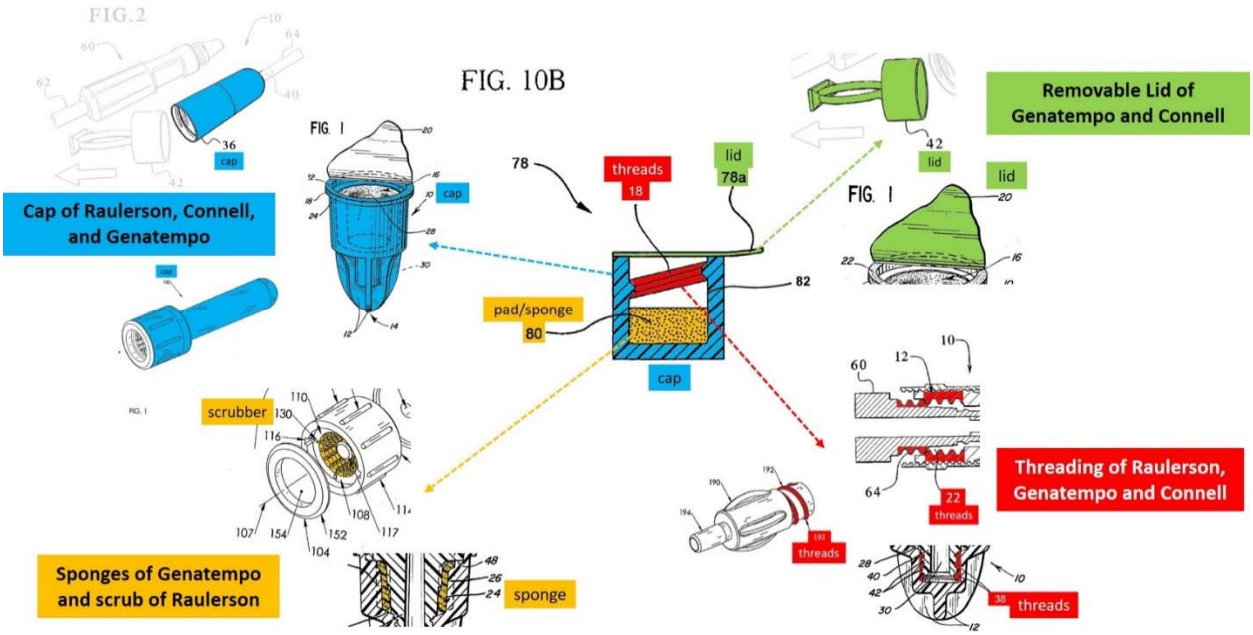
If *Connell* does not expressly disclose a mechanism for providing any physical cleaning motion (e.g., scrubbing), *Raulerson* teaches a scrubbing mechanism that uses rotational energy to clean the threading of a connector. (Ex. 1011, ¶4; Ex. 1002, ¶¶97-98). A POSA would have understood the value of a contact cleaning device, 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 this combination, there would be no dry spots or other infirmities associated with failure to break the seal. (Ex. 1002, ¶99).

Genatempo also achieves additional cleaning due to the migration of the antiseptic fluid. (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. (*Id.*).

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 '367 Patent are mechanical in nature, and each performs a similar function in the claimed combination as it did in the prior art, a POSA would have combined the references with an expectation of success. (Ex. 1002, ¶105).



(Ex. 1002, ¶100).

In the above illustration of this combination, a connector includes external threads (red) to permit threading engagement between an access end of the connector and a disinfectant cap (blue); the cap would include a wetted-sponge (orange) and a sealable peelable lid (green). (*See e.g.*, Ex. 1010, ¶¶77-78; Ex. 1002, ¶100).

The sponge is impregnated with an antiseptic cleaning solution. (*See e.g.*, Ex. 1006, 3:22-23, Fig. 3; Ex. 1011, ¶4, Fig. 3; Ex. 1002, ¶100). The cap includes 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). The cap includes a peelable lid to ensure that the solution does not 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

