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Paper No. 9
Date: April 17, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAXTER INTERNATIONAL INC.,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner.

IPR2020-00026
Patent 10,159,828 B2

Before SUSAN L. C. MITCHELL, KEVIN W. CHERRY, and DAVID COTTA, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Baxter International Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–14 of U.S. Patent No. 10,159,828 B2 (Ex. 1001, "the '828 patent").[1] Paper 1, Petition ("Pet."). Becton, Dickinson and Company ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 (Prelim. Resp.).[2]

Institution of *inter partes* review is authorized by statute only when "the information presented in the petition ... demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 314; *see* 37 C.F.R. § 42.4. For the reasons discussed below, upon consideration of the Petition, the Preliminary Response, and the supporting evidence, we deny institution of *inter partes* review.

A. Related Proceedings

Patent Owner and Petitioner both represent that the '828 patent is not involved in any other pending matters or prior litigations. Pet. v; Paper 4, 2. Both parties identify concurrently filed petitions involving three patents in the same family as the '828 patent: IPR2020-00024 (U.S. Patent No. 8,740,864); IPR2020-00025 (U.S. Patent No. 9,283,367); and IPR2020-00027 (U.S. Patent No. 10,335,584). Pet. v; Paper 4, 2.

[1] Petitioner identifies Baxter International Inc. and Baxter Healthcare Corp. as the real parties in interest. Pet. v.
[2] Patent Owner identifies Becton, Dickinson and Company as the real party in interest. Paper 4, 1.

D. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–14 of the '828 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–14	§ 103(a)	Menyhay,[3] Genatempo[4]
12	§ 103(a)	Menyhay, Genatempo, Miyahara[5]
1–14	§ 103(a)	Connell,[6] Raulerson,[7] Genatempo
12	§ 103(a)	Connell, Raulerson, Genatempo, Miyahara

Petitioner submits the Declaration of Richard Meyst (Ex. 1002) in support of institution of *inter partes* review. Patent Owner submits the Declaration of Michael Plishka (Ex. 2002) in support of its Preliminary Response.

B. The '828 Patent (Ex. 1001)

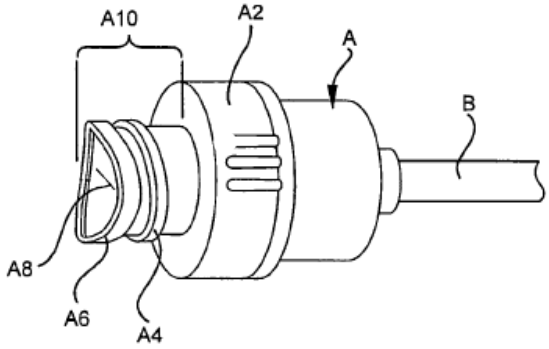
The '828 patent issued December 25, 2018, identifying Minh Quang Hoang and Jonathan Karl Burkholz as joint inventors. Ex. 1001, codes (45), (72). The patent relates to "a device for antiseptically maintaining a patient fluid line access valve." *Id.* at 1:51–52.

[3] Menyhay, U.S. Patent No. 5,554,135, issued Sep. 10, 1996 (Ex. 1007, "Menyhay").
[4] Genatempo et al., U.S. Patent No. 4,440,207, issued Apr. 3, 1984 (Ex. 1006, "Genatempo").
[5] Miyahara, U.S. Patent Publication No. 2004/0111078 A1, published June 10, 2004 (Ex. 1009, "Miyahara").
[6] Connell et al., U.S. Patent Publication No. 2003/0153865 A1, published Aug. 14, 2003 (Ex. 1010, "Connell").
[7] Raulerson et al., U.S. Patent Publication No. 2006/0030827 A1, published Feb. 9, 2006 (Ex. 1011, "Raulerson").

The ’828 patent teaches that blood stream infections caused by bacteria and/or fungi in intravascular catheters cause approximately 80,000 blood-stream infections each year. *Id.* at 1:20–25. These infection cause “anywhere from 2,400 to 20,000 death per year.” *Id.* at 1:25–27. Although the Centers for Disease Control and Prevention provide guidelines addressing this issue, “catheter-related bloodstream infections continue to plague our healthcare system.” *Id.* at 1:28–34. Addressing this problem by “[i]mpregnating catheters with various antimicrobial agents . . . [has] given less than satisfactory results.” *Id.* at 1:35–38. Although using “a catheter hub containing an antiseptic chamber . . . filled with three percent iodinated alcohol” has been “shown to be effective,” it is “expensive and does not fare as well in a formal cost-benefit analysis.” *Id.* at 1:42–45. Thus, according to the ’828 patent, “there is a need for an effective and inexpensive way to reduce the number of catheter-related infections.” *Id.* at 1:46–47.

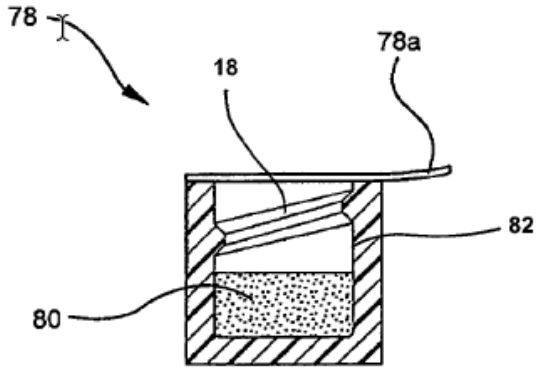
The ’828 patent discloses “[c]ap and cleaning devices [that] antiseptically maintain patient fluid line access valves to minimize the risk of infection via catheters.” *Id.* at Abstr. “The devices have a hood that contains a wet pad impregnated with a cleaning solution and, optionally, an antimicrobial agent. The wet pad cleans the access portion of the access valve prior to and optionally, after the access valve is utilized to access the patient fluid line.” *Id.*

Figure 1 of the '828 patent shows a "representative embodiment of cap/cleaner device and a patient fluid line access valve." *Id.* at 1:61–62. The portion of Figure 1 showing the patient fluid line access valve is reproduced below.



