UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

BAXTER INTERNATIONAL INC.
Petitioner

v.

BECTON, DICKINSON AND COMPANY
Patent Owner

CASE: IPR2020-00027
U.S. PATENT NO. 10,335,584

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 sole real parties-in-interest in this proceeding.

B. Related Matters

Petitioner is unaware of any presently pending matters related to U.S. Patent No. 10,335,584 ("the '584 Patent") (Ex. 1001).

Petitioner has filed concurrently herewith petitions requesting institution of *Inter Partes* Review ("IPR") of claims 1-20 of U.S. Patent No. 9,283,367 ("the '367 Patent), a parent patent to the '584 Patent, of claims 1-19 of U.S. Patent No. 8,740,864 ("the '864 Patent"), the ultimate parent patent to the '584 Patent, and of claims 1-14 of U.S. Patent No. 10,159,828, a parent patent to the '584 Patent, and the subsequent cancellation of all of those claims in IPR2020-00025, IPR2020-00024, and IPR2020-00026 respectively.

The '584 Patent has not been involved in any IPR proceeding or other litigation.

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.

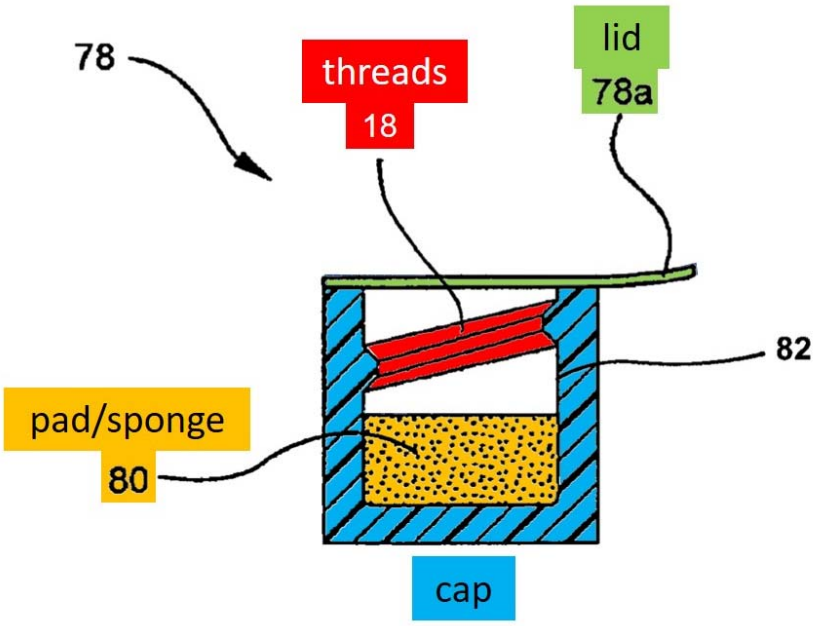
I. INTRODUCTION

Baxter requests institution of *Inter Partes* Review ("IPR") of claims 1-18 ("Challenged Claims") of the '584 Patent and the subsequent cancellation of the Challenged Claims in view of the Grounds described below.

The purported invention of the '584 Patent is, at its core, a threaded cap. The '584 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 '584 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 related '864 Patent in an earlier *inter partes* proceeding.[1]

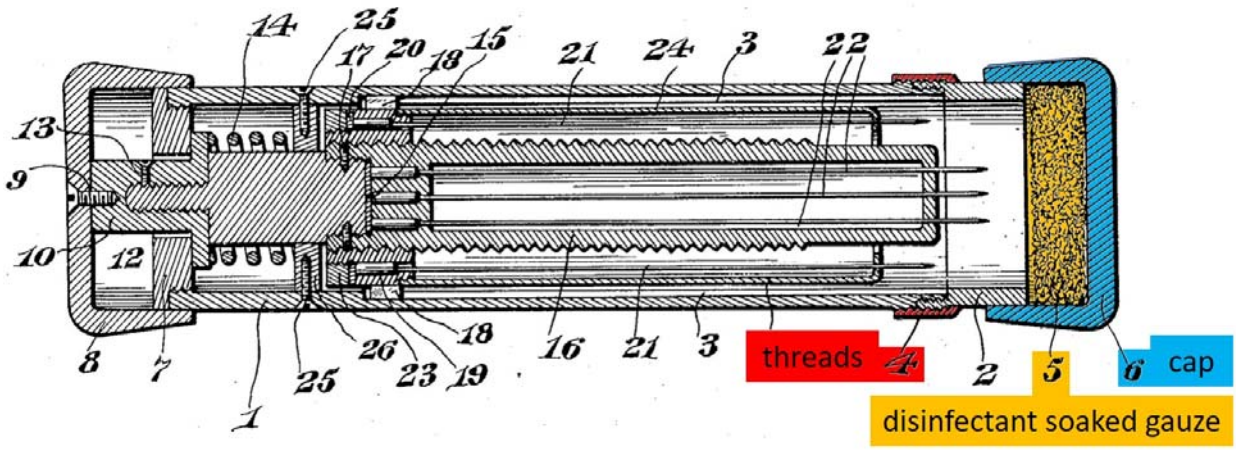
[1] The Parties in that prior proceeding stipulated to dismissal before the PTAB reached a final adjudication of the claims, necessitating this petition.

Figure 10b of the '584 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, 5:13-18).

As shown herein, the '584 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 '584 Patent does not add anything to the state of the art. Thus, Petitioner hereby requests *inter partes* review of the Challenged Claims of the '584 Patent in light of the prior art identified herein.

II. TECHNOLOGY OF THE '584 PATENT

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

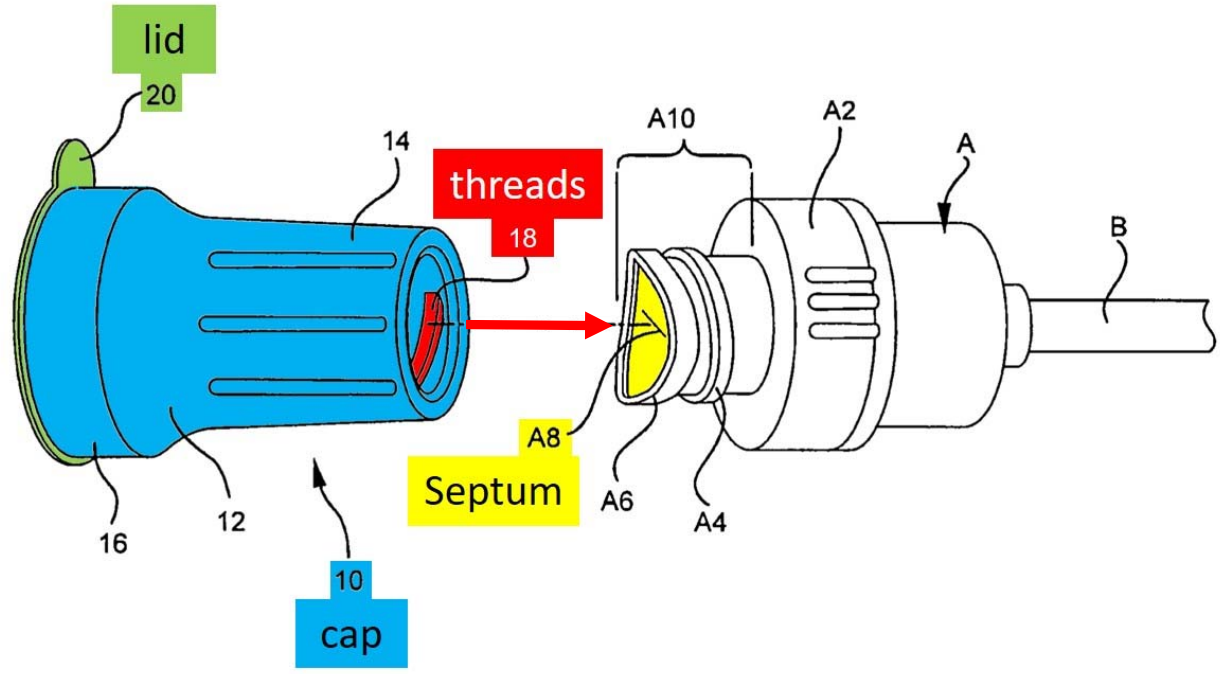
Connectors to patient fluid lines allow the administration of liquid drug formulations and other fluids via those lines without the use of syringes. (Ex. 1002, ¶¶19-20). These connectors rely upon antimicrobial solutions for disinfection. (Ex. 1002, ¶20). One well-known way to disinfect these connectors 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. '584 Patent Overview

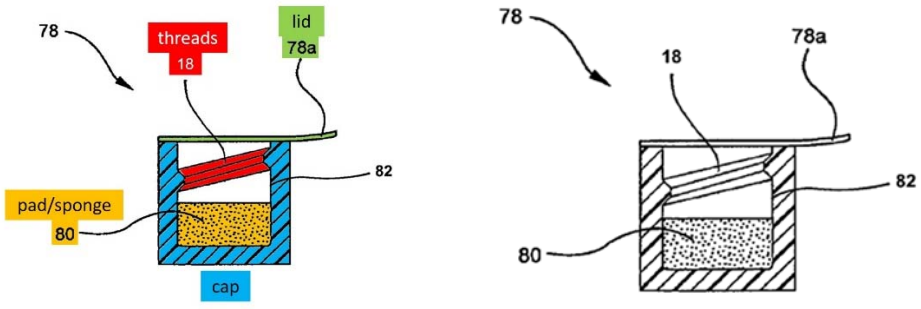
The '584 Patent is titled "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner," and relates to a device for antiseptically maintaining a clean patient fluid line access valve. (Ex. 1001, 1:49-50). Figure 1 of the '584 Patent is an exploded view of the claimed cleaner cap (10) and access valve (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, 2:17-19). 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, 2:34-45; Ex. 1002, ¶23). The open cap end (14) contains threading (18) for interlocking with the threading (A4) of access portion (A10) of the connector (A). A10 further includes the exposed surface of the septum (A6) and at least a portion of the exposed surface of housing (A2). (Ex. 1001, 2:15-54, 3:7-11; Fig. 3). In alternative embodiments (depicted in Figure 7), the pad in the cap may be either dry pad or wet. (Ex. 1001, 5:13-17).

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 '584 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 '584 Patent does not represent any improvement over the then-existing state of the art.

C. Prosecution History of the '584 Patent

The application leading to the '584 Patent was filed on February 11, 2016, as Application No. 15/041,939 ("the '939 Application"). (Ex. 1001, Cover). The '939 Application claims priority to U.S. Application No. 14,159,959 ("the '959 Application") leading to the '367 Patent, a continuation of U.S. Application No. 11/281,711 ("the '711 Application") leading to the '864 Patent, which was filed on November 17, 2005. (*Id.* at Cover, 1:6-13).

The '939 Application received just one substantive rejection. The Applicant filed a Terminal Disclaimer which led to allowance. During prosecution of the '711 Application, the Examiner concluded that the cited art failed to, in the Examiner's mind, 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 '584 Patent obvious.

D. Prior Proceedings

1. Prior IPR

The Board instituted review of claims 10, 12 and 14[2] of the '864 Patent as being 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).

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.

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

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

Petitioner certifies that (1) the '584 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 '584 Patent.

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

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

V. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSA") is a hypothetical person who is presumed to know the relevant prior art. *See Gnosis S.P.A et al. v. S. Ala. Med. Sci. Foundation*, Case IPR2013-00116, Paper 68 at 9, 37 (P.T.A.B. June 20, 2014). That person has ordinary creativity, is not an automaton, and is capable of combining teachings of the prior art. *Id*. (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-421 (2007)).

With respect to the '584 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, 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 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. "external threads on the access portion proximate the septum"

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

B. "length"

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

C. "access portion"

The Patent Owner previously argued that "access portion" should be construed as "the exposed surface of the septum and the exposed surface of the housing that surrounds the septum." (Ex. 1005, 148-149 *citing* Ex. 1020, 2:3-7).