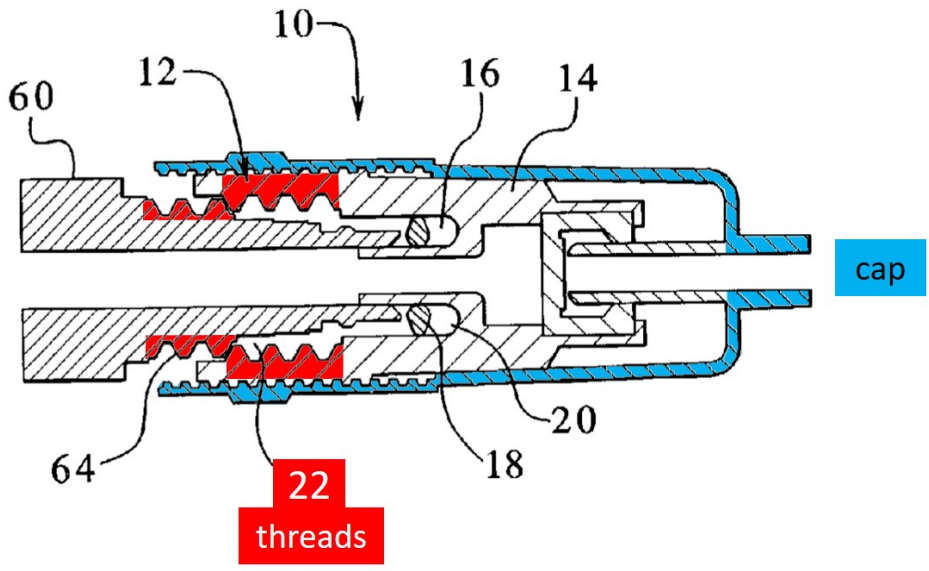
The combination of the cited art renders obvious the Challenged Claims of the ‘367 Patent.

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



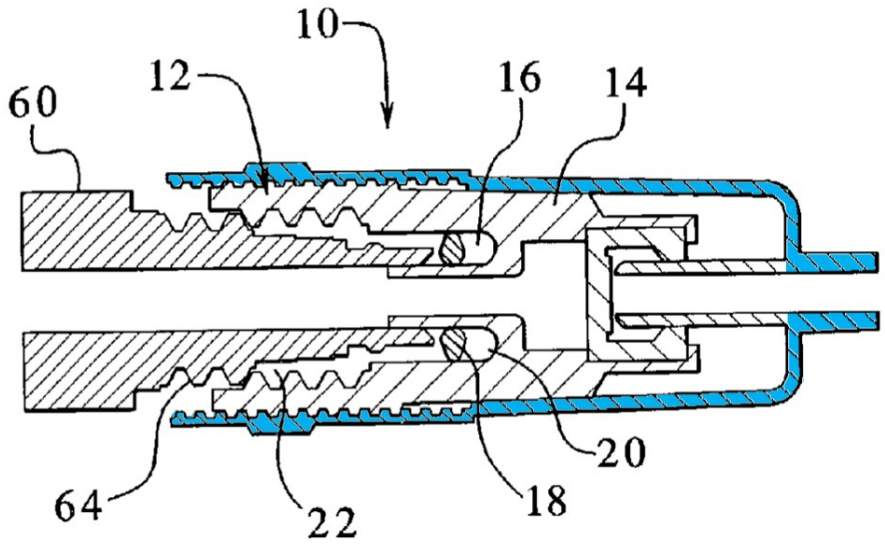
(Ex. 1010, Fig. 4, ¶100).

Genatempo also discloses a protector cap. (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 for disinfecting connector 60. (Ex. 1010, ¶¶101-104, Fig. 4; Ex. 1002, ¶53).