Ex. 1001, Fig. 1 (excerpted). As shown in partial Figure 1 above, "[a]ccess valve **A** includes housing **A2** with thread **A4** and septum **A6** with slit **A8.**" *Id.* at 2:21–22.

The "patient fluid line access valve" depicted in partial Figure 1 above may be cleaned by a cap/cleaner. *Id.* at 5:38–39. Figure 10B (reproduced below) shows "a representative embodiment of cap device **78** . . . ." *Id.* at 5:16–17.



As shown in Figure 10B above, the "cap device" may include "threading **18** having a length that is less than inner circumference **82**." *Id.* at 5:31–32. The "cap device" may also include a "lid **78*a*** and pad **80**." *Id.* at 5:16–17.

The pad may be "either [ ] a wet pad or a dry pad." *Id.* at 5:19–20. "Where pad **80** is a wet pad, cap device **78** may be used to clean access portion **A10** of valve A," in which case, "[t]he twisting motion involved in removing and placing cap device **78** with respect to access potion **A10** provides friction for cleaning." *Id.* at 5:22–26.

C. Challenged Claims

Petitioner challenges claims 1–14 of the '828 patent. Claims 1, 7, 10 and 14 are independent. Claims 1 and 14 are representative and are reproduced below.

> 1. A device for cleaning a patient fluid line access valve comprising:
>
> a cap having an inner sidewall and an opening to an inner cavity, the opening for receiving an access portion of an access valve, the access portion providing an access to a fluid line via the access valve when connected to the fluid line;
>
> a thread at least partially disposed on at least a portion of the inner sidewall of the cap;
>
> a pad including a cleaning agent, the pad at least partially disposed in the inner cavity and adapted to clean at least a portion of the access portion of the access valve;
>
> a space providing an air passage between an inner circumference of the cap and at least a portion of an outer surface of a sidewall of the access portion of the access valve when the access portion is received in the opening of the cap and when the inner sidewall of the cap comprising the thread provides a secured attachment of the cap to the access valve; and
>
> a removeable seal attached to the cap to cover the opening to the inner cavity, the pad being disposed in the inner cavity, prior to receipt of the access portion of the access valve.

Ex. 1001, 5:51–6:7.

> 14. A device for cleaning a needleless access valve having a threaded access portion comprising:
>
> a cap having an inner cavity for receiving a threaded access portion of a valve via an opening to the inner cavity, the threaded access portion providing an access to a fluid line via the access valve when connected to the fluid line;
>
> a protrusion extending inwardly at least partially around an inside surface of the cap, the protrusion to attach the cap to at least a portion of the threaded access portion of the valve received in the inner cavity to maintain the cap on the valve;
>
> a cleaning agent disposed in the inner cavity, the cleaning agent being formulated to clean at least a portion of the threaded access portion of the valve received in the inner cavity; and
>
> a removable seal covering the opening to the inner cavity, the cleaning agent being within the inner cavity of the cap,
>
> wherein a space providing an air passage is defined at least between a portion of an outer surface of a sidewall of the threaded access portion and the inside surface of the cap comprising the protrusion when the threaded access portion is received in the inner cavity and the cap is attached to the valve.

Id. at 8:4–31.

II. ANALYSIS

A. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying

factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness when presented. *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id*. Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id*. at 420. Accordingly, a party who petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted).

B. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct.

Cl. 1975); *see also Orthopedic Equip. Co., v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros*.).

Petitioner contends that the person of ordinary skill in the art ("POSA") "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." Pet. 9 (citing Ex. 1002, ¶¶ 26–28; Ex. 1005, 150). According to Petitioner, "[s]uch 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." *Id.*

At this stage in the proceeding, Patent Owner does not challenge Petitioner's identification of the qualifications for a POSA. *See generally* Prelim. Resp. Accordingly, for purposes of this Decision and based on the present record, we accept Petitioner's definition, as it is consistent with the level of skill reflected in the Specification and the asserted prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We construe claims "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100 (2019). [8] Therefore, we construe the

[8] On October 11, 2018, the USPTO revised its rules to harmonize the Board's claim construction standard with that used in federal district court.

challenged claims under the framework set forth in *Phillips v. AWH Corp*., 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art, at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.* Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co*., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999)).

Neither Petitioner nor Patent Owner offers construction of any claim term that either party submits is necessary for the resolution of determining whether we should institute *inter partes* review. *See* Pet. 10; Prelim. Resp. 6. For purposes of this decision, we agree and determine that no claim terms require express construction.

D. Obviousness over Menyhay and Genatempo

Petitioner asserts that claims 1–14 of the '828 patent would have been obvious over the combination of Menyhay and Genatempo. Pet. 21–50. Patent Owner opposes. Prelim. Resp. 6–26. We have reviewed Petitioner's and Patent Owner's assertions, as well as the evidence of record, and for the reasons discussed below, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing in showing that any of claims 1–14 of the

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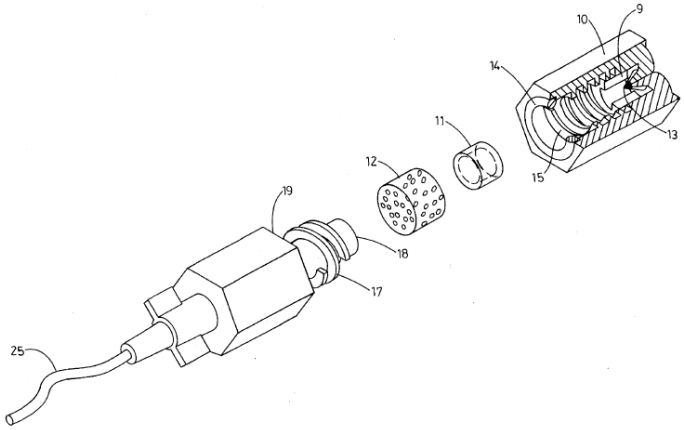
See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). This rule change applies to the instant Petition because it was filed after November 13, 2018. *See id*.