D. Remaining Terms

Petitioner submits that the remaining claim elements should 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*	1-18
2	§ 103	*Menyhay*, *Genatempo*, and *Raad*	5, 8-11, 14, 18
3	§ 103	*Menyhay*, *Genatempo*, and *Miyahara*	13, 16
4	§ 103	*Connell*, *Raulerson*, and *Genatempo*	1-18
5	§ 103	*Connell*, *Raulerson*, *Genatempo*, and *Raad*	5, 8-11, 14, 18
6	§ 103	*Connell*, *Raulerson*, *Genatempo*, and *Miyahara*	13, 16

Petitioner also provides the declaration of Mr. Richard Meyst, an expert in the field of the '584 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*, 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]

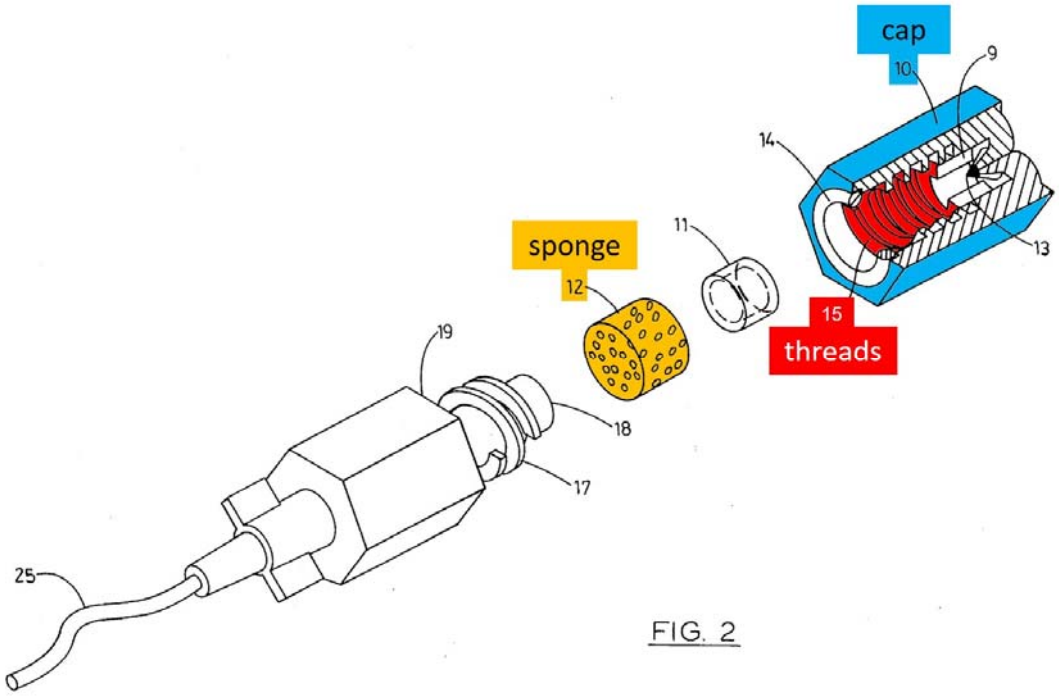


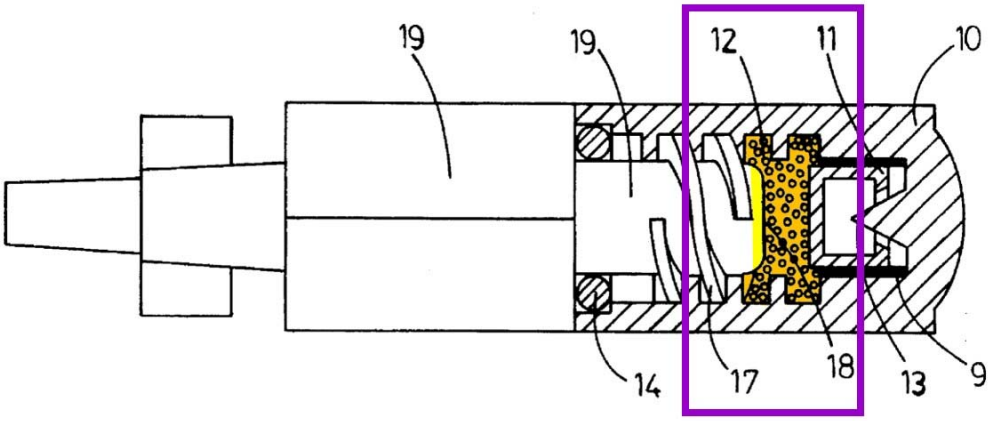
FIG. 2

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). *Menyhay* describes a cylinder or cap

[3] The '584 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

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

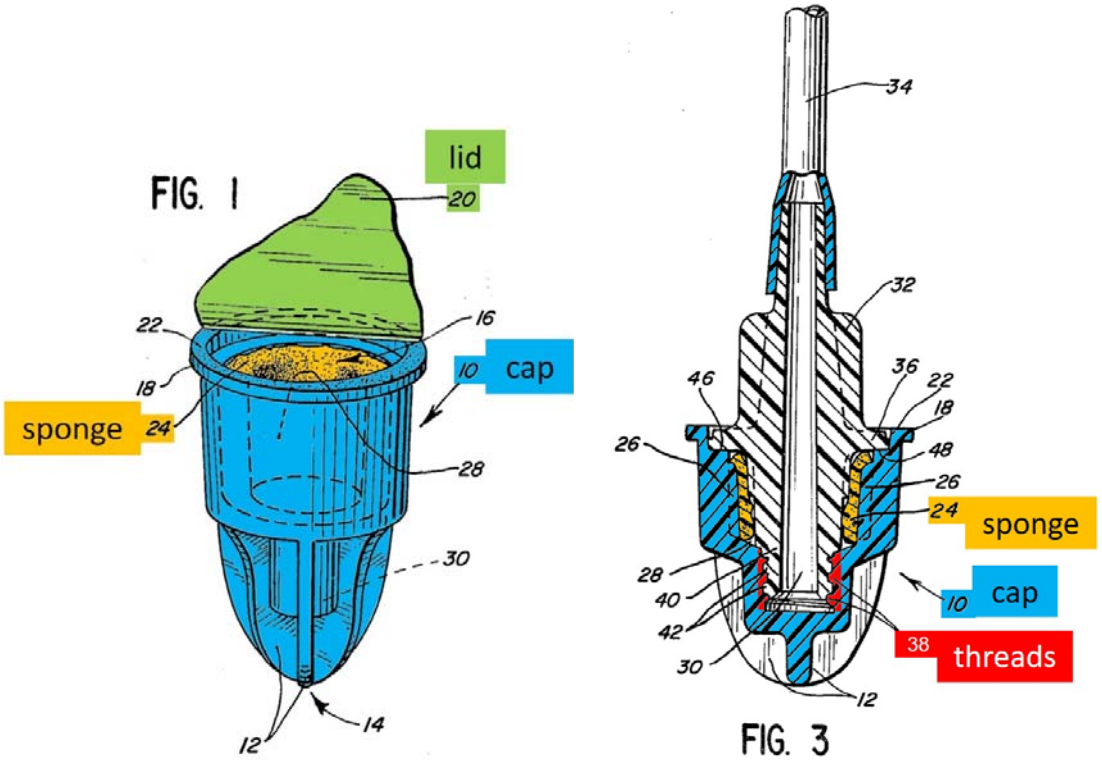
As the cylinder and connector port are screwed together, the wetted sponge contacts the septum 18 (in yellow), as shown below in the purple box. (*Id.* at 6:59-7:3).



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

3. *Raad*

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

Raad claims the use of an antiseptic agent that is selected from a group that includes, among others, isopropanol, povidone-iodine, and chlorhexidine, as well as using such a solution for cleaning a surface. (Ex. 1016, claims 10, 20; Ex. 1002, ¶39). The surface may include a catheter, and using the solution may 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 the 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).

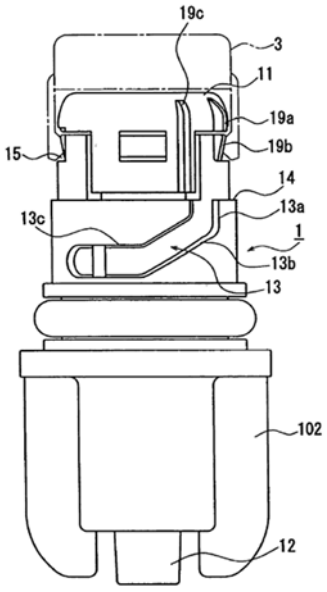


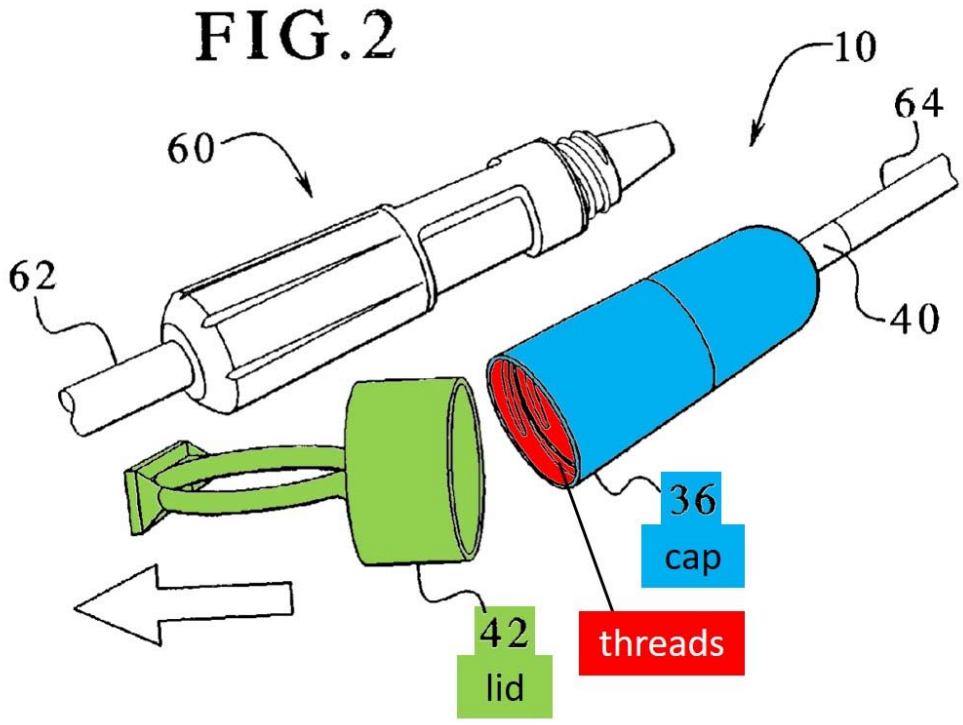
FIG. 3

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

5. *Connell*

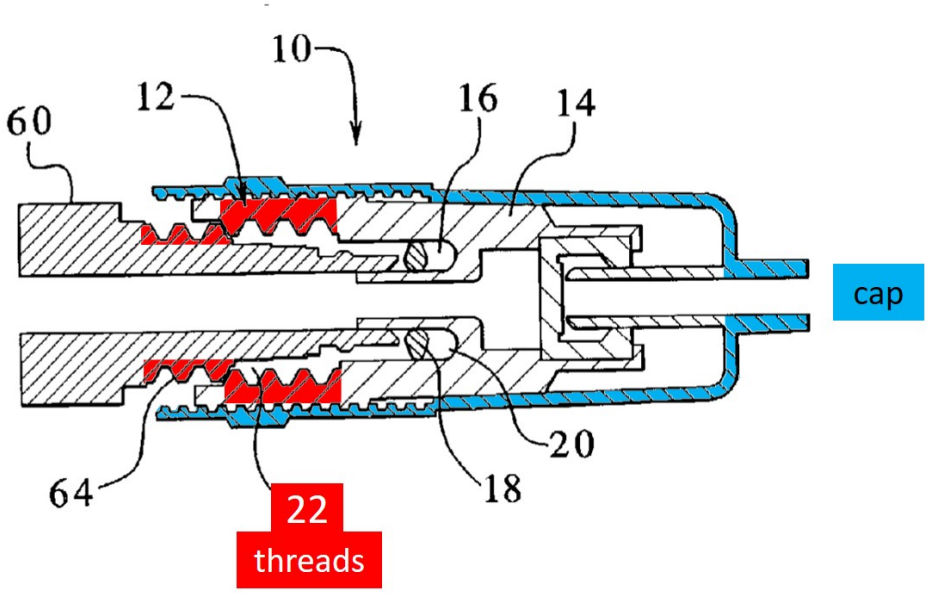
U.S. Patent Publication No. 2003/0153865 to Connell et al. ("*Connell*") published August 14, 2003 and is prior art under at least 35 U.S.C. §102(b). (Ex. 1010, Cover).

Connell discloses a cap and connector that provide for disinfecting a patient line. (Ex. 1010, ¶¶14-15, Fig. 2; 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, Fig. 4; Ex. 1002, ¶50). 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, *Raulerson* teaches a luer cleaner (100) that includes an end opening into a cavity with a plurality of bristles extending into the cavity to engage the outer surfaces of a luer proximal end (190) disposed within the cleaner. (Ex. 1011, Abstract; Ex. 1002, ¶56).