FIG.4



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

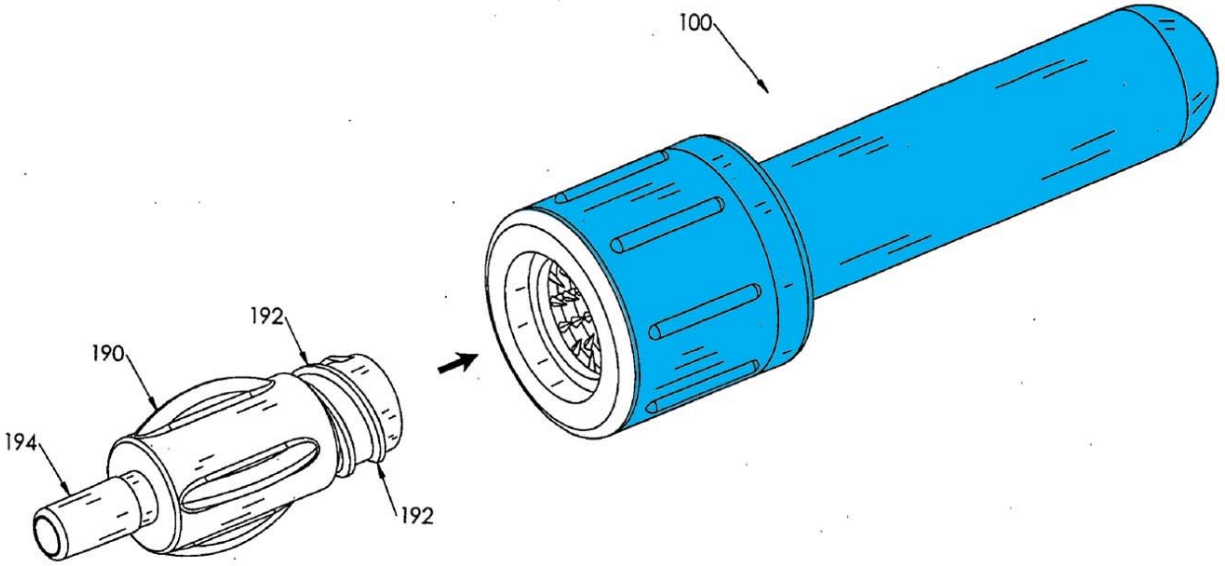


FIG. 1

(*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).

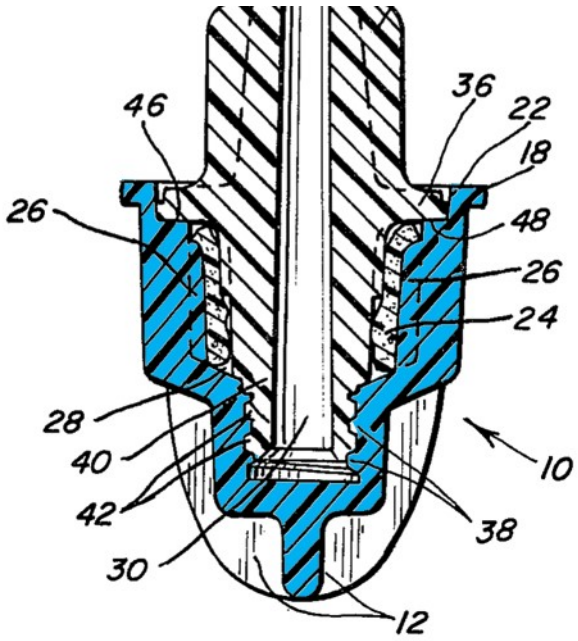


FIG. 3

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).

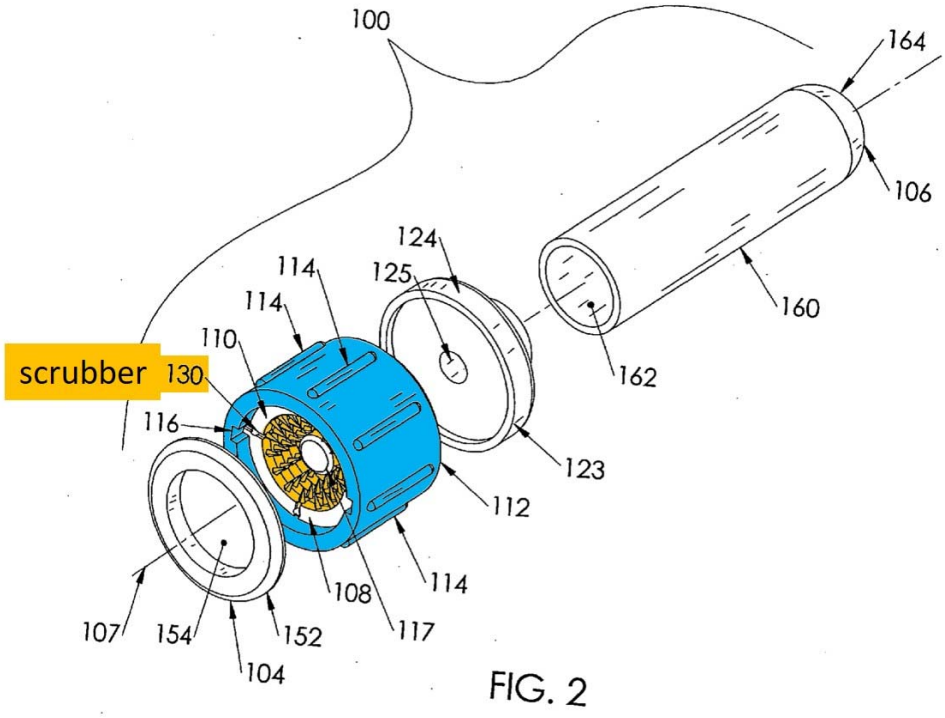


FIG. 2

(Ex. 1011, Fig. 2).