’828 patent would have been obvious over the combination of Menyhay and Genatempo.

1. Disclosures of the Asserted Prior Art

Menyhay (Ex. 1007)

Menyhay discloses an “easy-to-use sterile medical injection port and covering apparatus.” Ex. 1007, 1:7–8. Figure 2 (reproduced below) shows an “exploded partially cut away perspective and diagrammatic view of an external injection port catheter, and the covering of [Menyhay’s] invention.” *Id.* at 6:15–17.



As shown in Figure 2 above, Menyhay’s apparatus includes “cylinder **10** that is open on one end.” *Id.* at 6:38–39. The cylinder includes “set of screw threads **15** on the inside” and “inwardly pointing projection **13**.” *Id.* 6:39–42. “[B]reakable capsule **11**” “filled with . . . an antiseptic, bactericidal and virucidal solution” “is disposed inside cylinder **10** immediately adjacent to projection **13**” and “sponge **12** is provided inside cylinder **10** next to capsule **11** on the side opposite projection **13**.” *Id.* at 6:45–52.

Menyhay’s apparatus mates with “[e]xternal injection port **19**” that includes “thick septum **18**” and “set of screw threads **17**.” *Id.* at 6:53–55.

As "cylinder **10**" and "external injection port **19**" are screwed together, "the pressure between projection **13** and breakable capsule **11** causes the capsule to rupture thereby releasing the antiseptic agents inside to be soaked up by sponge **12**." *Id.* at 6:61–64. "When completely tightened, the antiseptically treated sponge comes into contact with the latex membrane **18** of the port, aseptically bathing the port until the cover is removed." *Id.* at 6:67–7:3. This can be seen in Figure 3 (reproduced below).

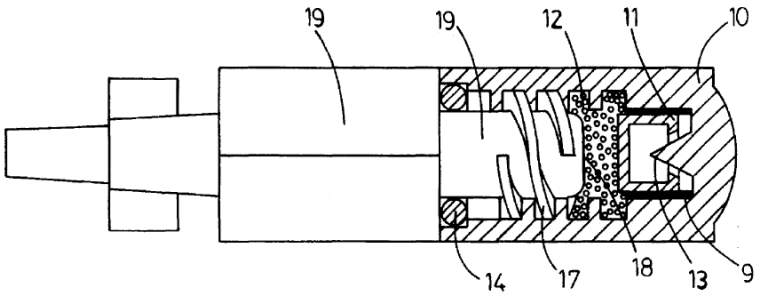
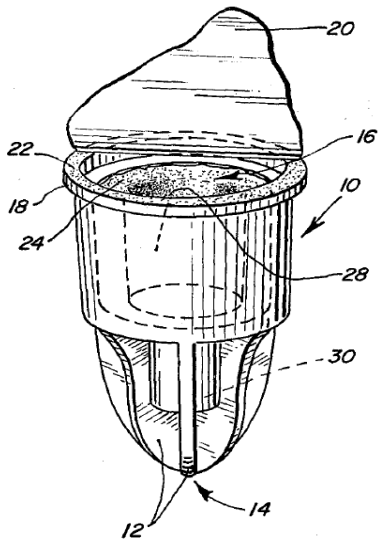


Figure 3 shown above is a "partially cut away side view showing the cover and port of the present invention after the cover has been tightly screwed over the port and the antiseptic capsule ruptured." *Id.* at 6:18–21.

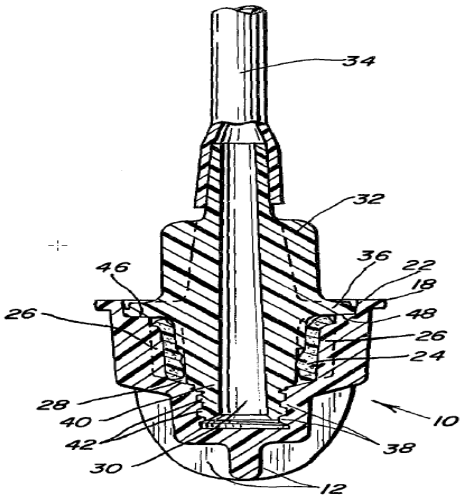
Genatempo (Ex. 1006)

Genatempo discloses "a protective cap for a medical connector or medical port opening which provides an antibacterial effect." Ex. 1006, 1:9–11. "At least a portion of the protective cap interior is lined with an absorbent material [such as a sponge] which retains an antiseptic." *Id.* 1:57–59. Figure 1 (reproduced below) provides a perspective view of Genatempo's cap. *Id.* at 2:45–46.



As shown in Figure 1 above, "[a]bsorbent material **24** lines protective cap **10** and is fixedly attached to the inside of the protective cap." *Id.* at 2:66–68. The absorbent material "retains a volatile antibacterial agent, such as povidone iodine." *Id.* at 3:4–5. "A removable water vapor barrier such as peelable lid **20**" covers "[e]xternal opening **16** of cap **10.**" *Id.* at 2:62–64. "When removable water vapor, microbial barrier lid **20** is closed, . . . loss by evaporation is greatly reduced." *Id.* at 3:1–5.

Figure 3 (reproduced below) provides a longitudinal cross sectional view of Genatempo's cap covering a connector. *Id.* at 2:51–53.



In Figure 3 set forth above, "connector **32[**,**]** **. . .** a typical connector used with CAPD tubing sets," "is shown engaged by protective cap **10**." *Id.* at 3:30–32. As Genatempo's cap receives the connector, "[i]nner chamber **30** having internal threads **38,** cooperates to threadedly lock with external threads **42** of connector **32**." *Id.* at 3:37–39. When threadedly locked in this manner, "[a]n antibacterial effect is provided to main tubular member 40 of connector 32, as well as threads 42 through migration of the antiseptic." *Id*. at 3:43–45.