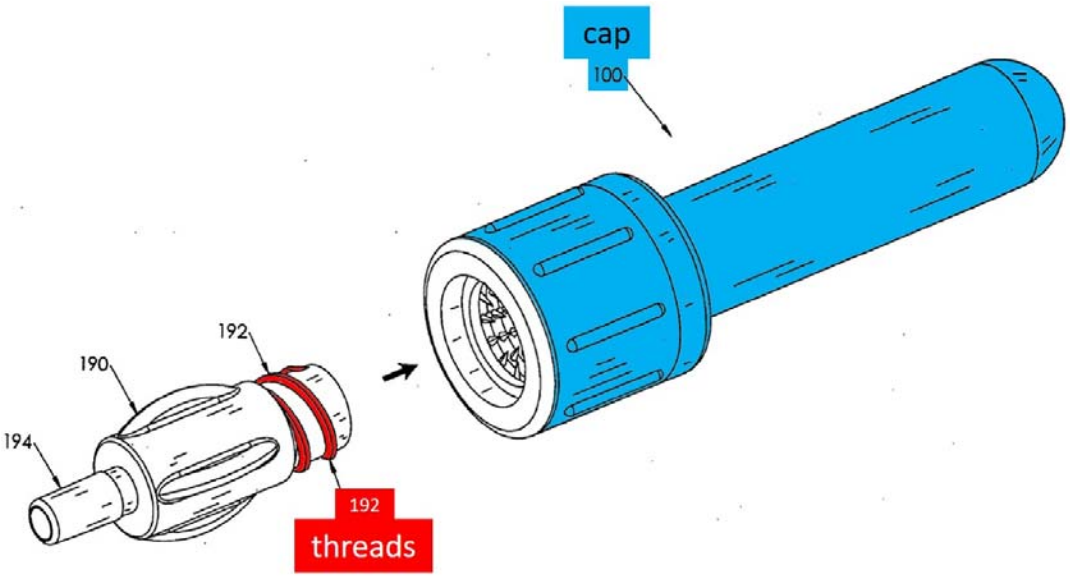


FIG. 1

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

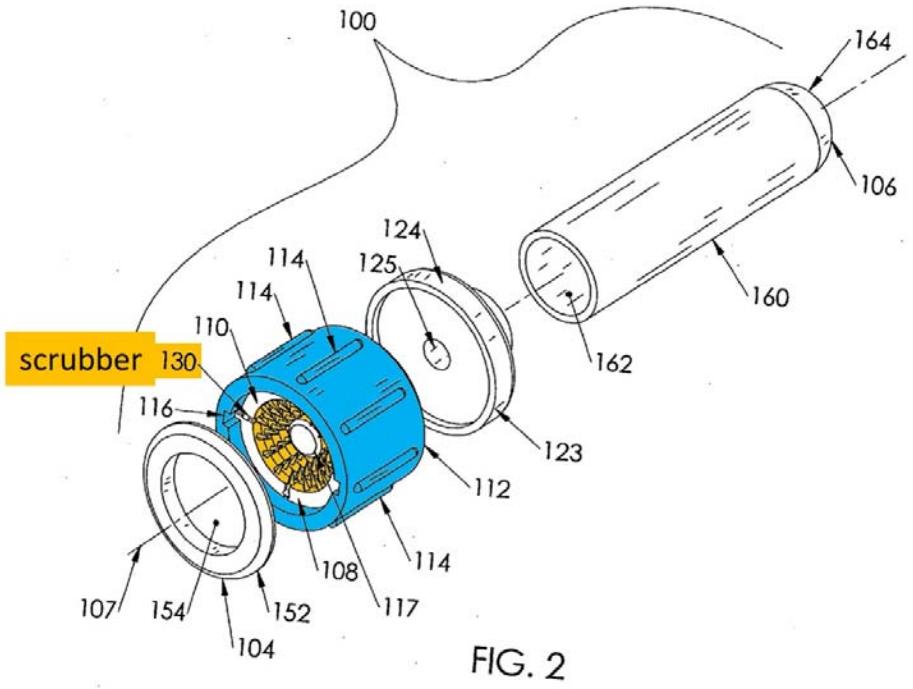


FIG. 2

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

C. Ground 1: Challenged Claims are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Genatempo* and *Menyhay*.

As supported by Mr. Meyst, independent claims 1, 12, and 15, and claims 2-11, 13-14, and 16-18 depending therefrom, are obvious in view of *Genatempo* and *Menyhay*. (Ex. 1002, ¶¶74-85).

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 '584 Patent). (*See* Ex. 1005, 168, 99-103, 105-108). *Genatempo* identifies the same problem and solution (Ex. 1006, 1:41-45) as the '584 Patent (Ex. 1020, 1:25-40).

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). 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).

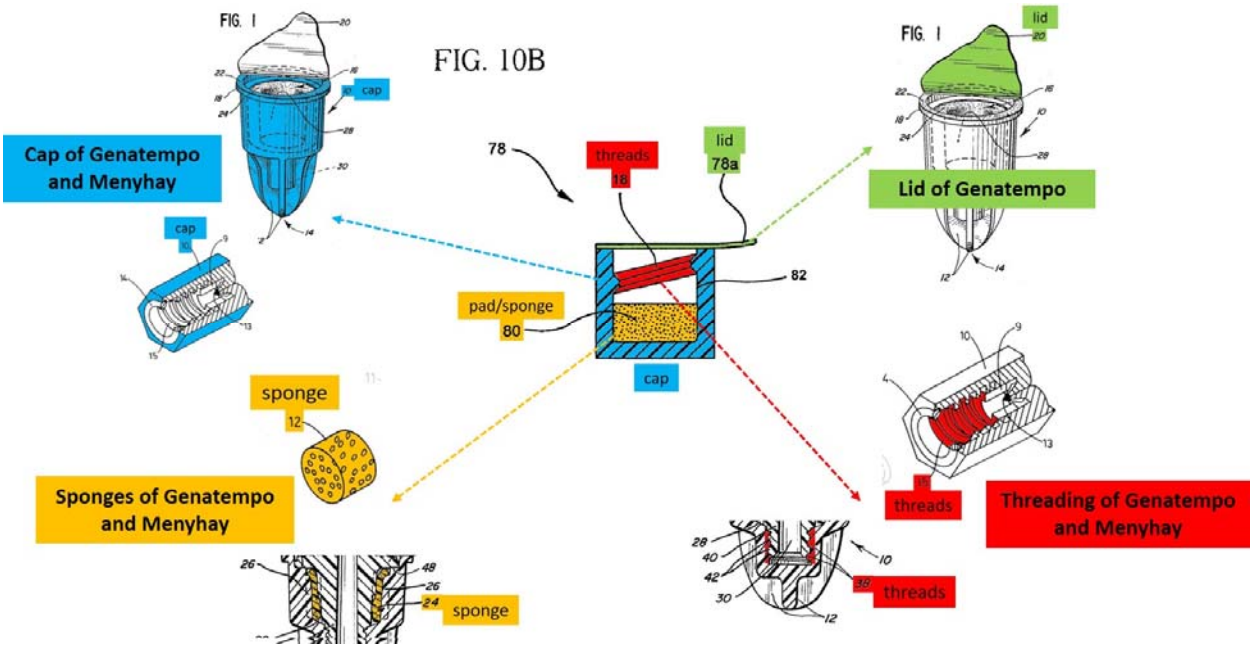
Having combined *Menyhay* with *Genatempo* in the manner described above, a POSA would have also modified the configuration to include a lid or seal (as

suggested by *Genatempo*) to ensure the resulting preloaded sponge neither dries out nor expels its liquid prematurely. (Ex. 1002, ¶¶76, 79). This lid would perform the same function in the resulting combination as in *Genatempo*, ensuring the cleaning cap is sealed and that the solution does not evaporate. (Ex. 1006, 2:62-3:8). 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. Claims of a patent are obvious if they are a rearrangement of known features that perform as expected. *KSR*, 550 U.S. at 420-21. "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." *Id.* at 417.

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 an 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 and would have had an expectation of success in doing so. (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 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). A sponge 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). 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 causes the advancement of the connector into the cap when rotated, which causes cleaning of the threads and septum at the end of the connector cap through the advancement of the face into the wetted sponge. (*See e.g.*, Ex. 1007, 6:54-7:3, Figs. 2-3; Ex. 1002, ¶79). The cap includes a peelable lid to ensure that the solution did not prematurely evaporate or become contaminated prior to use. (*See e.g.*, Ex. 1006, 2:63-66, Fig. 1; Ex. 1002, ¶79). The predictable nature of this art supports the proposed combination. *KSR*, 550 U.S. at 420. (Ex. 1002, ¶85).

2. The Challenged Claims are Obvious

a. Independent Claim 1

(1) <u>Preamble</u>

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* states that

threads of port 19 and threads of cover 10 will engage to screw the pieces together. (Ex. 1007, 6:53-53). Port 19 of *Menyhay* includes a rubber septum 18. (Ex. 1007, 6:52-53). *Genatempo* also discloses an antimicrobial protective cap. (Ex. 1006, 1:9-11).

(2) Part [a][4]

Part [a] recites "a housing having an inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine [sic] access valve." *Menyhay* discloses cylinder 10 that is designed to threadingly mate with threads 17 of a connector. (Ex. 1007, 6:38-56, Fig. 2; Ex. 1002, ¶¶31-32).

[4] *See* Claim Appendix of the Challenged Claims for specific notations as to what is considered Part [a], Part [b], etc.

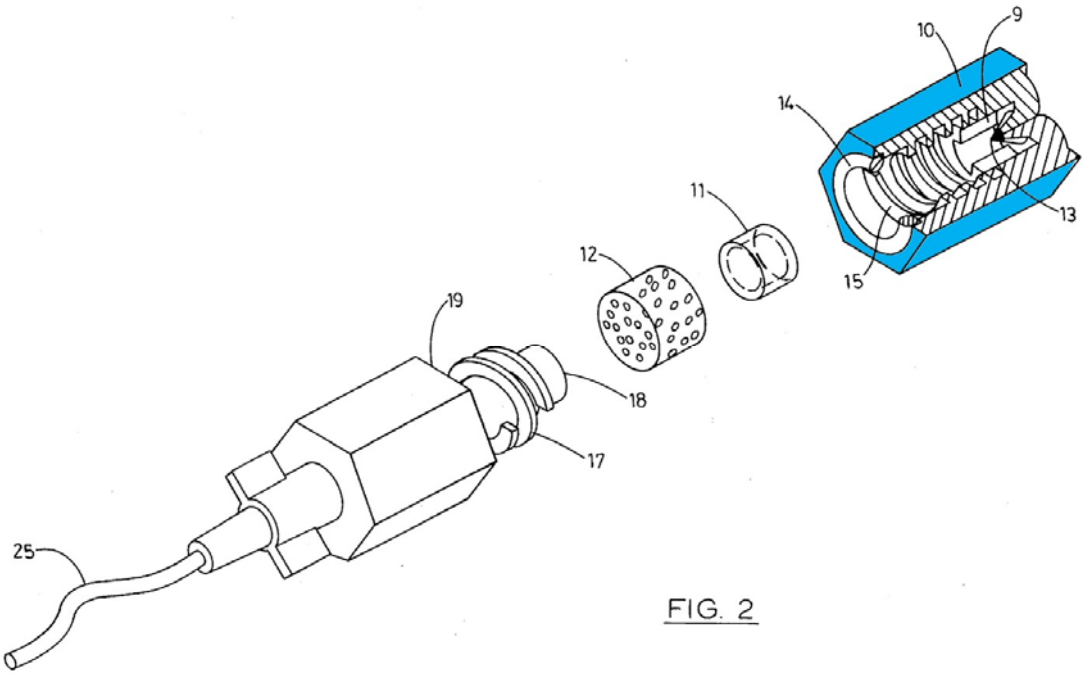


FIG. 2

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).

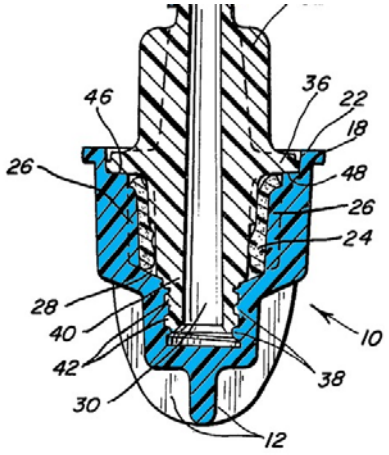


FIG. 3

(3) Part [b]

Part [b] recites "a material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve, wherein the material is disposed in the inner cavity." *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).

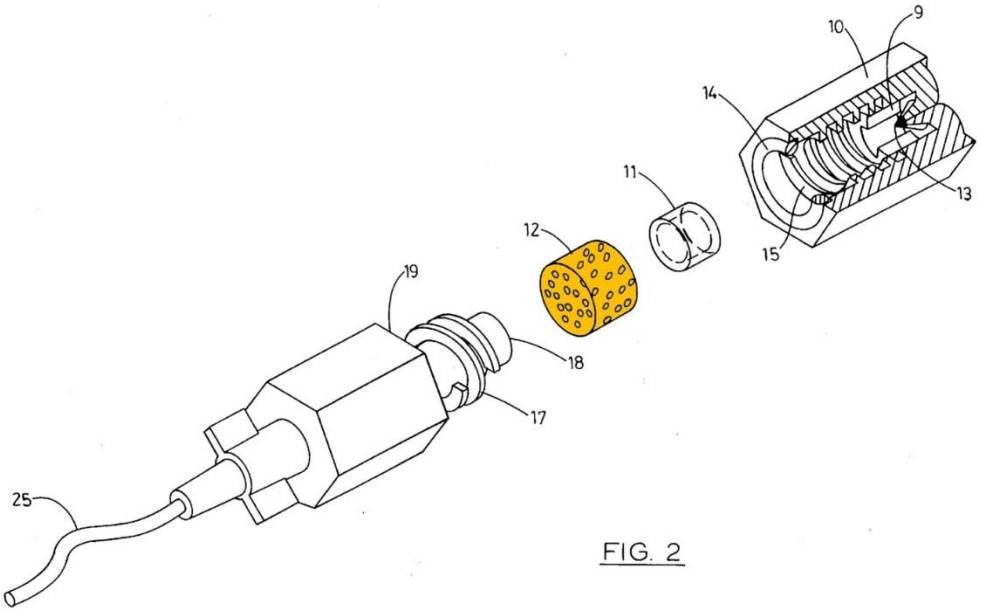


FIG. 2

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).