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

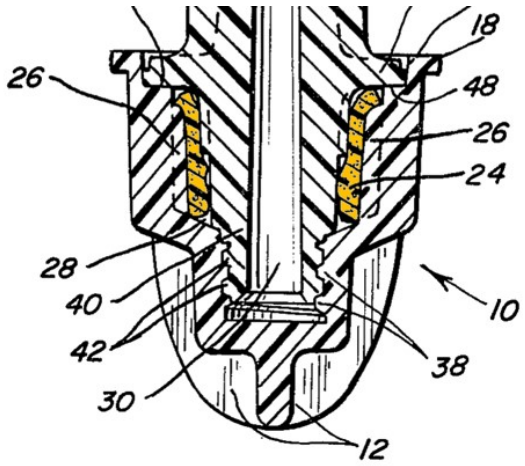


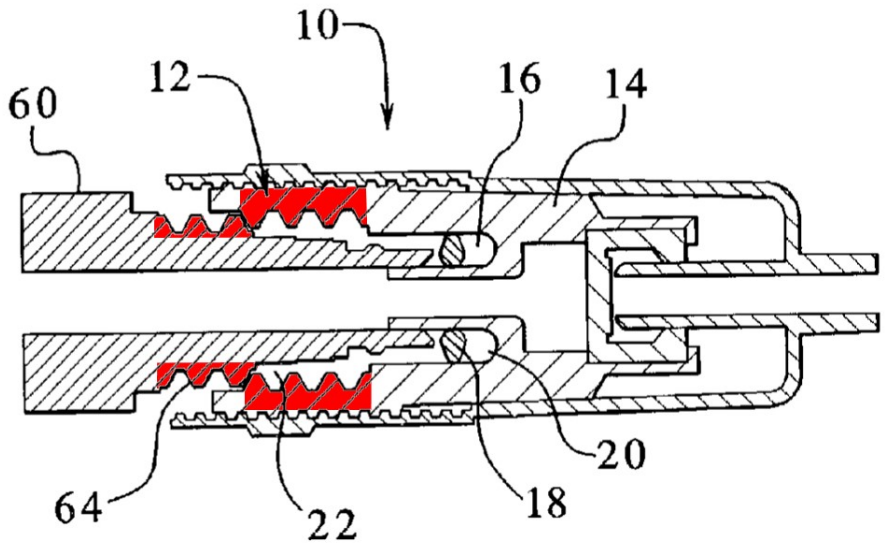
FIG. 3

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 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, describing the threading 38 of cleaning cap 10. (Ex. 1006, 2:21-24; Ex. 1002, ¶35).

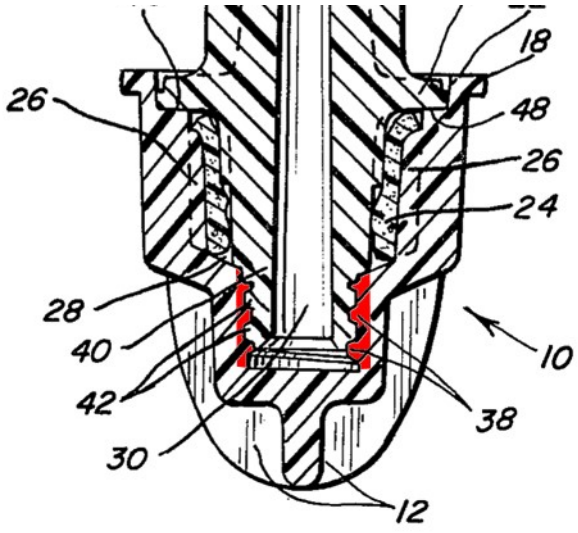


FIG. 3

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 resides). (Ex. 1011, ¶¶4, 31; Ex. 1002, ¶100).

vi. Part [c.ii]

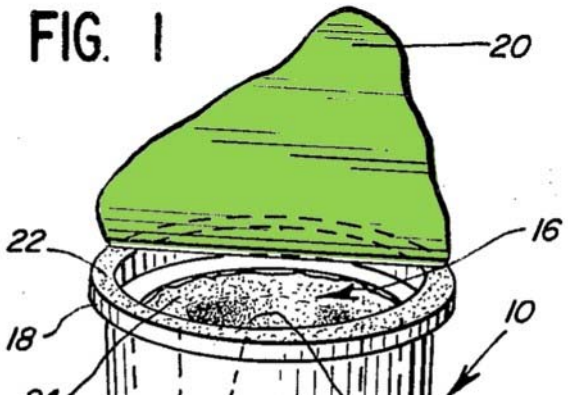
The relevant portions of *Genatempo* are set forth in connection with claim 1[c.ii] in the first challenge ground. (Ex. 1006, 3:42-45; Ex. 1002, ¶35). *Raulerson* discloses scrubbing to clean the luer and provides examples of known disinfectants. (Ex. 1011, ¶¶29, 31).