2. Analysis

Consistent with the requirement of independent claims 1 and 7, for a "pad including a cleaning agent" "at least partially disposed in the inner cavity" "prior to receipt of the access portion of the access valve," Petitioner proposes combining the cited art to produce a device having a sponge pre-wet with antiseptic solution. Pet. 21; *see* Ex. 1001, 5:60–62, 6:5–7 (claim 1), 6:29–32, 37–39 (claim 7).

Claims 10 and 14 do not require a "pad" instead requiring "a cleaning agent disposed in the inner cavity," and claim 14 does not expressly state that the pad is within the cavity "prior to the inner cavity of the cap receiving the access portion of the access valve" as set forth in claim 10. *See* Ex. 1001, 7:1–8, 8:5–31. But claim 14 requires a removable seal "covering the opening to the inner cavity" with "the cleaning agent being within the inner cavity of the cap," hence tacitly requiring the cleaning fluid to be within the inner cavity prior to removal of the seal and receipt of the access portion of the valve. *See* Ex. 1001, 8:22–31, 4:22–4; Pet. 49 (discussing claim 14 with reference to language from claim 1 concerning "the pad being disposed in

the inner cavity, *prior to receipt of the access portion of the access valve*") (emphasis added).

Petitioner's argument with respect to claims 10 and 14 is premised on combining the cited art to produce a device that includes a pad including a cleaning agent, i.e., a pre-wet sponge. Pet. 45 (discussing claim 10 with reference to language from claim 1 concerning "a pad including a cleaning agent"), 49 (same discussion for claim 14); Ex. 1002 ¶ 24 (describing '828 patent technology as a patient line disinfecting cap that "is, at its essence, a threaded cap with an antiseptic-soaked sponge within the cap"). Accordingly, our analysis of Petitioner's explanation of the combination and rationale for combining the art to produce a device with such a pad applies to all of the challenged claims.

The Petition includes two passages addressing how the allegedly obvious combination results in a pad that is wet before the patient fluid access valve is attached to the housing. The first passage appears under the "Basis for Combination" subheading. It reads:

> An ordinarily skilled person would have known to preload sponge 12 of *Menyhay* (Ex. 1007, 6:49-64) with the antiseptic solution as suggested by *Genatempo* (Ex. 1006, Abstract) to ensure full-wetting of the sponge and thus avoid[] dry spots in the event that the capsule of *Menyhay* fails to break sufficiently to wet sponge 12. (Ex. 1002, ¶¶75-76). An ordinarily skilled person would have also understood that preloading *Menyhay's* sponge as suggested by *Genatempo*, along with the additional sponge location of *Genatempo* would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety. (Ex. 1002, ¶¶75-78).

Pet. 21–22. The second passage appears in Petitioner's analysis of claim 1, under the subheading "Part [c]." It reads:

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

Pet. 30.

We have reviewed the Petition and supporting declaration in detail and do not find any other instance in which Petitioner explains why it would have been obvious to include a pre-wet sponge or otherwise addresses the motivation to substitute the sponge arrangement of Genatempo for that of Menyhay. Accordingly, we limit our analysis of the rationale for including a pre-wet sponge in the device that Petitioner contends is suggested by the cited art to the rationale set forth in the above quoted passages. *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) ("in an inter partes review the petitioner is master of its complaint"); *Sirona Dental Sys. GMBH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018) (citing *SAS*, 138 S. Ct. at 1356–57) (explaining that because "the petitioner's contentions, not the Director's discretion, define the scope ... [i]t would . . . not be proper for the Board to deviate from the grounds in the petition and raise its own obviousness theory").

We analyze Petitioner's obviousness rationale in the order in which it is presented. Petitioner first posits that it would have been obvious "to preload sponge 12 of *Menyhay* (Ex. 1007, 6:49-64) with the antiseptic solution as suggested by *Genatempo* (Ex. 1006, Abstr.) to ensure full-wetting of the sponge and thus avoiding dry spots in the event that the

capsule of *Menyhay* fails to break sufficiently to wet sponge 12." Pet. 21. The current record, however, does not include persuasive evidence to support the concern that the capsule of Menyhay would fail to break sufficiently to wet the sponge.

Menyhay teaches that its capsule should be "made of a thin-layered brittle plastic (such as acrylic) that can be sealed in order to hold the fluid of the antiseptic, but which will rupture under nominal pressure." Ex. 1007, 7:48–50. Absent evidence to the contrary, this teaching is presumed to be enabled. *In re Antor Media Corp*., 689 F.3d 1282, 1288 (Fed. Cir. 2012); *Amgen Inc. v. Hoechst Marion Roussel, Inc.,* 314 F.3d 1313, 1355 (Fed. Cir. 2003). In addition to the presumption that Menyhay's capsule would work as described, an in vitro study testing the effectiveness an "antiseptic barrier cap" with a design similar to Menyhay's "injection port cover" confirms that the effectiveness of capsule/release disinfection. Ex. 2003, 4 (journal article reporting that only 1.6% of tested connectors indicated transmission of bacterial contaminants); *see also,* Ex. 2002 ¶ 44 (Plishka testimony that the testing of Menyhay's connectors in Exhibit 2003 "confirm[s] the reliability of Menyhay's device").

Petitioner cites the testimony of Mr. Meyst to support its argument that Menyhay's capsule may fail to break sufficiently, *see* Pet. 21 (citing Ex. 1002 ¶¶ 75–76), but the cited testimony does not support that the Menyhay's capsule would fail to break sufficiently to wet the sponge. Ex. 1002 ¶¶ 75–76 (Meyst testimony not addressing concern that capsule may fail to break sufficiently). Accordingly, the current record does not support Petitioner's assertion that the POSA would have been concerned that Menyhay's capsule would fail to break sufficiently.

Petitioner next asserts that "A [POSA] would have also understood that preloading *Menyhay's* sponge as suggested by *Genatempo*, along with the additional sponge location of *Genatempo* would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety." Pet 21–22. Although we recognize that providing an additional sponge location might provide additional disinfection, we are not persuaded that Petitioner has established that preloading Menyhay's sponge would provide additional disinfection as compared to Menyhay's capsule/release system.