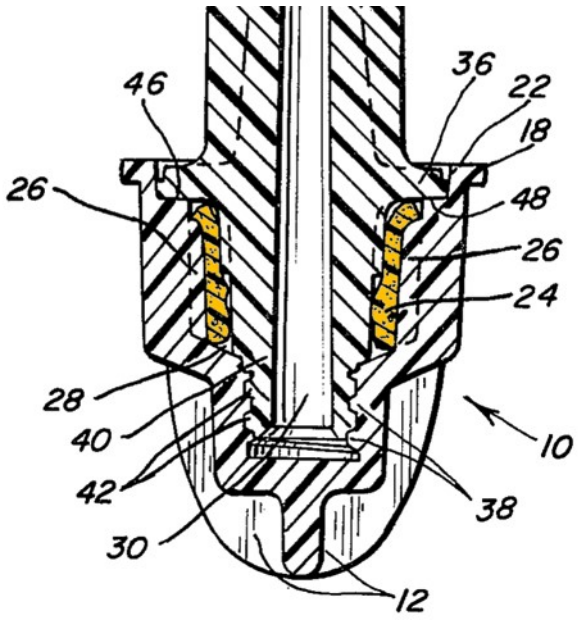


FIG. 3

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 becoming fully wetted in the time between breaking the seal and the disinfecting process. (Ex. 1002, ¶¶75-76; Ex. 1006, 1:44-52).

(4) 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). Threads 15 of *Menyhay*, annotated in red below, are located near the opening of cap 10. (Ex. 1007, Fig. 2; Ex. 1002, ¶31).

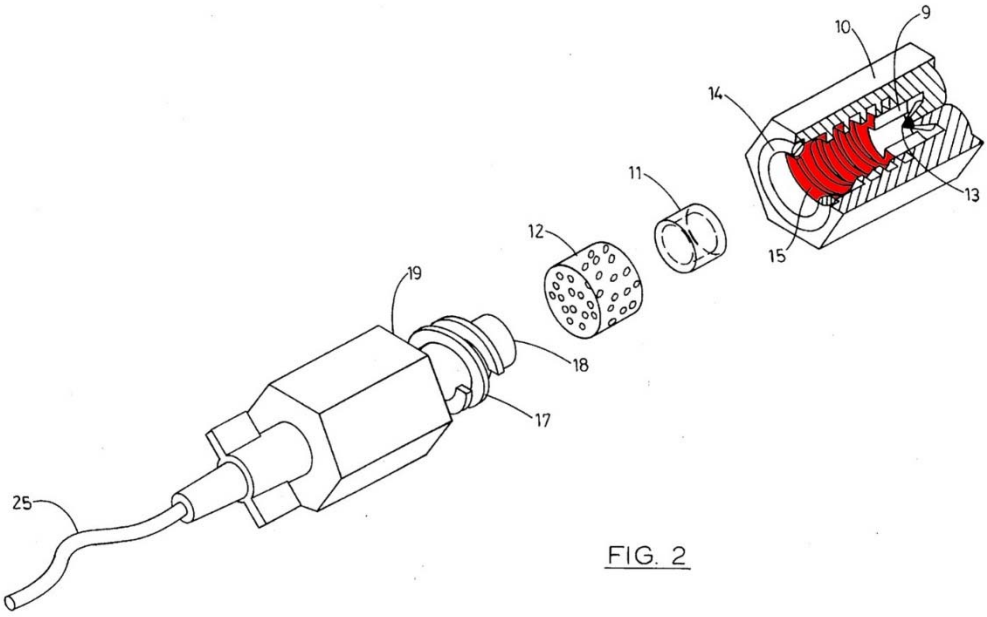


FIG. 2

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

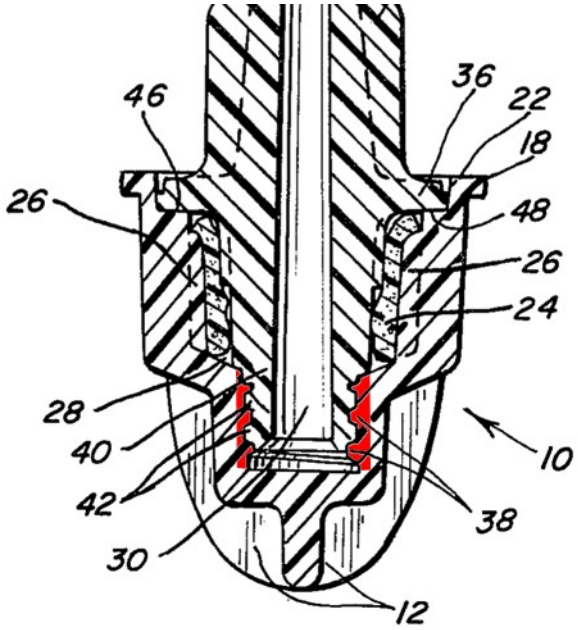
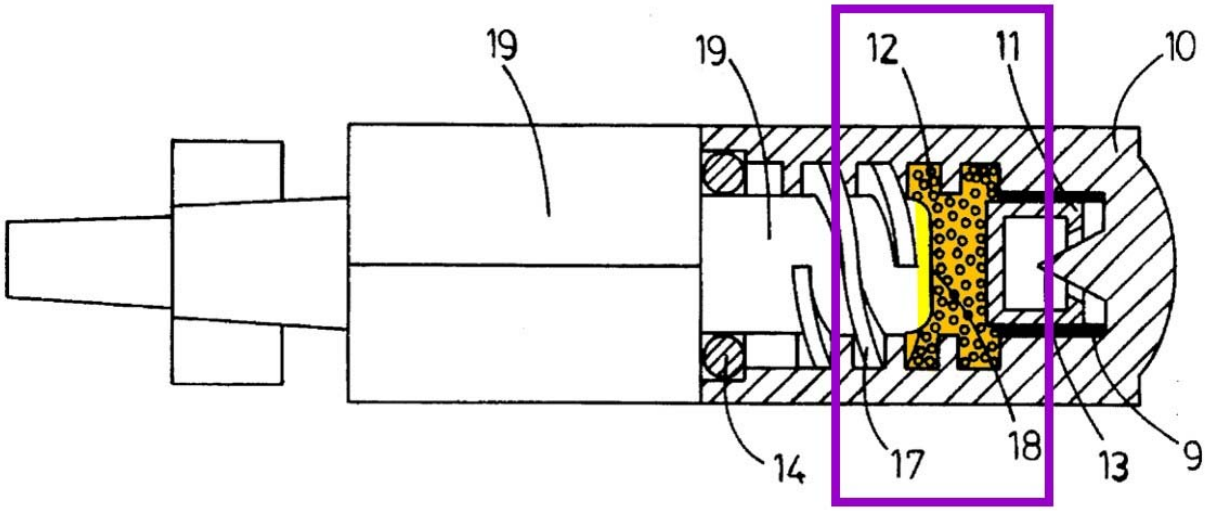


FIG. 3

(5) Part [c.i]

Part [c.i] recites "the threading configured 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 material 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 above), as shown in purple above. (Ex. 1007, 6:67-7:3; Fig. 3; Ex. 1002, ¶30).

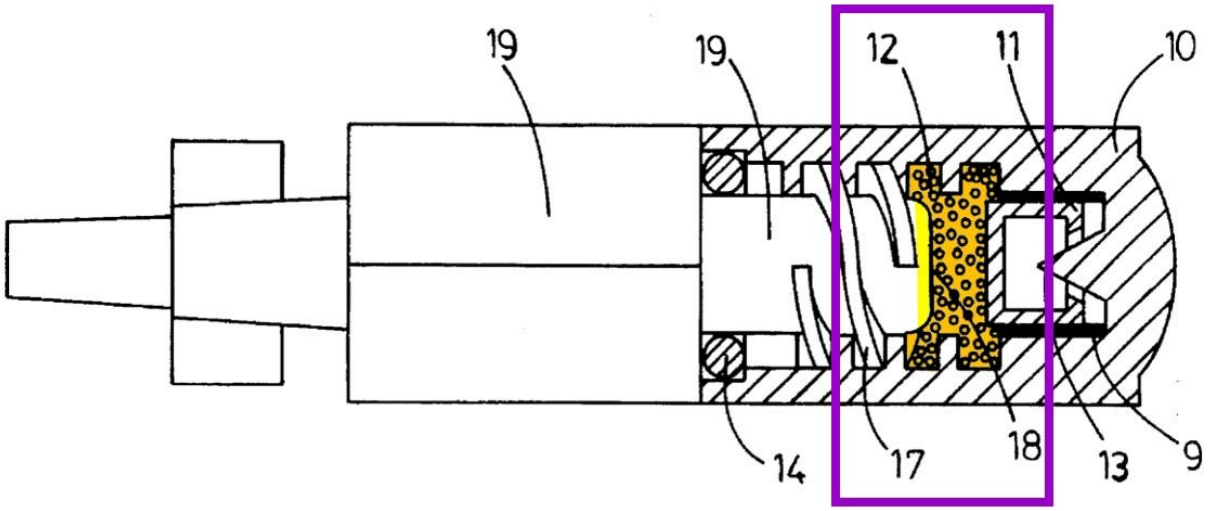
(6) Part [c.ii]

Part [c.ii] recites "configured 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 liquid antimicrobial agent from the material." *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).

(7) Part [d]

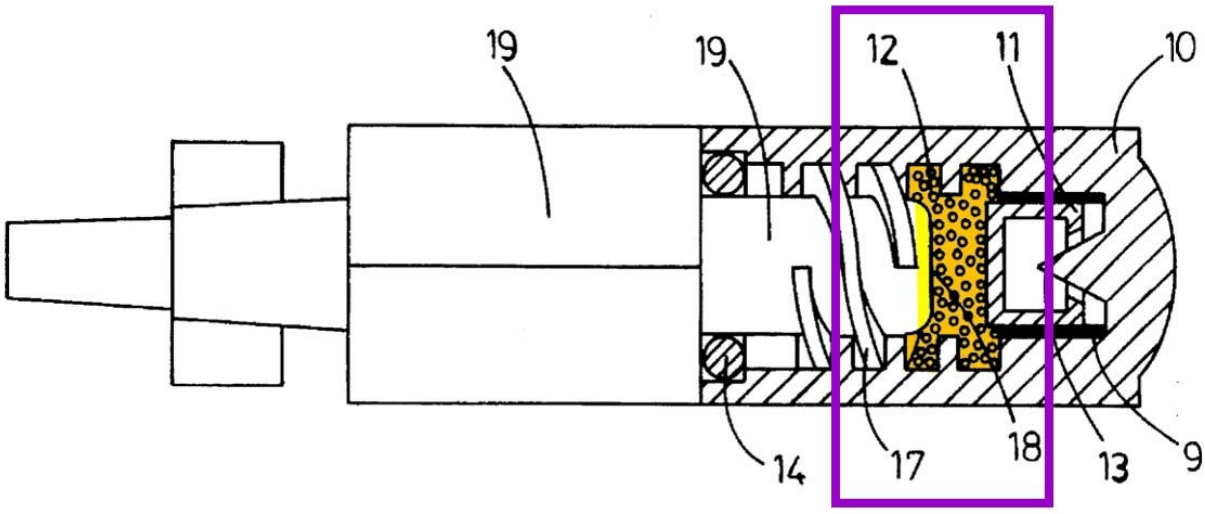
Part [d] recites "wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the material." *Menyhay* discloses that the engagement between threads 17 and 15 cause 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).



b. Dependent Claims 2-11, 13

(1) Claim 2

Claim 2 recites: "The device of claim 1, wherein a threaded interaction between the threading and the external threads is configured to provide adjustable positioning of the septum within the inner cavity." *Menyhay* states that cover 10 and port 19 threadingly engage. (Ex. 1007, 6:38-56, Figs. 2-3).



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

(2) Claim 3

Claim 3 recites: "The device of claim 2, wherein adjustable positioning of the septum within the inner cavity is configured to allow the septum to contact the material, and is further configured to allow the septum to contact and compress the material 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 4. (Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1002, ¶¶32, 79).

(3) Claim 4

Claim 4 recites: "The device of claim 1, 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 '584 Patent identifies no specific benefit obtained by using "polyethylene or polypropylene" and states that the housing may be made from any number of known plastics. (Ex. 1001, 2:29-33). The '584 Patent acknowledges that these plastics are known materials for manufacturing medical devices. (Ex. 1001, 2:29-33; Ex. 1002, ¶22). The known plastics of *Menyhay* and *Genatempo* render obvious the known plastics of the '584 Patent. *See KSR*, 550 U.S. at 420-21.

(4) Claim 5

Claim 5 recites: "The device of claim 1, 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 '584 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad, including the claimed chlorhexidine and the povidone iodine of the prior art. (Ex. 1001, 2:49-54). A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents. (Ex. 1002, ¶¶81-84). A POSA would have found the selection of the claimed chlorhexidines obvious. (Ex. 1002, ¶¶81-84, 87-91).

(5) Claim 6

Claim 6 recites: "The device of claim 1, wherein the material comprises a dry pad." The material of claim 1 is "impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve." (Ex. 1001, Claim 1). The "dry pad" of claim 6 must encompass this liquid impregnated material of independent claim 1, from which claim 6 depends. The '584 Patent specification confirms that the dry pad is impregnated with a liquid. (*Id.* at 2:60-66). For at least the reasons set forth in [1b], the sponges of the *Menyhay*/*Genatempo* combination render obvious this limitation as they are dry before they are impregnated with

antiseptic solution. *See 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).

(6) Claim 7

Claim 7 recites: "The device of claim 6, wherein the dry pad comprises a sponge." *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).