vii. Part [d]

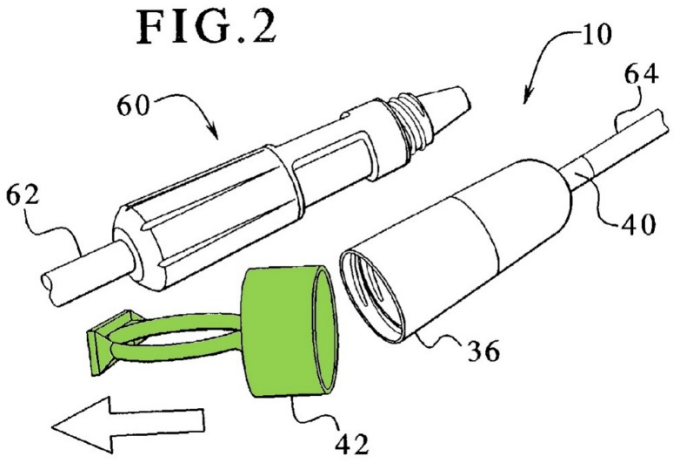
Connell states that the connector and cap are threadingly connected. (Ex. 1010, ¶101, Figs. 4-7). The resulting combination would include this threading advancement of *Connell* that causes the septum to contact the wetted sponge. (Ex. 1002, ¶102).

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). *Connell* describes a lid to seal the cleaning solution within a portion of the inner cavity and tip protector 42, a removable cover for connector 10. (Ex. 1010, ¶¶74, 87-88, Fig 2).



b. Claim 2

Connell describes the threaded advancement of claim 2. (Ex. 1010, ¶101, Figs. 4-7; Ex. 1002, ¶97).

c. Claim 3

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), renders this claim obvious. (Ex. 1002, ¶100).

d. Claim 4

Genatempo teaches the use of absorbent materials and sponges in connector cleaners. (Ex. 1006, Claim 11, 3:41-45).

e. Claim 5

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

f. Claim 6

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 6 in the first challenge ground. A POSA would understand that an antiseptic is an antimicrobial. (Ex. 1002, ¶102).

g. Claim 7

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* discloses the use of povidone iodine as a disinfectant. (Ex. 1010, ¶¶75-76). The '367 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, 2:64:32) A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents. (Ex. 1002, ¶¶102-104). A POSA would have found the selection of the claimed chlorhexidines to be obvious. (Ex. 1002, ¶¶102-104, 107-111).

h. Claim 8

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

i. Claim 9

The following claim chart shows how the combination of *Menyay* and *Genatempo* renders claim 9 obvious in the same manner as claim 1.

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
9 [Preamble] A device for maintaining a patient	1 [Preamble] A device for maintaining a patient	*See* Claim 1 [Preamble].

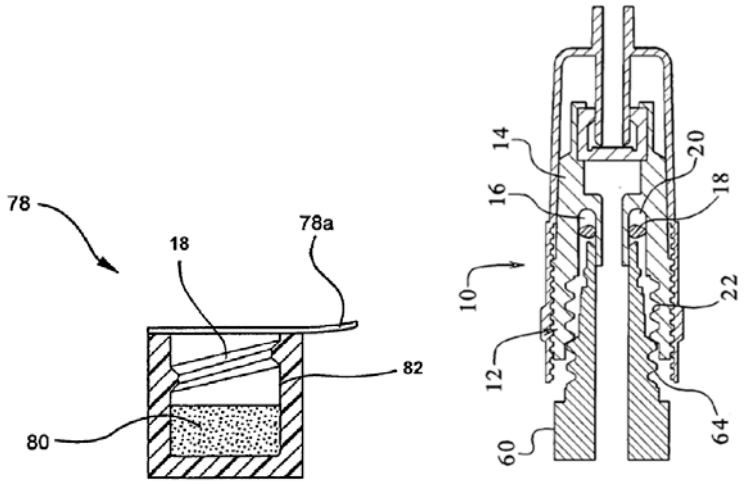
Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face	fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face	(Ex. 1006, 1:9-11; Ex. 1010, ¶¶66, 71, 74, 77, 80, 100, Fig. 4; Ex. 1006, 1:9-11; Ex. 1011, ¶4; Ex. 1002, ¶46).
9[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 proximate the open end for engaging the external threads on the access portion of the 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 1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 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 distalmost end face of the access portion of the patient fluid line access valve	*See* Claim 1[a], [c], and [c.i]. (Ex. 1006, 2:21-24, 3:37-39, Figs. 2-3; Ex. 1010, ¶¶101-104, Figs. 4-7; Ex. 1011, ¶¶14, 31, Fig. 1; Ex. 1002, ¶¶35, 53, 56).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
9[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 distalmost end face of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion	1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve 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 distalmost end face of the access portion of the patient fluid line access valve 1[c.ii] to disinfect the distalmost 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], 1[c.i], and 1[c.ii]. (Ex. 1006, 1:44-52, 2:64-3:8, 3:22-23, 3:42-45; Fig. 3; Ex. 1010, ¶72; Ex. 1011, ¶¶4, 21, 29 31, Fig. 2; Ex. 1002, ¶¶35, 53, 57, 99-100).
9[c] a lid over the open end of the housing to close the cavity with the wet pad within the cavity and provide a moisture barrier, the lid being removable to expose the	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening	*See* Claim 1[c], 1[c.i], 1[d], and 1[e]. (Ex. 1006, 2:21-24, 2:63-66, 3:42-45, Figs. 1, 4-7; Ex. 1010, ¶¶87-88, 101-103, Figs. 4-7; Ex. 1011,