Menyhay discloses that its "antiseptically treated sponge **12** comes into contact with the latex membrane **18** of the port, aseptically bathing the port until the cover is removed." Ex. 1007, 7:1–3. Absent evidence to the contrary, the teaching that Menyhay's sponge bathes the port is presumed to be enabled. *In re Antor Media Corp.*, 689 F.3d at 1288; *Amgen*, 314 F.3d at 1355. It is not clear how a preloaded sponge would provide additional disinfection of Menyhay's port as compared to a sponge described as "aseptically bathing" the port.

Mr. Meyst testifies that "the [antiseptic] solution does not begin to wet the sponge until after the capsule has been broken" and that as a result, "the sponge may be partially dry when it comes in contact with the connector face." Ex. 1002 ¶ 75. Mr. Meyst further testifies that "a POSA would understand that this would lead to reduced cleaning power." *Id.* But Menyhay clearly intends for its sponge to be saturated. *See,* Ex. 1007, 7:52–54 (teaching that the sponge "should have an absorption capacity roughly equal to or slightly less than the volume of fluid contained in the capsule," which would result in a saturated sponge contacting the port); *see*

also, Ex. 2002 ¶ 46 (Plishka testimony that "Menyhay intends its sponge to be saturated once the capsule has been broken"). Accordingly, the principle difference between the sponge of Menyhay and that of Genatempo is not that Menyhay's sponge would be "partially dry," but rather the timing of when Menyhay's becomes saturated. Manyhay's sponge becomes saturated after the capsule ruptures while Genatempo's sponge is saturated initially at manufacture.

The current record does not include persuasive evidence that the difference in timing as to when the sponge becomes saturated would negatively impact the ability of Menyhay's sponge to disinfect. Mr. Meyst's testimony regarding the "reduced cleaning power" of Menyhay's sponge is not persuasive because Mr. Meyst does not explain why the timing of sponge saturation would lead to "reduced cleaning power" and does not cite to evidence supporting his opinion. Ex. 1002 ¶ 75. Moreover, the evidence of record supports the conclusion that Menyhay's sponge provides effective disinfection, and thus the timing of Menyhay's sponge saturation does not appear to negatively impact its ability to disinfect. Ex. 2003, 4 (journal article reporting that only 1.6% of tested connectors indicated transmission of bacterial contaminants); *see also,* Ex. 2002 ¶ 44 (opining that the testing of Menyhay's connectors in Exhibit 2003 "confirm[s] the reliability of Menyhay's device"). Accordingly, the current record does not support Petitioner's assertion that "preloading *Menyhay's* sponge as suggested by *Genatempo* . . . would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety." Pet. 21–22.

Finally, Petitioner asserts that "[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." Pet. 30. We are not persuaded because, as discussed above, the current record does not support Petitioner's contention that Menyhay's sponge would fail to become fully wetted or that the timing Menyhay's sponge saturation would negatively impact its ability to disinfect.

In sum, the current record does not include persuasive evidence that the POSA would have been motivated to use Genatempo's pre-wetted sponge in place of Menyhay's sponge for the reasons articulated in the Petition. We recognize that the Board previously instituted on a ground asserting that similar claims in a related patent would have been obvious over the combination of Genatempo and Menyhay. Ex. 1005, 154 (Institution Decision in IPR2014-00880 ("the Prior Proceeding"). In this regard we note that: 1) the current record includes different arguments and different evidence than were presented in the Prior Proceeding; 2) Patent Owner in the Prior Proceeding did not address the merits of Petitioner's arguments, focusing instead on whether the Board should exercise its discretion to deny institution under 35. U.S.C. § 325(d); and 3) the Board instituted on the combination of Menyhay and Genatempo as an alternative to a ground that the Board found demonstrated a reasonable likelihood that the challenged claims were unpatentable, whereas here, we find that the alternative grounds provided in the Petition fall short of that threshold. *Id.* at 126–145 (Patent Owner's Preliminary Response, arguing that institution should be denied because the Examiner had already considered the arguments presented in the Petition); *id.* at 166 (decision on institution

concluding "[w]e determine that Petitioner has demonstrated a reasonable likelihood of prevailing in establishing that claim 10 is unpatentable over White, Harding, and Genatempo and, alternatively, over Menyhay and Genatempo.").

E. Obviousness over Menyhay, Genatempo, and Miyahara

Petitioner asserts that claim 12 of the '864 patent would have been obvious over the combination of Menyhay, Genatempo, and Miyahara. Pet. 50–52. In this ground, Petitioner applies Menyhay and Genatempo as discussed above, and relies on Miyahara to address a limitation in claim 12 regarding the length of the threading. *Id.* As Petitioner does not rely upon Miyahara to address the deficiency discussed above, we find that Petitioner has not carried its burden to establish that a reasonable likelihood that it will prevail in showing that the challenged claims would have been obvious for the reasons already discussed in connection with the combination of Menyhay and Genatempo.

F. Obviousness over Connell, Raulerson, and Genatempo

Petitioner asserts that claims 1–14 of the '828 patent would have been obvious over the combination of Connell, Raulerson, and Genatempo. Pet. 52–83. Patent Owner opposes. Prelim. Resp. 29–46. We have reviewed Petitioner's and Patent Owner's assertions, as well as the evidence of record, and for the reasons discussed below, we conclude that Petitioner has not demonstrated a reasonable likelihood of prevailing in showing that claims 1–14 of the '828 patent would have been obvious over the combination of Connell, Raulerson, and Genatempo.

As Genatempo is discussed above in section III.D.1., we begin our analysis with an overview of Connell and Raulerson, and then discuss the Petitioner's contentions.