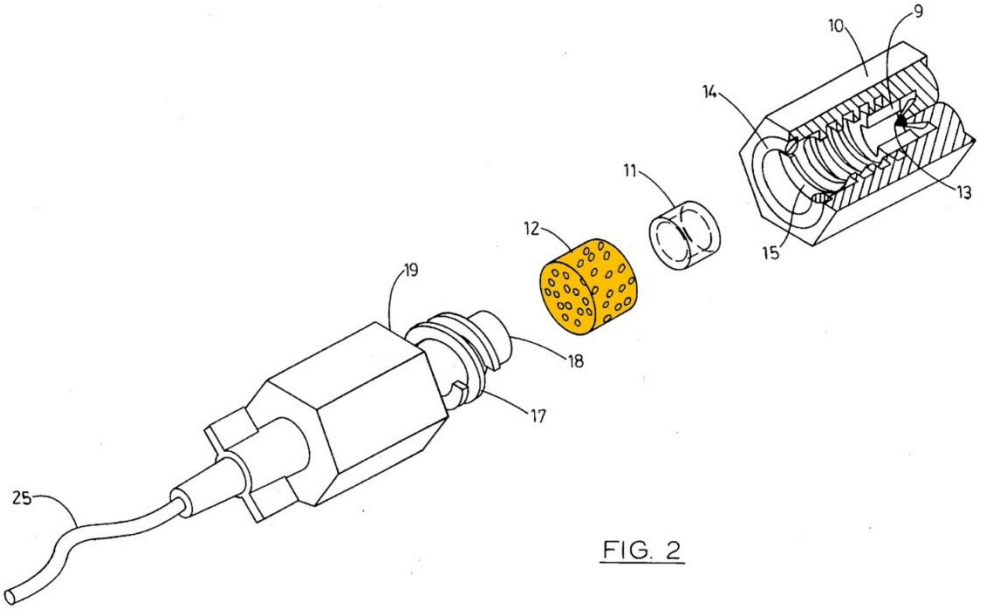


FIG. 2

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).

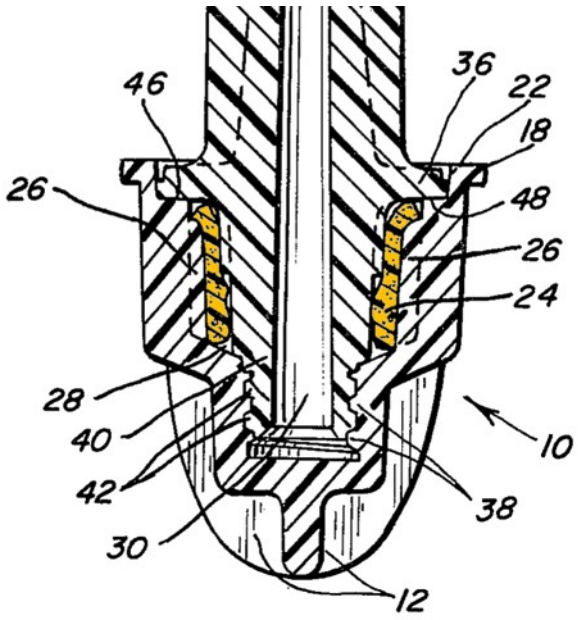


FIG. 3

(7) Claim 8

Claim 8 recites: "The device of claim 1, wherein the liquid antimicrobial agent comprises chlorhexidine." *Menyhay* and *Genatempo* both describe the use of povidone iodine. (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23). The '584 Patent confirms that "any of a number of antimicrobial agents may be used." (Ex. 1001, 2:49-54). A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents. (Ex. 1002, ¶¶81-84). A POSA would

have found the selection of the claimed chlorhexidines obvious. (Ex. 1002, ¶¶81-84, 87-91).

(8) Claim 9

Claim 9 recites: "The device of claim 1, wherein the liquid antimicrobial agent comprises one or more of the following: chloroxylenol, povidone iodine, Triclosan, and benzethonium chloride." *Menyhay* and *Genatempo* both describe the use of povidone iodine. (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23).

(9) Claim 10

Claim 10 recites: "The device of claim 1, wherein the liquid antimicrobial agent comprises one or more of the following: benzalkonium chloride and octenedine."

Menyhay and *Genatempo* both describe the use of povidone iodine. (Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23). The '584 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad, including the claimed benzalkonium chloride and octenedine, as well as the povidone iodine of the prior art. (Ex. 1001, 2:49-54). A POSA would have been acquainted with benzalkonium chloride and octenedine as common antimicrobial agents. (Ex. 1002, ¶¶81-84). A POSA would have found the selection of the claimed benzalkonium chloride and/or octenedine obvious. (Ex. 1002, ¶¶81-84, 87-91).

(10) Claim 11

Claim 11 recites: "The device of claim 1, wherein the liquid antimicrobial agent comprises an antibiotic." *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). The '584 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad. (Ex. 1001, 2:49-54). A POSA would have been acquainted with common antimicrobial agents, including antibiotics. (Ex. 1002, ¶¶81-84). A POSA would have found the use of an antibiotic within the antimicrobial solution obvious. (Ex. 1002, ¶¶81-84, 87-91).

(11) Claim 13[5]

Claim 13 recites: "The device of claim 12, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference." The '584 Patent identifies no benefit from fixing the threading at "a length that is less than the inner circumference" of the inner cavity.

The claimed threading length, as depicted in the figures, closely mirrors that of the prior art references used herein. For example, the threading of Figure 10b of

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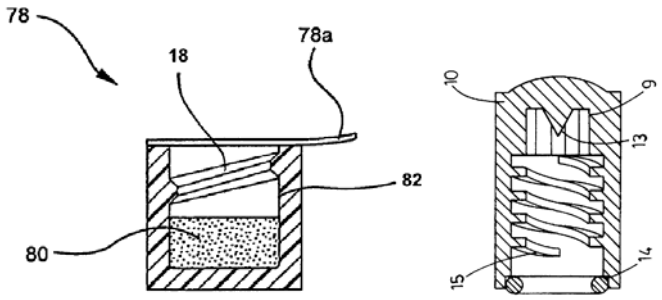
[5] Claim 13 depends from Claim 12, which is addressed in greater detail in the table below.

the '584 patent completes one rotation, whereas the threading 15 of *Menyhay's* Figure 4 similarly completes 4 rotations. (*Compare* Ex. 1001, Fig. 10b *with* Ex. 1007, Fig. 4).



This election of size of the threading is only an unpatentable design choice. *See* MPEP 2144.04(IV)(A); *Gardner v. TEC Syst., Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830 (1984) (holding where the only difference between the prior art and the claims is a change in relative dimension, the claimed device with the change in relative dimension would not perform differently than the prior art and the claimed device is therefore not patentably distinct); *Lockwood v. AA*, 107 F.3d at 1570.

c. The Remaining Claims

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

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
12[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.	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.	Ex. 1007, 4:13-22, 6:52-57; Ex. 1002, ¶¶30-31; Ex. 1006, 1:9-11
12[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 inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine [sic] 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 configured to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed	Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 34-35; Ex. 1006, 2:21-24, 3:37-39, Fig. 3

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
	over the access portion of the patient fluid line access valve to contact the material with the distalmost end face of the access portion of the patient fluid line access valve	
12[b] a material impregnated with a liquid antimicrobial agent prior to attachment of the housing to the access portion of the patient fluid line access valve, the material 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 material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve, wherein the material is disposed in the inner cavity 1[c.i] the threading configured 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 material with the distalmost end face of the access portion of the patient fluid line access valve 1[c.ii]	Ex. 1007, 6:38-56, 6:64-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 75-76, 79; Ex. 1006, 1:44-52, 2:62-3:8, 3:22-23, 3:42-45, Fig. 3

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
	configured 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 liquid antimicrobial agent from the material.	
12[c] wherein in response to insertion of the access portion of the patient fluid line access valve into the cavity, the thread is configured to engage 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 material to provide the liquid antimicrobial agent to the septum and at least a portion of the external threads	1[c.ii] configured 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 liquid antimicrobial agent from the material. 1[d] wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the material	Ex. 1007, 6:54-7:3, Figs. 2-3; Ex. 1002, ¶¶31-32, 35, 79; Ex. 1006, 3:42-45
14 The device of claim 12, wherein the antimicrobial agent comprises at least one	5 The device of claim 1, wherein the antimicrobial agent comprises at least one of	Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23; Ex. 1002, ¶¶81-84, 87-91

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
of chlorhexidine gluconate and chlorhexidine diacetate.	chlorhexidine gluconate and chlorhexidine diacetate	
15[pre] 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[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.	Ex. 1007, 4:13-22, 6:52-57; Ex. 1002, ¶¶30-31; Ex. 1006, 1:9-11
15[a] a housing having an inner cavity for covering the access portion of the patient fluid line access valve	1[a] a housing having an inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine [sic] access valve	Ex. 1007, 6:38-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 34-35; Ex. 1006, 2:21-24, 3:37-39, Fig. 3
15[b] a material within the housing and impregnated with a liquid antimicrobial agent prior to contacting the patient fluid line access valve, the material being configured to contact at least a portion o the	1[b] a material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve, wherein the material is disposed in the inner cavity	Ex. 1007, 6:38-56, 6:64-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 75-76, 79; Ex. 1006, 1:44-52, 2:62-3:8, 3:22-23, 3:42-45, Fig. 3

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
threaded patient fluid line access valve and the distalmost end face of the patient fluid line access valve to reduce the amount of microbes on the patient fluid line access valve	1[c.i] the threading configured 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 material with the distalmost end face of the access portion of the patient fluid line access valve 1[c.ii] configured 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 liquid antimicrobial agent from the material	
15[c] a thread within the inner cavity of the housing and positioned between the material and an opening to the inner cavity, the thread for engaging the external threads of the threaded	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 1[c.i] the threading configured to engage the external	Ex. 1007, 6:38-56, 6:64-7:3, Figs. 2-3; Ex. 1002, ¶¶30-32, 35-36, 75-76, 79; Ex. 1006, 1:44-52, 2:62-3:8, 3:22-23, 3:42-45, Fig. 3

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
patient fluid line access valve to cause the material to contact the distalmost end face of the patient fluid line access valve.	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 material with the distalmost end face of the access portion of the patient fluid line access valve	
15[d] wherein in response to the distalmost end face of the access valve being inserted into the housing, the distalmost end face contacts the material to provide the liquid antimicrobial agent to the septum and at least a portion of the external threads	1[c.ii] configured 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 liquid antimicrobial agent from the material 1[d] wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the material.	Ex. 1007, 6:54-7:3, Figs. 2-3; Ex. 1002, ¶¶31-32, 35, 79; Ex. 1006, 3:42-45
16	13	Ex. 1007, Fig. 4; Ex. 1007, Fig. 4

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
The device of claim 15, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference	The device of claim 12, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference	
17 The device of claim 15, wherein the housing comprises a polyethylene or polypropylene material	4 The device of claim 1, wherein the housing comprises a polyethylene or polypropylene material.	Ex. 1006, 3:19-21; Ex. 1007, 7:37-39; Ex. 1002, ¶36
18 The device of claim 15, wherein the liquid antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate	5 The device of claim 1, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate	Ex. 1007, 6:64-7:3; Ex. 1006, 3:22-23; Ex. 1002, ¶¶81-84, 87-91

D. Ground 2: Claims 5, 8-11, 14, and 18 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Menyhay*, *Genatempo* and *Raad*.

If the Board finds that Claims 5, 8-14, and 18 would not have been obvious in view of *Menyhay* and *Geantempo* alone (*see* Section VII.C), the disclosures of *Raad* explicitly confirm that a POSA would have understood the additional limitations of Claims 5, 8, 14, and 18 to be obvious.

1. Basis for Combination

A POSA would have known that povidone iodine (the antiseptic solution of the *Menyhay/Genatempo* combination described above) is a known alternative for chlorhexidine gluconate, such that they are interchangeable. (Ex. 1002, ¶¶86-91). *Raad* discloses that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28). *Raad* also confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27). A POSA would understand that the povidone iodine of the *Menyhay/Genatempo* combination would be readily replaced with the chlorhexidine gluconate[6] solution of *Raad* with an expectation of success. (Ex. 1002, ¶¶88, 91).

Each of *Menyhay* and *Genatempo* disclose the use of povidone iodine but state that modifications to the disclosed invention (which a POSA would understand to

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[6] 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).

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, 2:14-15, 8:4-9; Ex. 1007, 3:57-59, 6:47-49).

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

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

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

examination of the '584 Patent. (Ex. 1017, 2 ("this work was supported by an education grant from Becton Dickinson, UK")). A POSA would know that povidone iodine and chlorhexidine are known, interchangeable, antiseptic solutions. (Ex. 1002, ¶90).

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

2. Claims 5, 8-11, 14, and 18 are Obvious

a. Claim 5

Raad confirms that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28; Ex. 1002, ¶87). *Raad* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶88, 91).

b. Claim 8

For at least the reasons set forth above for Claim 5, the combination of *Menyhay*, *Genatempo*, and *Raad* renders obvious Claim 8.

c. Claim 9

Raad confirms that other known antiseptic solutions at the time also included chloroxylenol and triclosan. (Ex. 1016, ¶32). In addition to the povidone iodine of *Menyhay* and *Genatempo* outlined above in Ground 1, a POSA would have understood that the other known antiseptic solutions of *Raad*, which constitute well-studied ingredients and combinations in the medical field and medical device field, would have been readily used as a known replacement for the povidone iodine explicitly disclosed by *Menyhay* and *Genatempo*, with each performing in a predictable manner. (Ex. 1002, ¶¶87-91).

d. Claim 10

Raad confirms that known antiseptic solutions at the time included benzalkonium chloride (Ex. 1016, ¶28) and octenidine (*id.* at ¶30). A POSA would have understood that the known antiseptic solutions of *Raad*, which constitutes well-studied ingredients and combinations in the medical field and medical device field, would have been readily used as a known replacement for the povidone iodine explicitly disclosed by *Menyhay* and *Genatempo*. (Ex. 1002, ¶¶87-91)

e. Claim 11

Raad teaches that, in the context of its disclosure, each of the antibacterial agents it discusses "are represented by antibiotics." (Ex. 1016, ¶13). *Raad* therefore confirms the understanding of a POSA that "antibiotics" were a general category of antiseptic. (Ex. 1002, ¶87).

f. Claim 14

For at least the reasons set forth above for Claim 5, the combination of *Menyhay*, *Genatempo*, and *Raad* renders obvious Claim 14.

g. Claim 18

For at least the reasons set forth above for Claim 5, the combination of *Menyhay*, *Genatempo*, and *Raad* renders obvious Claim 18.