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
wet pad and allow insertion of the access portion of the patient fluid line access valve into the cavity such that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads	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 distalmost end face of the access portion of the patient fluid line access valve 1[d] wherein the threading threadedly receives the external threads thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad 1[e] a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve	¶¶4, 27, 31; Ex. 1002, ¶¶35, 100, 102).

j. Claim 10

The '367 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, mirrors that of the prior art references. For example, the threading of Figure 10b of the '367 Patent completes one rotation, whereas the threading 22 of *Connell's* Figure 4 completes 4 rotations. (*Compare* Ex. 1001, Fig. 10b *with* Ex. 1007, 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*, 725 F.2d 1338).

k. The Remaining Claims

The following claim chart shows how the combination of *Connell*, *Raulerson*, and *Genatempo* renders the remaining claims obvious in the same manner as the claims discussed above.

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
11. The device of claim 9, wherein the cleaning solution comprises an antimicrobial agent.	6. The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.	*See* Claim 6. (Ex. 1006, 3:22-23; Ex. 1010, ¶76; Ex. 1011, ¶29; Ex. 1002, ¶102).
12. The device of claim 11, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	7. The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	*See* Claim 7. (Ex. 1006, 3:22-23; Ex. 1010, ¶¶75-76; Ex. 1011, ¶29; Ex. 1002, ¶¶102-104, 107-111).
13. The device of claim 11, wherein the cleaning solution is an alcohol-based cleaning solution.	8. The device of claim 6, wherein the cleaning solution is an alcohol-based cleaning solution.	*See* Claim 8. (Ex. 1011, ¶29).
14 [Preamble] A device for maintaining a threaded patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the	1 [Preamble] A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the	*See* Claim 1[Preamble] (Ex. 1006, 1:9-11; Ex. 1010, ¶¶66, 71, 74, 77, 80, 100, Fig. 4; Ex. 1006, 1:9-11; Ex. 1011, ¶4; Ex. 1002, ¶46).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
access portion proximate the distalmost end face	access portion proximate the distalmost end face	
14[a] a housing having an inner cavity for covering the access portion 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 1[c.1] 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 distalmost end face of the access portion of the patient fluid line access valve	*See* Claim 1[a] and 1[c.i] (Ex. 1006, 3:37-39, Figs. 2-3; Ex. 1010, ¶¶101-104, Figs. 4-7; Ex. 1011, ¶14, 31, Fig. 1; Ex. 1002, ¶¶35, 53, 56, 100).
14[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 distalmost end face of the threaded patient fluid line access valve to	1[b] a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve 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	*See* Claim 1[b], 1[c.i], and 1[c.ii]. (Ex. 1006, 1:44-52, 2:64-3:8, 3:22-23, 3:42-45; Fig. 3; Ex. 1010, ¶72; Ex. 1011, ¶¶4, 21, 29 31, Fig. 2; Ex. 1002, ¶¶35, 53, 57, 99-100).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
reduce the amount of microbes on the threaded patient fluid line access valve	patient fluid line access valve to contact the wet pad with the distalmost end face of the access portion of the patient fluid line access valve 1[c.ii] to disinfect the distalmost 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	
14[c] a thread within the inner cavity of the housing and positioned between the wet pad and an opening to the inner cavity, the thread for engaging the external threads of the threaded patient fluid line access valve to cause the wet pad to contact the distalmost end face of the threaded patient fluid line access valve	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 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 distalmost end face of the access portion of the patient fluid line access valve	*See* Claim 1[c], 1[c.i]. (Ex. 1006, 2:21-24; Ex. 1010, ¶¶77-78, Figs. 4-7; Ex. 1011, ¶¶4, 29, 31; Ex. 1002, ¶¶35, 100).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
14[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 distalmost end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 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 distalmost end face of the access portion of the patient fluid line access valve 1[e] a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve	*See* Claim 1[c], 1[c.i], and 1[e] (Ex. 1006, 2:21-24, 2:63-66, Fig. 1; Ex. 1010, ¶¶74, 77-78, 87-88, Figs. 2, 4-7; Ex. 1011, ¶¶4, 27, 29, 31; Ex. 1002, ¶¶35, 100).
15. The device of claim 14, wherein the inner cavity comprises an inner circumference and the thread comprises a length	10. The device of claim 9, wherein the cavity comprises an inner circumference and the thread comprises a length	*See* Claim 10. (Ex. 1007, Fig. 4; Ex. 1002, ¶101).