1. Disclosures of the Asserted Prior Art

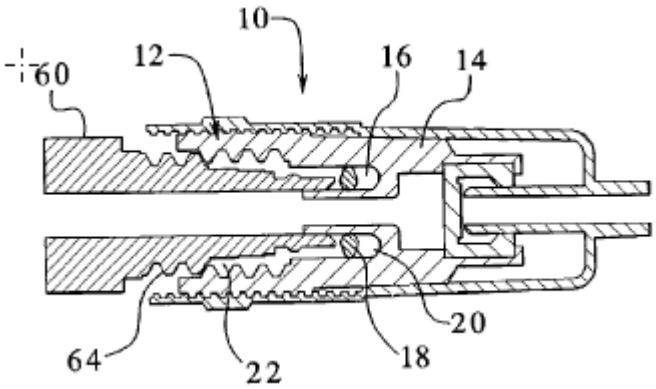
Connell (Ex. 1010)

Connell discloses "[a] frequent problem that occurs with PD [peritoneal dialysis] is peritoneal infection or peritonitis which can readily occur given the repeated disconnecting and reattaching of the dialysate containers." Ex. 1010 ¶ 10. According to Connell, attempts have been made to address this problem by "thoroughly cleansing the connector and the tube connecting the dialysate container before the connection is made" and by "saturat]ing] an absorbent material with disinfectant and dispos[ing] the material in the connector such that it contacts the tube/connector interface." *Id.* ¶¶ 11–12. Notwithstanding these attempts, Connell discloses that "[a] need still exists . . . to improve the efficiency, effectiveness and cost of providing sterile connections for PD." *Id.* ¶ 12.

To address these issues, Connell discloses "a connector and a cap . . . that easily and readily attaches to a dialysate container and a catheter inserted into a patient's peritoneal cavity." Ex. 1010, Abstr. "The cap . . . includes a sealed disinfectant within an interior receptacle." *Id.* "When the catheter . . . attaches to the cap, the seal breaks and the disinfectant spreads over the threads between the catheter set and the cap." *Id.* An advantage of Connell's system is that it "contains a continuous amount of disinfectant and does not require an absorbent material to hold the disinfectant." *Id.* ¶ 53. Connell's system "do[es] not create a mess and do[es] not make the

user/patient perform special handling in order not to spill the disinfectant contained therein." *Id.* ¶ 66.

Figure 4 (reproduced below) illustrates Connell's cap and connecter at a point in the process of inserting the connector 60 into the cap 12. *Id.* ¶ 100.



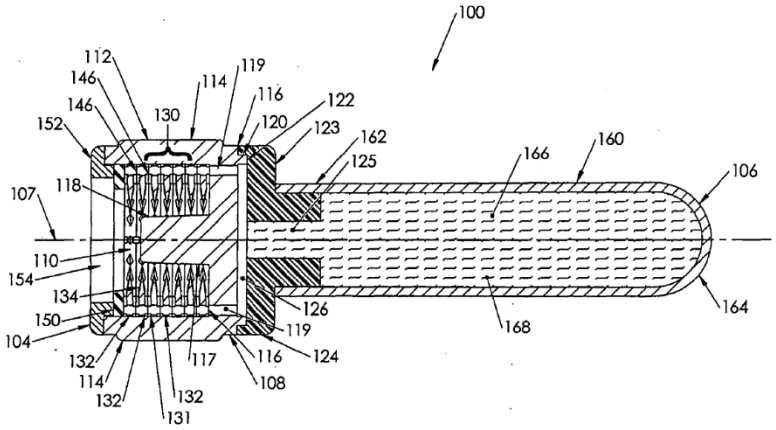
Id. at Fig. 4. As shown in Figure 4, "connector . . . **60** includes external threads **64** that mate[] with the internally facing threads **22** of the body **14** of the cap **12**." *Id.* ¶ 100. The cap includes "disinfectant **20**" that is held in place by "seal **18**." *Id.* "When the user or patient desires to connect the catheter from the peritoneal cavity to the connector **10,** the user or patient threads the connector or transfer set **60** (connecting to the catheter extending to the peritoneal cavity) into the body **14** of the cap **12** so that ends **66** of the connector transfer set **60** engage the seal **18** and either move it or rupture it." *Id.* ¶ 101. When "seal **18**" moves or ruptures, "the disinfectant **20** runs out over the external threads **64** of connector **60.**" *Id.*

Raulerson (Ex. 1011)

Raulerson discloses "a luer cleaner that includes a generally hollow body having an open first end . . . sized to receive therein the proximal end of the luer connector." Ex. 1011 ¶ 4. The first end includes "a plurality of bristles . . . to engage the luer connector disposed therein." *Id.* When the

cleaner is rotated "the bristles engage and mildly scrub the outer surfaces of the luer connector's proximal end . . . to dislodge debris." *Id.* A second end of the luer cleaner comprises a "reservoir containing a fluid" that is transmitted to the first end. *Id.* The fluid "washes and thus cleans and decontaminates the luer connector end." *Id.*

Figure 3 (reproduced below) provides a sectional view of Reulerson's luer cleaner.



Id. at Fig. 3. As shown in Figure 3, "luer cleaner **100** includes an open end **104,** a closed end **106,** and a longitudinal axis **107** extending therethrough between the open end **104** and the closed end **106**." *Id.* ¶ 15. Within the open end of the luer cleaner, "scrubber **130** is disposed within the longitudinal passage." *Id.* ¶ 21. The scrubber is "preferably constructed from . . . a plurality of scrubber discs **131**[,] . . . each scrubber disk **131** . . . having a plurality of scrubber bristles **134**." *Id.* "[B]ristles **134** extend sufficiently far toward the center of each ring **132** so as to engage the luer threads of the luer when the luer is inserted into the luer cleaner **100**." *Id.*

"[C]losed end **106** of the luer cleaner **100** includes a generally bulbous body **160**." *Id.* ¶ 28. "The interior of the bulbous body **160** defines a compressible reservoir **166** . . . [containing] fluid **168**." *Id.* "Preferably, the fluid **168** is a fluid having antiseptic properties." *Id.* ¶ 29. When

"bulbous body **160**" is compressed, the fluid in the reservoir is forced "from the reservoir **166** and eventually into the longitudinal passage **110** of the generally tubular body **108** by way of being forced through the connecting passage **125,** the circular throughway **126**, the passages **119,** the through-passages **140,** and the radial passages **146**." *Id.* ¶ 31.