E. Ground 3: Claims 13 and 16 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 afore-described *Menyhay/Genatempo* combination in view of the disclosure of *Miyahara* in recognition of the fact that a single-turn threading arrangement is within the knowledge of a POSA. (Ex. 1002, ¶¶92-95). *Miyahara* discloses that a disinfecting and protective cap may be securely adhered to a connector with rotation that is less than one full rotation of the cap, confirming that the threading in the aforementioned

combinations may be sized to have a length less than the internal circumference of the cap. (Ex. 1009, ¶¶55-56, Fig. 3).

A POSA would understand that the length of the threads of the *Menyhay*/*Genatempo* combination would be modifiable to a variety of lengths as dictated by the specific circumstances of an application. (Ex. 1002, ¶¶92-95). In particular, because of the seal in the combination, the thread length need not be sufficiently long to prevent liquid from escaping, as the seal provides this function. (Ex. 1002, ¶94). A POSA would also understand that threading with a shorter length reduces the number of rotations needed to advance the cap onto the connector. (Ex. 1002, ¶04). A reduced number of rotations makes the product easier to use for patients and health care providers. (Ex. 1002, ¶94).

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

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

2. Claims 13 and 16 are Obvious

a. Claim 13

As discussed above, Claim 1 is obvious in view of *Menyhay* and *Genatempo*. *Miyahara* depicts guide protrusion 42 which mates with guide groove 13, and the screw action generated between the two causes the advancement of patient side connector 1 and cap 3. (Ex. 1009, ¶¶55-56). *Miyahara* confirms that a rotational distance greater than the inner circumference of the inner cavity is not necessary for advancement or for coupling, and that sufficient cleaning can occur with threading that is shorter (and therefore requiring less rotational movement) than the internal circumference. (Ex. 1002, ¶¶44, 95). As such, the selection of the length of threading in the combination of *Menyhay* and *Genatempo* is a design choice, as evidenced by *Miyahara*. (*Id.*)

b. Claim 16

As discussed above with regard to Claim 13, *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*.

1. Basis for Combination

The controlling case law on combination is set forth above in Section VII.C.1. *Connell* identifies the same problem and solution as that of the '584 Patent, noting that disinfecting connectors is essential, but contamination occurred with the then-existing methods. (Ex. 1010, ¶¶10-11; Ex. 1002, ¶49). *Connell* teaches the use of a cap to enclose and disinfect the patient line. (Ex. 1010, ¶¶15-25; Ex. 1002, ¶53). This is precisely the same solution to the same problem addressed by the '584 Patent—an "effective and inexpensive way to reduce catheter-related infections" taking the form of "a housing for covering the access portion of the access valve," (e.g., a cap). (Ex. 1001, 1:25-40).

Connell provides a fluid connector cleaner that provides sealed disinfectant to clean the threading of the connector. (Ex. 1010, ¶¶101-103; Ex. 1002, ¶97). *Connell* confirms that it was known to use a cap that threadingly mates with a connector to protect and clean a patient tube. (Ex. 1010, ¶100; Ex. 1002, ¶97). *Connell's* disinfectant is contained in a chamber sealed with seal 18. (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).

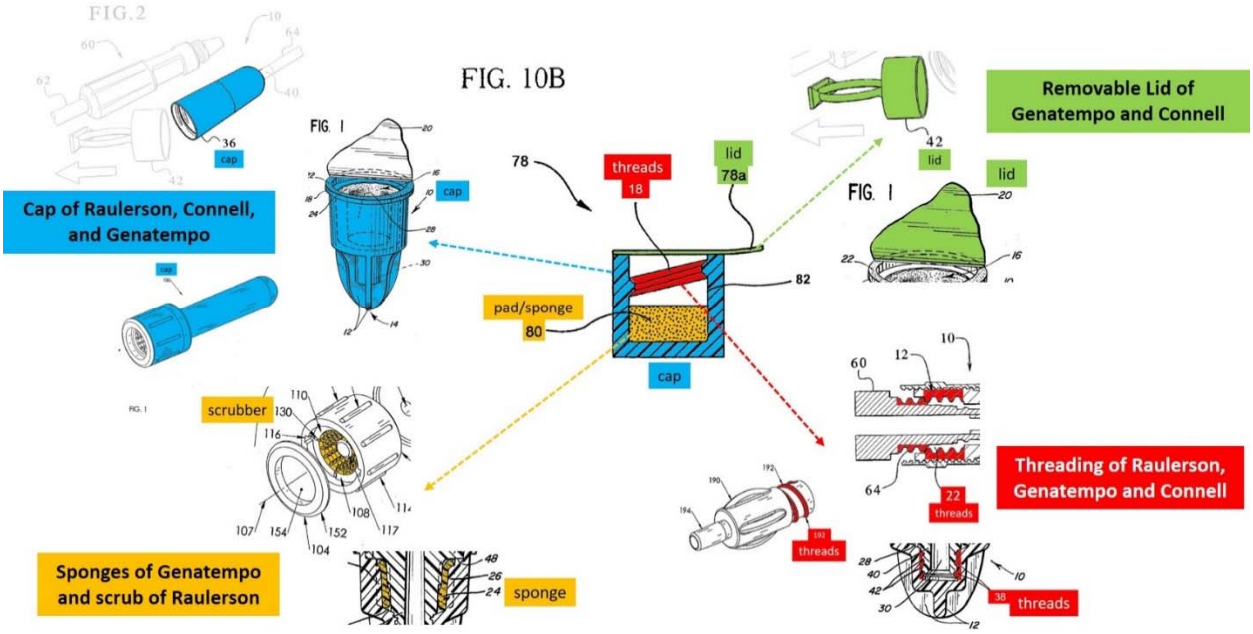
Raulerson teaches a physical scrubbing mechanism that uses rotational energy (such as that produced by a threading engagement or other twisting motion) to clean the threading of a connector. (Ex. 1011, ¶4; Ex. 1002, ¶¶97-98). A POSA would have understood the value of a contact cleaning device (such as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

Connell and *Raulerson* disclose either a small sealed portion with disinfectant (Ex. 1010, ¶100), or a separate squeezable body for the release of cleaning solution (Ex. 1011, ¶31). A POSA would understand that the use of a pre-impregnated absorbent material, such as that of *Genatempo* (Ex. 1006, Abstract), would provide the added benefit of ensuring sufficient wetting of the sponge in advance. (Ex. 1002, ¶99). As discussed above, in such a combination, there would be no dry spots or other infirmities associated with a failure to break the seal. (Ex. 1002, ¶99).

Genatempo also confirms that additional cleaning due to the migration of the antiseptic fluid can be achieved. (Ex. 1006, 3:43-45; Ex. 1002, ¶99). By adopting the pre-impregnated sponge of *Genatempo*, as previously discussed, a POSA would understand that additional liquid can be provided, sufficient to, when the sponge is compressed, release liquid to flow throughout the threading portions of the coupling. (Ex. 1002, ¶99). *Genatempo* describes the use of a removable lid, ensuring that

Genatempo's pre-impregnated sponge does not dry out or expel its liquid prematurely. (Ex. 1002, ¶99).

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



(Ex. 1002, ¶100).

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

The sponge of this combination would be impregnated with an antiseptic cleaning solution. (*See e.g.*, Ex. 1006, 3:22-23, Fig. 3; Ex. 1011, ¶4, Fig. 3; Ex. 1002, ¶100). Additionally, in the resulting combination, the cap would include threading to engage with the threading of the connector. (*See e.g.*, Ex. 1010, ¶¶77-78; Ex. 1002, ¶100). The threading causes the advancement of the connector into the cap when rotated, and the rotation causes cleaning of the threads and septum at the end of the connector cap through the advancement of the face into the wetted sponge. (*See e.g.*, Ex. 1010, ¶¶77-78, 80, 101-103, Fig. 5; Ex. 1002, ¶100). Additionally, the cap would include a peelable lid to ensure that the solution did not prematurely evaporate or become contaminated prior to use. (*See e.g.*, Ex. 1006, 2:63-66, Fig. 1; Ex. 1010, ¶¶14-15, 68, Fig. 2; Ex. 1002, ¶100).

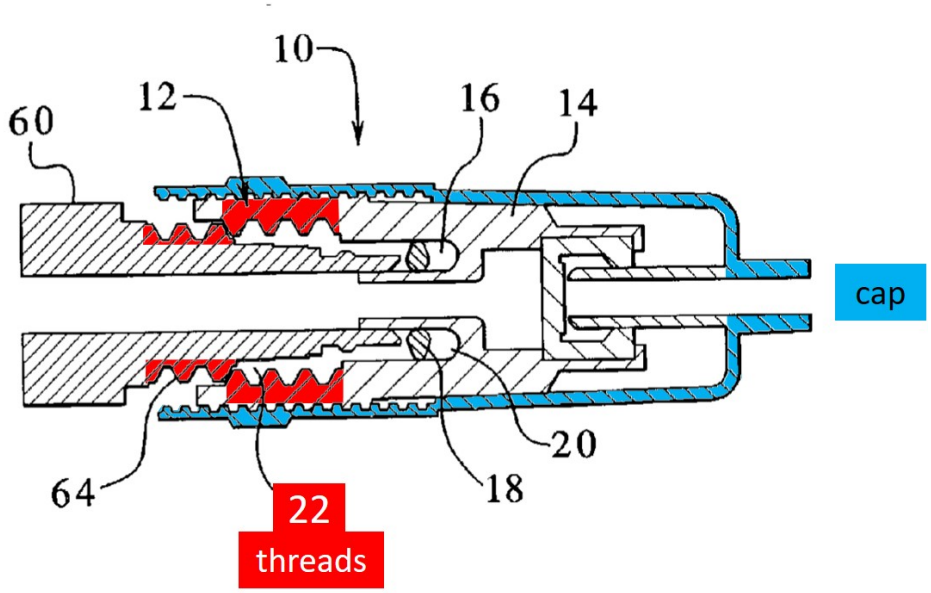
2. The Challenged Claims are Obvious

a. Independent Claim 1

(1) Preamble

Connell describes a connector and a cap for disinfecting the system. (Ex. 1010, ¶66; Ex. 1002, ¶46). Cap 12 includes body 14 that defines 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 members move relative each other via threads 22 and 24. (Ex. 1010, ¶77).

FIG.4



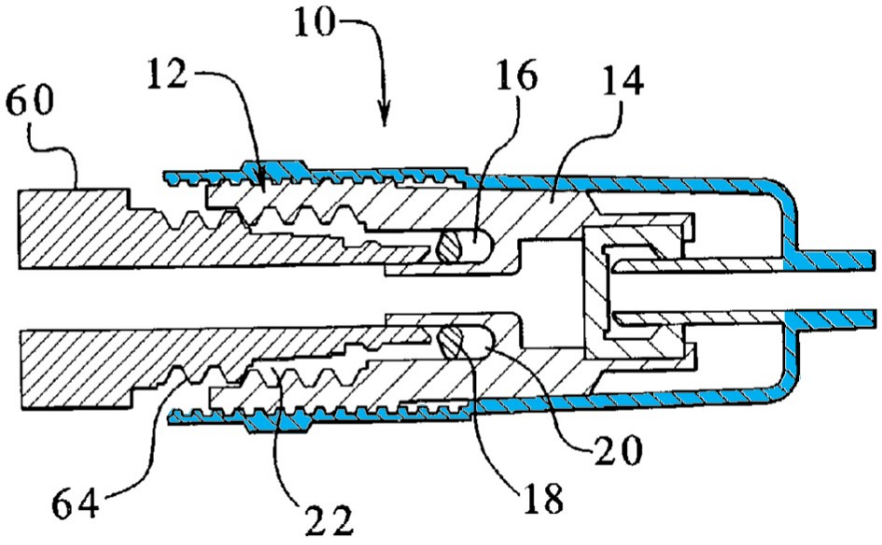
(Ex. 1010, Fig. 4, ¶100).

Genatempo also discloses such a 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).