Claim Limitation	Already-Discussed Claim Language	Prior Art Teaching
that is less than the inner circumference.	that is less than the inner circumference.	
16. The device of claim 14, wherein the wet pad is a sponge.	4. The device of claim 1, wherein the wet pad is a sponge.	*See* Claim 4. (Ex. 1006, Claim 11, 3:41-45).
17. The device of claim 14, wherein the housing comprises a polyethylene or polypropylene material.	5. The device of claim 1, wherein the housing comprises a polyethylene or polypropylene material.	*See* Claim 5. (Ex. 1006, 3:19-21; Ex. 1010, ¶68).
18. The device of claim 14, wherein the cleaning solution is an alcohol-based cleaning solution.	8. The device of claim 6, wherein the cleaning solution is an alcohol-based cleaning solution.	*See* Claim 8. (Ex. 1011, ¶29).
19. The device of claim 14, wherein the cleaning solution comprises an antimicrobial agent.	6. The device of claim 1, wherein the cleaning solution comprises an antimicrobial agent.	*See* Claim 6. (Ex. 1006, 3:22-23; Ex. 1010, ¶76; Ex. 1011, ¶29; Ex. 1002, ¶102).
20. The device of claim 19, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	7. The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.	*See* Claim 7. (Ex. 1006, 3:22-23; Ex. 1010, ¶¶75-76; Ex. 1011, ¶29; Ex. 1002, ¶¶102-104, 107-111).

G. Ground 5: Claims 7, 12, and 20 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Connell*, *Raulerson*, *Genatempo,* and *Raad*.

If the Board finds that claims 7, 12, and 20 would not have been obvious in view of *Connell*, *Raulerson*, and *Genatempo*, the disclosure of *Raad* explicitly teaches the additional limitations of claims 7, 12, and 20.

1. Basis for Combination

A POSA would have understood that the antiseptic solution of the *Connell*/*Raulerson*/*Genatempo* combination, povidone iodine, 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* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27). A POSA would understand that povidone iodine could be replaced with the chlorhexidine gluconate solution of *Raad* with an expectation of success. (Ex. 1002, ¶¶106-108).

Raulerson states that fluids other than those explicitly identified may be used. (Ex. 1011, ¶29). *Connell* teaches the same. (Ex. 1010, ¶¶75-76). *Genatempo* identifies povidone iodine as the antiseptic retained by the absorbent material. (Ex. 1006, 2:14-15). Each of *Connell*, *Raulerson* and *Genatempo* states that

modifications to their respective disclosures may be made without deviating from the scope and spirit thereof. (Ex. 1006, 8:4-9; Ex. 1010, ¶109; Ex. 1011, ¶36).

Exhibit 1015 confirms that one way of cleaning these device surfaces is with "antimicrobial agents or antimicrobial compositions." (Ex. 1015, 17:47-49). Ex. 1015 lists povidone iodine and chlorhexidine as suitable alternatives for each other. (Ex. 1015, 17:47-67). These antiseptic solutions may act as antimicrobials for medical devices. (Ex. 1002, ¶109).

Scholz confirms that chlorhexidine diacetate and gluconate are an improvement over povidone-iodine. (Ex. 1012, 3:55-67, 15:35-41). Exhibit 1017 confirms that chlorhexidine gluconate solutions may be used to clean needleless connectors describing work funded by Patent Owner (or related affiliate) from 2002. (Ex. 1017, 1, 2). 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* could have replaced that of the *Connell*/*Raulerson*/*Genatempo* combination. (Ex. 1002, ¶111). The solution of *Raad* would perform in a predictable manner to yield predictable results when incorporated, which a POSA would have done with an expectation of success. (Ex. 1002, ¶¶107-111; *KSR*, 550 U.S. at 416-17 (2007)).