2. Analysis

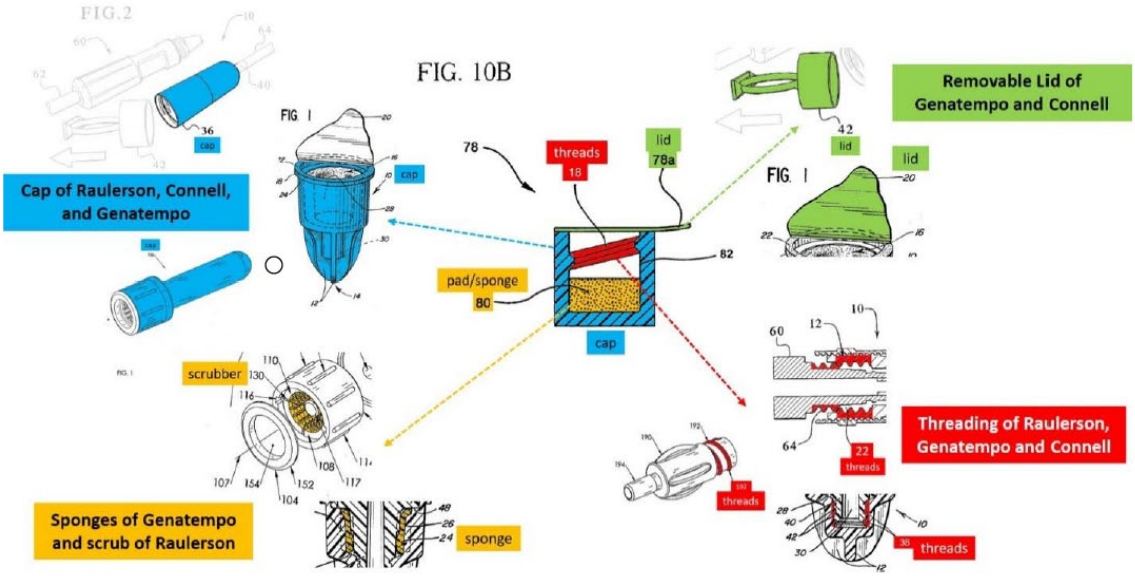
Consistent with the requirement of independent claims 1 and 7, for a "pad including a cleaning agent" "at least partially disposed in the inner cavity" "prior to receipt of the access portion of the access valve," Petitioner proposes combining the cited art to produce a device having a sponge pre-wet with antiseptic solution. Pet. 54; *see* Ex. 1001, 5:60–62, 6:5–7 (claim 1), 6:29–31, 37–39 (claim 7). As discussed above, claims 10 and 14 do not require a "pad" instead requiring "a cleaning agent disposed in the inner cavity," and claim 14 does not expressly state that the pad is within the cavity "prior to the inner cavity of the cap receiving the access portion of the access valve" as set forth in claim 10. *See* Ex. 1001, 7:1–8, 8:5–31. As explained previously, claim 14 requires a removable seal "covering the opening to the inner cavity" with "the cleaning agent being within the inner cavity of the cap," hence tacitly requiring the cleaning fluid to be within the inner cavity prior to removal of the seal and receipt of the access portion of the valve. *See* Ex. 1001, 8:22–31, 4:22–4; Pet. 49 (discussing claim 14 with reference to language from claim 1 concerning "the pad being disposed in the inner cavity, *prior to receipt of the access portion of the access valve*") (emphasis added).

Consistent with the first two grounds, Petitioner's argument with respect to claims 10 and 14 is premised on combining the cited art to

produce a device that includes a pad including a cleaning agent, i.e., a pre-wet sponge. Pet. 78–79 (discussing claim 10 with reference to language from claim 1 concerning "a pad including a cleaning agent"), 82 (same discussion for claim 14); Ex. 1002 ¶ 24 (describing '828 patent technology as a patient line disinfecting cap that "is, at its essence, a threaded cap with an antiseptic-soaked sponge within the cap"). Accordingly, our analysis of Petitioner's explanation of the combination and rationale for combining the art to produce a device with such a pad applies to all of the challenged claims.

To arrive at the claimed combination, Petitioner asserts that a person of ordinary skill in the art need do nothing more than arrange old elements from the four asserted references. Pet. 55. Because each of these elements would perform a similar function in the claimed combination, Petitioner reasons, a person of ordinary skill would have a reasonable expectation of success in making the combination. *Id*.

To illustrate that the claimed combination is such a combination of old elements, Petitioner provides the following figure showing the elements to be gleaned from each asserted reference of the combination.



Pet. 56 (citing Ex. 1002 ¶ 100).

In relation to the figure above, Petitioner asserts the following:

> 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).

Pet. 56–57.

In describing why one of skill in the art would combine these different features from Connell, Raulerson, and Genatempo, Petitioner explains:

> However, to the extent *Connell* does not expressly disclose a mechanism for providing any physical cleaning motion (e.g., scrubbing), *Raulerson* teaches a scrubbing mechanism that uses rotational energy (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 skilled person 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 surfaced. (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 skilled person 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 skilled person would understand that additional liquid can be provided, sufficient to, when the sponge is compressed, release liquid to flow throughout the threading portions of the coupling. (Ex. 1002, ¶99). Relatedly, *Genatempo* describes the use of a removable lid, which a skilled person would recognize as necessary to ensure that *Genatempo's* pre-impregnated sponge does not dry out or expel its liquid prematurely. (Ex. 1002, ¶99).

Pet. 54–55.