(2) Part [a]

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

FIG.4



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

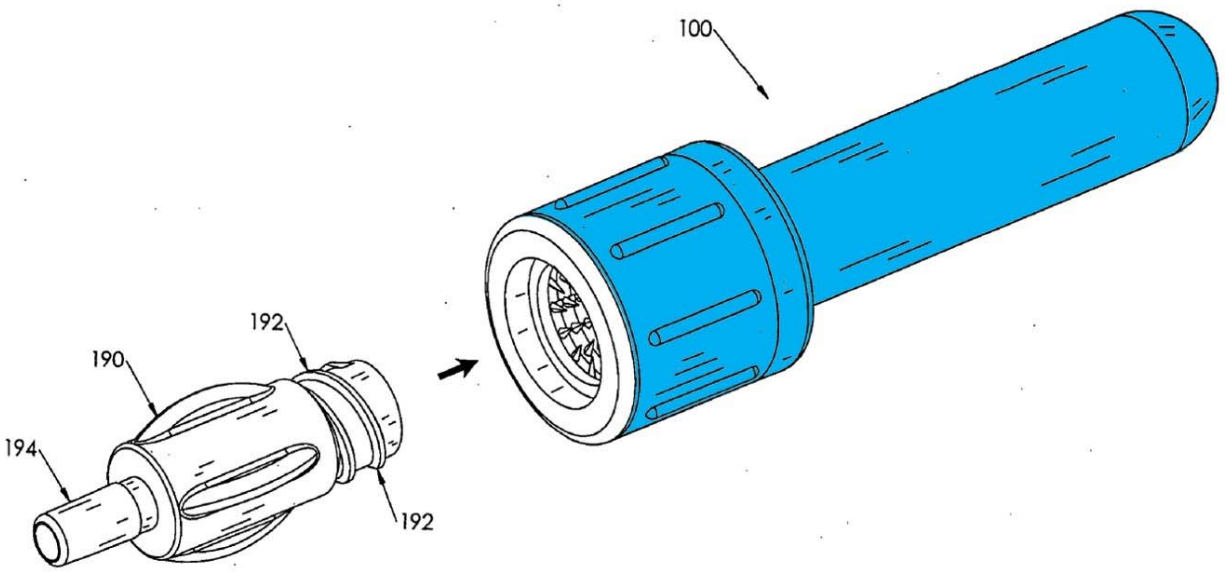


FIG. 1

(*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).

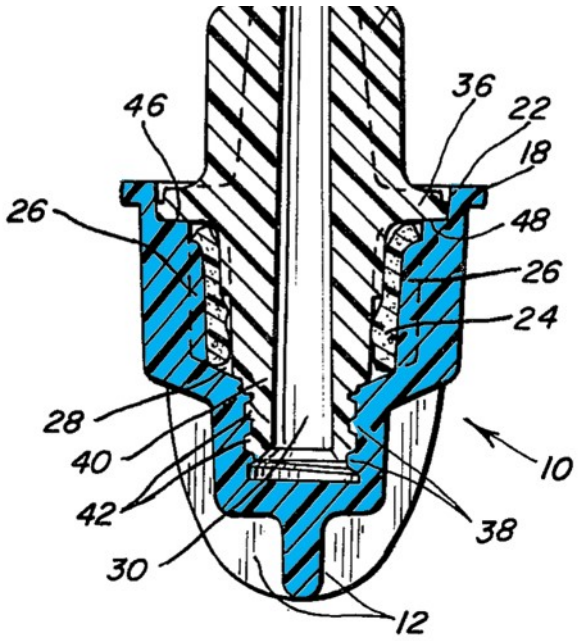


FIG. 3

(3) Part [b]

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

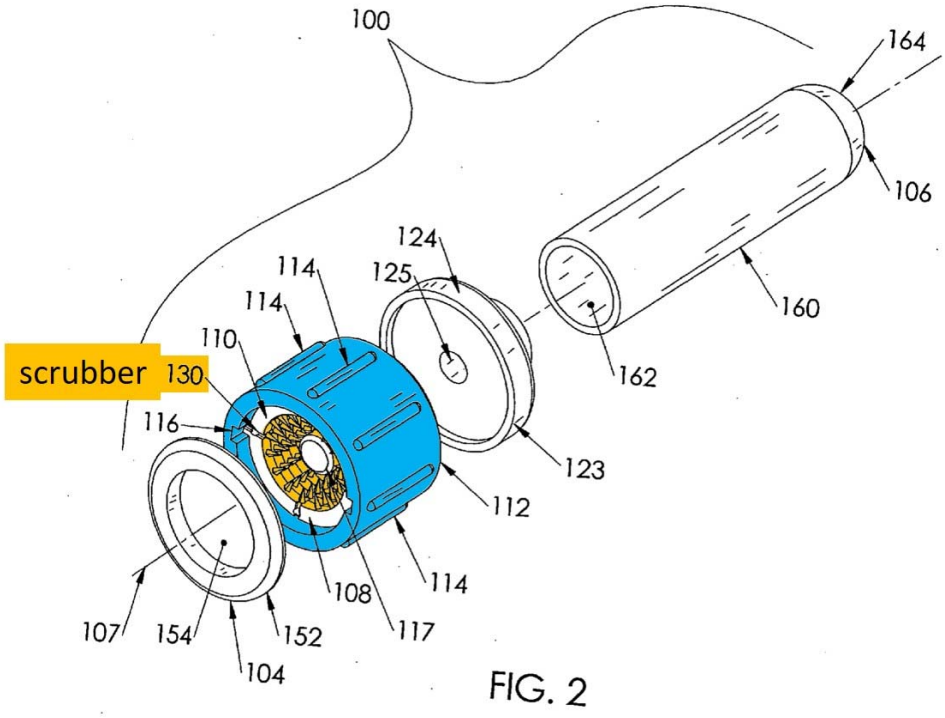


FIG. 2

(Ex. 1011, Fig. 2).

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

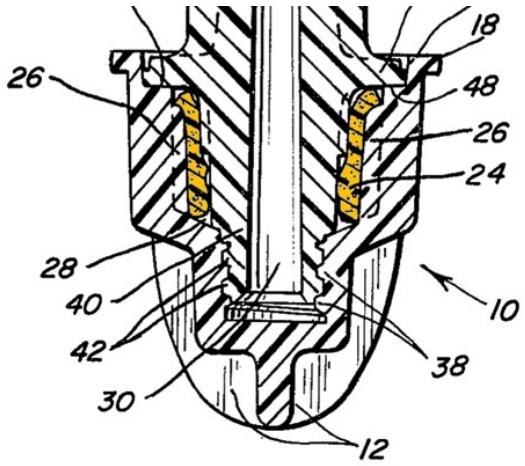


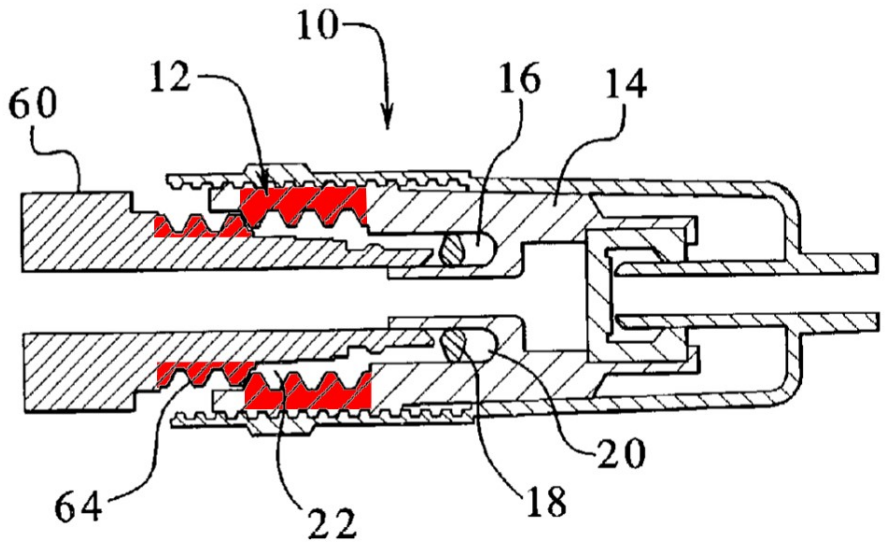
FIG. 3

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

(4) Part [c]

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

FIG.4



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

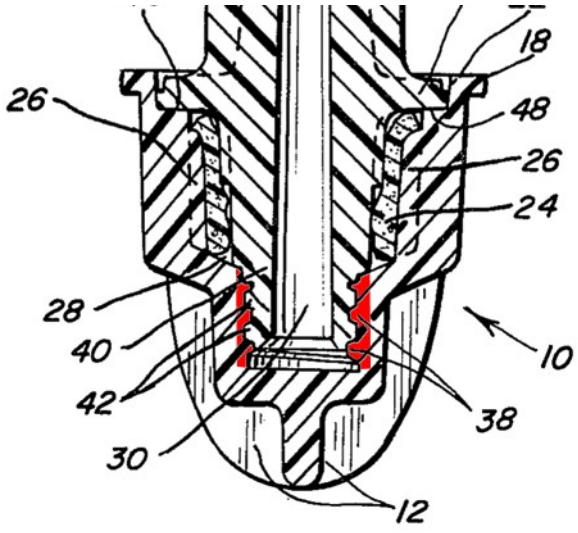


FIG. 3

(5) Part [c.i]

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

(6) Part [c.ii]

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

(7) Part [d]

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* cleans the end face. (Ex. 1011, ¶¶4, 31; Ex. 1002, ¶100).

b. Dependent Claims 2-11, 13

(1) Claim 2

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* cleans the end face. (Ex. 1011, ¶¶4, 31; Ex. 1002, ¶100).

(2) Claim 3

The advancement of *Connell* (as set forth above for Claim 2), in combination with the wet pad of *Genatempo* (absorbent material 24) and scrubbing/septum arrangement of *Raulerson* (Ex. 1011, ¶¶94, 115-118), renders obvious Claim 3. (Ex. 1002, ¶35).

(3) Claim 4

Connell teaches the use of known medical device grade plastics including polyethylene or polypropylene. (Ex. 1010, ¶68).

(4) Claim 5

Connell, *Raulerson* and *Genatempo* disclose the use of povidone iodine, yet recognize that any suitable solution may be used. (Ex. 1010, ¶89; Ex. 1011, ¶29; Ex. 1006, 2:14-15). The '584 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. 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 have been obvious. (Ex. 1002, ¶¶102-104, 107-111).

(5) Claim 6

Claim 6 recites: "The device of claim 1, wherein the material comprises a dry pad." The material of claim 1 is "impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve." (Ex. 1001, Claim 1). In this regard, the "dry pad" of claim 6 must encompass this liquid impregnated material of independent claim 1. The '584 Patent's specification confirms the dry pad may be impregnated with a liquid. (*Id*. at 2:60-66). For at least the reasons set forth in [1b], the sponges of the combination of *Connell*, *Genatempo*, and *Raulerson* render obvious this limitation as they are dry before they are impregnated with antiseptic solution. *See Lockwood v. AA*, 107 F.3d at 1570.

(6) Claim 7

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

(7) Claim 8

Connell, *Raulerson* and *Genatempo* disclose the use of povidone iodine, yet recognize that any suitable solution may be used. (Ex. 1010, ¶89; Ex. 1011, ¶29; Ex. 1006, 2:14-15). The '584 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad, including the claimed chlorhexidine and the povidone iodine of the prior art. (Ex. 1001, 2:49-54) A POSA would have been acquainted with chlorhexidine, both gluconate and diacetate, as common antimicrobial agents and would have found the selection of the claimed chlorhexidines to have been obvious. (Ex. 1002, ¶¶102-104, 107-111).

(8) Claim 9

Connell, *Raulerson* and *Genatempo* disclose the use of povidone iodine. (Ex. 1010, ¶89; Ex. 1011, ¶29; Ex. 1006, 2:14-15).

(9) Claim 10

Connell, *Raulerson* and *Genatempo* disclose the use of povidone iodine, yet recognize that any suitable solution may be used. (Ex. 1010, ¶89; Ex. 1011, ¶29; Ex. 1006, 2:14-15). The '584 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad, including the claimed benzalkonium chloride and octenedine, as well as the povidone iodine of the prior art. (Ex. 1001, 2:49-54). A POSA would have been acquainted with benzalkonium chloride and octenedine, as

common antimicrobial agents and would have found the selection of the claimed benzalkonium chloride and/or octenedine to have been obvious. (Ex. 1002, ¶¶81-84, 87-91).

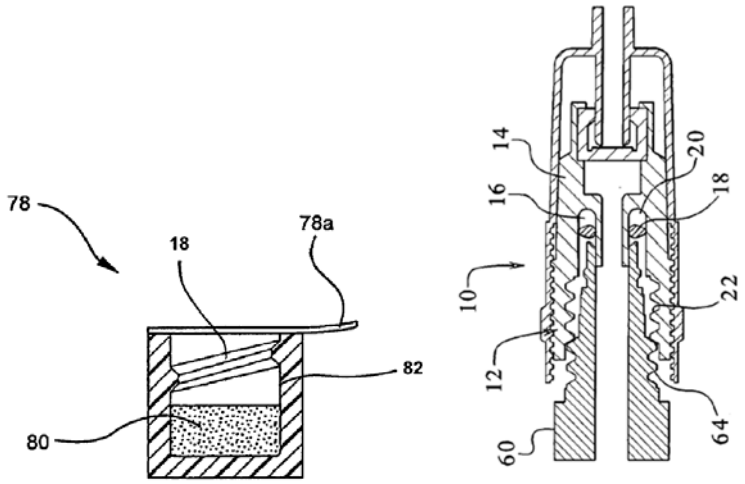
(10) Claim 11

Connell discloses the use of iodine-containing antimicrobials as a disinfectant. (Ex. 1010, ¶76). *Raulerson* discloses antiseptic fluids, for example an isopropyl alcohol, povidone iodine, or hydrogen peroxide, but recognizes any suitable fluid may be used. (Ex. 1011, ¶29). The relevant portions of *Genatempo* are set forth in connection with Claim 7 in Ground 1. (Ex. 1006, 2:64-68, 3:22-23, Fig. 3; Ex. 1002, ¶¶35-36). A POSA would understand that an antiseptic is an antimicrobial. (Ex. 1002, ¶102). The '584 Patent confirms that "any of a number of antimicrobial agents may be used" in its pad. (Ex. 1001, 2:66-3:4). A POSA would have been acquainted with common antimicrobial agents, including antibiotics and would have found the use of an antibiotic within the antimicrobial solution to have been obvious. (Ex. 1002, ¶¶81-84, 87-91).