2. Claim 7

For at least the reasons set forth above, claim 6 is obvious. *Raad* teaches that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28; Ex. 1002, ¶107). *Raad* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions suitable for cleaning a medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27).

A POSA would have understood that the antiseptic solutions of *Raad*, well-studied ingredients and combinations in the medical field and medical device field, could have replaced the povidone iodine disclosed by *Connell*, *Raulerson*, and *Genatempo*. (Ex. 1002, ¶¶107-108).

3. Claim 12

For at least the reasons set forth above for claim 7, the combination of *Connell*, *Raulerson*, *Genatempo*, and *Raad* renders obvious claim 12. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶107-108).

4. Claim 20

For at least the reasons set forth above for claim 7, the combination of *Connell*, *Raulerson*, *Genatempo*, and *Raad* renders obvious claim 20. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶107-108).

H. Ground 6: Claims 10 and 15 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Connell*, *Raulerson*, *Genatempo*, and *Miyahara*.

1. Basis for Combination

A POSA would have been motivated to modify the *Connell*/*Raulerson*/*Genatempo* combination with *Miyahara* to specify the length of the threading used for the engagement between the cap and the connector. (Ex. 1002, ¶¶112-115). If the *Connell*/*Raulerson*/*Genatempo* combination does not expressly disclose the length of the threading, a POSA would understand that this length could be modified. The combination's thread length need not prevent liquid from escaping because the seal 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 shorter threading 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).

Miyahara discloses that a cleaning and protective cap may be 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 smaller than the internal circumference of the cap. (Ex. 1009, ¶¶55-56, Fig. 3). *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 *Connell*/*Raulerson*/*Genatempo* combination to reduce the number of rotations necessary to adhere the cap to the patient access line. (Ex. 1002, ¶¶114-115).

2. Claim 10

As set forth above, claim 9 is obvious in view of *Connell*, *Raulerson*, 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 and sufficient cleaning can occur with threading that is shorter. (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 15

As set forth above regarding claim 10, *Connell*, *Raulerson*, *Genatempo*, and *Miyahara* renders obvious Claim 15. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 115).

VIII. CONCLUSION

This Petition demonstrates a reasonable likelihood that at least one claim of the '367 Patent is unpatentable under 37 C.F.R. § 42.108(c). Accordingly, all grounds in this Petition should be instituted. *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 a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, 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 distalmost end face of the access portion of the patient fluid line access valve, and

[c.ii] to disinfect the distalmost 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 of the access portion of the patient fluid line access valve thereby causing the distalmost

end face to advance into the inner cavity such that the septum contacts the wet pad; and

[e] a removable lid enclosing the inner cavity to maintain the wet pad and the 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 a threaded interaction between the threading and the external threads provides adjustable positioning of the septum within the inner cavity.

3. The device of claim 2, 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.

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

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

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

7. The device of claim 6, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

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

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

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 proximate the open end for engaging the external threads on the access portion of the patient fluid line access valve;

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 distalmost end face of the access portion of the patient fluid line access valve when the housing is positioned over and covers the access portion to reduce the amount of microbes on the access portion; and

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 such that the thread engages the external threads on the access portion

as the access portion is advanced into the inner cavity so that the distalmost end face of the access portion contacts the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads.

10. The device of claim 9, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

11. The device of claim 9, wherein the cleaning solution comprises an antimicrobial agent.

12. The device of claim 11, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

13. The device of claim 11, wherein the cleaning solution is an alcohol-based cleaning solution.

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

a housing having an inner cavity for covering the access portion of the threaded patient fluid line access valve;

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 distalmost end face of the threaded patient fluid line access valve to reduce the amount of microbes on the threaded patient fluid line access valve;

a thread within the inner cavity of the housing and positioned between the wet pad and an opening to the inner cavity, the thread for engaging the external thread of the threaded patient fluid line access valve to cause the wet pad to contact the distalmost end face of the threaded patient fluid line access valve; and

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 distalmost end face of the threaded patient fluid line access valve to be inserted into the housing and contact the wet pad to provide the cleaning solution to the septum and at least a portion of the external threads.

15. The device of claim 14, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

16. The device of claim 14, wherein the wet pad is a sponge.

17. The device of claim 14, wherein the housing comprises a polyethylene or polypropylene material.

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

19. The device of claim 14, wherein the cleaning solution comprises an antimicrobial agent.

20. The device of claim 19, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

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 **13,979** 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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