Petitioner offers further guidance as to the inclusion of a removable lid in relation to the sponge of Genatempo. Petitioner states that "*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." Pet. 63 (citing Ex. 1002 ¶¶ 99–100; Ex. 1006, 1:44–52).

Patent Owner acknowledges that all of the components of the claimed combination are in the prior art, but asserts that "Petitioner fails to demonstrate why one of ordinary skill would have arrived at the claimed arrangements of the '828 patent." Prelim. Resp. 28. We agree.

Petitioner fails to explain why a person of ordinary skill in the art in reading Connell or Raulerson would add a sponge from Genatempo at all.[9] *See* Prelim. Resp. 42–45; *id*. at 39 ("Petitioner has not explained why Connell's solution is insufficient and why it needs to be altered."). As Patent Owner points out, neither Connell nor Raulerson identifies any problems with "dry spots" or "other deficiencies associated with failure of breaking" of the seal to release the disinfectant. *See id*. at 43–44; Ex. 2002 ¶¶ 81–85; *see generally* Exs. 1010, 1011. In fact, Connell touts as an

[9] As previously discussed, independent claims 1 and 7 each require a "pad including a cleaning agent," but independent claims 10 and 14 require simply a "cleaning agent." Ex. 1001, 5:60 (claim 1), 6:29 (claim 7), 7:1 (claim 10), 8:17 (claim 14). Petitioner's argument with respect to claims 10 and 14, however, is premised on combining the cited art to produce a device that includes a pad including a cleaning agent, i.e., a pre-wet sponge. *See* Pet. 78–79, 82–83.

advantage of its invention that its cap "contains a continuous amount of a disinfectant and does not require an absorbent material to hold the disinfectant." Ex. 1010 ¶ 53; Prelim. Resp. 44; Ex. 2002 ¶ 82.

Connell also indicates that use of an absorbent material, such as a sponge, does not solve the problems it seeks to address. For instance, Connell states:

> Accordingly, the frequent connections that must be made and broken between the catheter residing in the peritoneal cavity and a succession of dialysate containers has created a need to ensure the sterilization of connectors used in performing CAPD [Continuous Ambulatory Peritoneal Dialysis] and APD [Automated Peritoneal Dialysis]. Attempts have been made to saturate an absorbent material with disinfectant and dispose the material in the connector such that it contacts the tube/connector interface. A need still exists however to improve the efficiency, effectiveness and cost of providing sterile connections for PD [Peritoneal Dialysis].

Ex. 1010 ¶ 12.

Also, we agree that Connell cannot be read by one of ordinary skill in the art as concerned with a failure of breaking of the seal containing the cleaning fluid. *See* Prelim. Resp. 45. In fact, Connell appears concerned that the seal may prematurely break. *See* Ex. 1010 ¶ 95; Ex. 2002 ¶ 84. To prevent this, Connell describes an inner extension on the tip protector that "extends so that it abuts or is directly adjacent to the seal 18." Ex. 1010 ¶ 95. Connell asserts that "[t]hus, it should be appreciated that the tip connector 42 enables the connector 10 to be handled and shipped without destroying the seal 18 and/or losing the disinfectant 20 maintained by the seal 18." *Id*.

By the same token, Raulerson does not appear concerned with dry spots. Raulerson describes using bristles and cleaning fluid to clean a luer connector. Ex. 1011, Abstr. Raulerson describes its device as follows:

> When the luer cleaner is inserted over the proximal end of the luer connector and preferably is rotated reciprocally several times about the luer's axis, the bristles engage and mildly scrub the outer surfaces of the luer connector's proximal end, including the male connector threads, to dislodge debris, and the fluid washes and thus cleans and decontaminates the luer connector end when the luer cleaner is removed from the luer connector.

Ex. 1011 ¶ 4. To prevent the cleaning fluid from escaping the luer connector and entering the catheter, Raulerson includes a guide member that "prevents fluid from entering the catheter 194 through the interior of the luer 190 after the fluid has been forced into the longitudinal passage 110 from the reservoir." *Id.* ¶ 16. As Patent Owner points out, it appears that Raulerson "is concerned with the fluid entering 'the interior of the luer 190' after it has been released from the reservoir." Prelim Resp. 44–45 (citing Ex. 1011 ¶ 16; Ex. 2002 ¶ 83).

In light of these teachings of Connell and Raulerson, which Petitioner does not address, Petitioner has failed to show why "[a] skilled person would understand that the use of a pre-impregnated absorbent material, such as that of *Genatempo* (Ex. 1006, Abstr.), would provide the added benefit of ensuring sufficient wetting of the sponge in advance," such that "there would be no dry spots or other infirmities associated with a failure to break the seal." *See* Pet. 54 (citing Ex. 1002 ¶ 99). Because Petitioner has failed to provide a rationale as to why one of ordinary skill in the art would combine the teachings of Connell, Raulerson, and Genatempo to arrive at the claimed invention, Petitioner has not carried its burden to establish a

reasonable likelihood that it will prevail in showing that any challenged claim would have been obvious over the combination of Connell, Raulerson, and Genatempo.

G. Obviousness over Connell, Raulerson, Genatempo, and Miyahara

Petitioner asserts that claim 12 of the '828 patent would have been obvious over the combination of Connell, Raulerson, Genatempo, and Miyahara. Pet. 83–85. In this ground, Petitioner applies Connell, Raulerson, and Genatempo as discussed above, and relies on Miyahara to address a limitation in claim 12 regarding the length of the threading. *Id.* As Petitioner does not rely upon Miyahara to address the deficiency discussed above, we find that Petitioner has not carried its burden to establish that a reasonable likelihood that it will prevail in showing that the challenged claims would have been obvious for the reasons already discussed in connection with the combination of Connell, Raulerson, and Genatempo.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner will prevail in showing that any challenged claim of the '828 patent is unpatentable. Accordingly, we decline to institute an *inter partes* review of claims 1–14 of the '828 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied; and

FURTHER ORDERED that the requested *inter partes* review is not instituted with respect to any claim of the '828 patent.

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