(11) Claim 13

The '584 Patent teaches no benefit from fixing the threading at "a length that is less than the inner circumference" of the inner cavity. The claimed threading length, as depicted in the figures, closely mirrors that of the prior art references used

herein. For example, the threading of Figure 10b of the '584 patent completes one rotation, whereas the threading 22 of *Connell's* Figure 4 similarly completes four 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 v. TEC Syst., Inc.*, 725 F.2d 1338 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830 (1984)).

c. The Remaining Claims

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

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
12[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.	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.	Ex. 1010, ¶¶66, 71-72, 74, 77, 80; Ex. 1002, ¶46; Ex. 1006, 1:9-11; Ex. 1011, ¶4
12[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 inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine [sic] 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 configured to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed	Ex. 1010, ¶¶77-78, 101-104, 115, Figs. 4-7; Ex. 1002, ¶35. 53, 56, 100; Ex. 1011, ¶¶4, 14, 31, Fig. 1; Ex. 1006, 2:21-24, 3:37-39, Fig. 3

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
	over the access portion of the patient fluid line access valve to contact the material with the distalmost end face of the access portion of the patient fluid line access valve	
12[b] a material impregnated with a liquid antimicrobial agent prior to attachment of the housing to the access portion of the patient fluid line access valve, the material 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 material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve, wherein the material is disposed in the inner cavity 1[c.i] the threading configured 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 material with the distalmost end face of the access portion of the patient fluid line access valve 1[c.ii]	Ex. 1010, ¶¶72, 77-78, 115, Fig. 4-7; Ex. 1002, ¶¶35, 53, 57, 99-100; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 2:21-24, 2:64-68, 3:22-23, 3:52-45

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
	configured 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 liquid antimicrobial agent from the material.	
12[c] wherein in response to insertion of the access portion of the patient fluid line access valve into the cavity, the thread is configured to engage 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 material to provide the liquid antimicrobial agent to the septum and at least a portion of the external threads	1[c.ii] configured 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 liquid antimicrobial agent from the material. 1[d] wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the material	Ex. 1010, ¶¶72, 77-78, 115, Fig. 4-7; Ex. 1002, ¶¶35, 53, 57, 99-100; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 2:21-24, 2:64-68, 3:22-23, 3:52-45
14 The device of claim 12, wherein the antimicrobial agent comprises at least one	5 The device of claim 1, wherein the antimicrobial agent comprises at least one of	Ex. 1006, 3:22-23; Ex. 1011, ¶29; Ex. 1010, ¶¶75-76; Ex. 1002, ¶¶102-104, 107-111

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
of chlorhexidine gluconate and chlorhexidine diacetate.	chlorhexidine gluconate and chlorhexidine diacetate	
15[pre] 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[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.	Ex. 1010, ¶¶66, 71-72, 74, 77, 80; Ex. 1002, ¶46; Ex. 1006, 1:9-11; Ex. 1011, ¶4
15[a] a housing having an inner cavity for covering the access portion of the patient fluid line access valve	1[a] a housing having an inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine [sic] access valve	Ex. 1010, ¶¶77-78, 101-104, 115, Figs. 4-7; Ex. 1002, ¶¶35. 53, 56, 100; Ex. 1011, ¶¶4, 14, 31, Fig. 1; Ex. 1006, 2:21-24, 3:37-39, Fig. 3
15[b] a material within the housing and impregnated with a liquid antimicrobial agent prior to contacting the patient fluid line access valve, the material being configured to contact at least a portion o the	1[b] a material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve, wherein the material is disposed in the inner cavity	Ex. 1010, ¶¶72, 77-78, 115, Fig. 4-7; Ex. 1002, ¶¶35, 53, 57, 99-100; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 2:21-24, 2:64-68, 3:22-23, 3:52-45

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
threaded patient fluid line access valve and the distalmost end face of the patient fluid line access valve to reduce the amount of microbes on the patient fluid line access valve	1[c.i] the threading configured 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 material with the distalmost end face of the access portion of the patient fluid line access valve 1[c.ii] configured 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 liquid antimicrobial agent from the material	
15[c] a thread within the inner cavity of the housing and positioned between the material and an opening to the inner cavity, the thread for engaging the external threads of the threaded	1[c] threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening 1[c.i] the threading configured to engage the external	Ex. 1010, ¶¶72, 77-78, 115, Fig. 4-7; Ex. 1002, ¶¶35, 53, 57, 99-100; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 2:21-24, 2:64-68, 3:22-23, 3:52-45

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
patient fluid line access valve to cause the material to contact the distalmost end face of the patient fluid line access valve.	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 material with the distalmost end face of the access portion of the patient fluid line access valve	
15[d] wherein in response to the distalmost end face of the access valve being inserted into the housing, the distalmost end face contacts the material to provide the liquid antimicrobial agent to the septum and at least a portion of the external threads	1[c.ii] configured 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 liquid antimicrobial agent from the material 1[d] wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the material.	Ex. 1010, ¶¶72, 77-78, 115, Fig. 4-7; Ex. 1002, ¶¶35, 53, 57, 99-100; Ex. 1011, ¶¶4, 21, 29, 31, Fig. 2; Ex. 1006, 1:44-52, 2:21-24, 2:64-68, 3:22-23, 3:52-45
16	13	Ex. 1007, Fig. 4; Ex. 1002, ¶101

Claim Limitation	Already Discussed Claim Language	Prior Art Teaching
The device of claim 15, wherein the inner cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference	The device of claim 12, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference	
17 The device of claim 15, wherein the housing comprises a polyethylene or polypropylene material	4 The device of claim 1, wherein the housing comprises a polyethylene or polypropylene material.	Ex. 1010, ¶68
18 The device of claim 15, wherein the liquid antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate	5 The device of claim 1, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate	Ex. 1006, 3:22-23; Ex. 1011, ¶29; Ex. 1010, ¶¶75-76; Ex. 1002, ¶¶102-104, 107-111

G. Ground 5: Claims 5, 8-11, 14, and 18 are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over *Connell*, *Raulerson*, *Genatempo,* and *Raad*.

If the Board finds that Claims 5, 8-11, 14, and 18 would not have been obvious in view of *Connell*, *Raulerson*, and *Genatempo* (*see* Section VII.F.2), the disclosures

of *Raad* explicitly confirm that a POSA would have understood that the additional limitations of Claims 5, 8-11, 14, and 18 are obvious.

1. Basis for Combination

A POSA would have known that povidone iodine is a known alternative for chlorhexidine gluconate, such that they are interchangeable. (Ex. 1002, ¶¶86-91). *Raad* discloses that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28). *Raad* also confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27). A POSA would understand that the povidone iodine of the *Connell*/*Raulerson*/*Genatempo* combination would be readily replaced with the chlorhexidine gluconate solution of *Raad* with an expectation of success. (Ex. 1002, ¶¶88, 91).

Each of *Connell*, *Raulerson* and *Genatempo* states that modifications to their respective disclosed inventions may be made without deviating from the scope and spirit thereof. (Ex. 1006, 8:4-9; Ex. 1010, ¶109; Ex. 1011, ¶36).

Exhibit 1015, which relates to cleaning medical devices that are likely to—or have already—become contaminated with microorganisms, confirms that one way of cleaning these devices surfaces is with "antimicrobial agents or 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, ¶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 and describes work funded by the Patent Owner (or related affiliate) dating back to 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*, which constitutes well studied ingredients and combinations in the medical field, would have been readily used as a known replacement in each of *Connell*, *Raulerson*, and *Genatempo*, as well as in the combination resulting from the three. (Ex. 1002, ¶111). The composition of *Raad* would perform in a predictable manner to yield predictable results when incorporated in this combination. (Ex. 1002, ¶¶107-111; *KSR*, 550 U.S. at 416-17).

2. Claims 5, 8-11, 14, and 18 are Obvious

a. Claim 5

Raad confirms that known antiseptic solutions include chlorhexidine and alcohols. (Ex. 1016, ¶28; Ex. 1002, ¶87). *Raad* confirms that chlorhexidine and povidone iodine are known alternative anti-microbial solutions that are suitable for cleaning/reducing the number of microbes on a medical device such as an indwelling medical device. (Ex. 1016, ¶¶26-27, Claims 10, 20, 26 and 27; Ex. 1002, ¶¶88, 91).

b. Claim 8

For at least the reasons set forth above for Claim 5, the combination of *Connell*, *Raulerson*, *Genatempo*, and *Raad* renders obvious Claim 8.

c. Claim 9

Raad confirms that known antiseptic solutions at the time also included chloroxylenol and triclosan. (Ex. 1016, ¶32). A POSA would have understood that the antiseptic solutions of *Raad*, would have been readily used as a known replacement for the povidone iodine of *Connell*, *Raulerson*, and *Genatempo*. (Ex. 1002, ¶¶107-111)

d. Claim 10

Raad confirms that known antiseptic solutions at the time included benzalkonium chloride (Ex. 1016, ¶28) and octenidine (*id*. at ¶30). A POSA would

have understood that the antiseptic solutions of *Raad*, would have been readily used as a known replacement for the povidone iodine of *Connell*, *Raulerson*, and *Genatempo*. (Ex. 1002, ¶¶107-111)

e. Claim 11

Raad teaches that, in the context of its disclosure, each of the antibacterial agents it discusses "are represented by antibiotics." (Ex. 1016, ¶13). *Raad* demonstrates the understanding of a POSA that "antibiotics" were a general category of antiseptic. (Ex. 1002, ¶107).

f. Claim 14

For at least the reasons set forth above for Claim 5, the combination of *Connell*, *Raulerson*, *Genatempo*, and *Raad* renders obvious Claim 14.

g. Claim 18

For at least the reasons set forth above for Claim 5, the combination of *Connell*, *Raulerson*, *Genatempo*, and *Raad* renders obvious Claim 18.

H. Ground 6: Claims 13 and 16 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 in view of the disclosure of *Miyahara*

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

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

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

2. Claims 13 and 16 are Obvious

a. Claim 13

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

b. Claim 16

As set forth above with regard to Claim 13, *Connell*, *Raulerson*, *Genatempo*, and *Miyahara* render obvious this limitation. (Ex. 1009, ¶¶55-56; Ex. 1002, ¶¶44, 115).

VIII. CONCLUSION

This Petition demonstrates a reasonable likelihood that at least one claim of the '584 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 inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine [sic] access valve;

[b] a material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line access valve, wherein the material is disposed in the inner cavity;

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

[c.i] the threading configured 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 material with the distalmost end face of the access portion of the patient fluid line access valve, and

[c.ii] configured 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 liquid antimicrobial agent from the material,

[d] wherein the threading receives the external threads of the access portion of the access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the material.

2. The device of claim 1, wherein a threaded interaction between the threading and the external threads is configured to provide 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 is configured to allow the septum to contact the material, and is further configured to allow the septum to contact and compress the material between the septum and the inner cavity.

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

5. The device of claim 1, wherein the antimicrobial agent comprises at least one of chlorhexidine gluconate and chlorhexidine diacetate.

6. The device of claim 1, wherein the material comprises a dry pad.

7. The device of claim 6, wherein the dry pad comprises a sponge.

8. The device of claim 1, wherein the liquid antimicrobial agent comprises chlorhexidine.

9. The device of claim 1, wherein the liquid antimicrobial agent comprises one or more of the following: chloroxylenol, povidone iodine, Triclosan, and benzethonium chloride.

10. The device of claim 1, wherein the liquid antimicrobial agent comprises one or more of the following: benzalkonium chloride and octenedine.

11. The device of claim 1, wherein the liquid antimicrobial agent comprises an antibiotic.

12. **[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 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;

[b] a material impregnated with a liquid antimicrobial agent prior to attachment of the housing to the access portion of the patient fluid line access valve, the material 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,

[c] wherein in response to insertion of the access portion of the patient fluid line access valve into the cavity, the thread is configured to engage 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 material to provide the liquid antimicrobial agent to the septum and at least a portion of the external threads.

13. The device of claim 12, wherein the cavity comprises an inner circumference and the thread comprises a length that is less than the inner circumference.

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

15. **[pre]** 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] a housing having an inner cavity for covering the access portion of the patient fluid line access valve;

[b] a material within the housing and impregnated with a liquid antimicrobial agent prior to contacting the patient fluid line access valve, the material being configured to contact at least a portion o the threaded patient fluid line access valve and the distalmost end face of the patient fluid line access valve to reduce the amount of microbes on the patient fluid line access valve;

[c] a thread within the inner cavity of the housing and positioned between the material 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 material to contact the distalmost end face of the patient fluid line access valve,

[d] wherein in response to the distalmost end face of the access valve being inserted into the housing, the distalmost end face contacts the material to provide the liquid antimicrobial agent to the septum and at least a portion of the external threads.

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

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

18. The device of claim 15, wherein the liquid 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 **13,969** 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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