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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAXTER INTERNATIONAL INC.,
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,
Patent Owner

IPR2020-00025
Patent 9,283,367 B2

Before SUSAN L. C. MITCHELL, ROBERT A. POLLOCK and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *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 1–20 of U.S. Patent No. 9,283,367 B2 (Ex. 1001, "the '367 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

Petitioner represents that it is unaware of any pending matters related to the '367 patent. Pet. vii. Petitioner represents that the parent of the '367 patent, U.S. Patent No. 8,740,864 ("the'864 patent"), was involved in the following terminated district court litigations: *Hospira, Inc. v. Ivera Medical Corp.*, 1-14-cv-03513 (D.N.J., Jun. 3, 2014); *Catheter Connections, Inc. v. Ivera Medical Corp.*, 1-14-cv-03512 (D.N.J., Jun. 3, 2014); *Excelsior Medical Corp. v. Ivera Medical Corp.*, 1-14-cv-03502 (D.N.J., Jun. 3, 2014); *Ivera Medical Corp. v. Excelsior Medical Corp.*, 3-14-cv-01348 (S.D. Cal. Jun. 3, 2014); *Ivera Medical Corp. v. Catheter Connections, Inc.*, 3-14-cv-

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

01346 (S.D. Cal. Jun. 3, 2014); and *Ivera Medical Corp. v. Hospira, Inc.*, 3-14-cv-01345 (S.D. Cal. Jun. 3, 2014). Pet. vii; Paper 4, 2. Petitioner also identifies terminated *inter partes* review proceeding IPR2014-00880 as relating to the parent of the '367 patent. Pet. vii. In addition, the parties identify IPR2020-00024, IPR2020-00026, and IPR2020-00027, as related to the '367 patent in that the patents at issue in those proceedings are part of the same patent family as the '367 patent. Pet. vii; Paper 4, 2. Finally, Patent Owner identifies U.S. Patent Application No. 16/428,083, which is currently pending before the Office, as claiming priority from the application that resulted in the '367 patent. Paper 4, 2.

B. The '864 Patent (Ex. 1001)

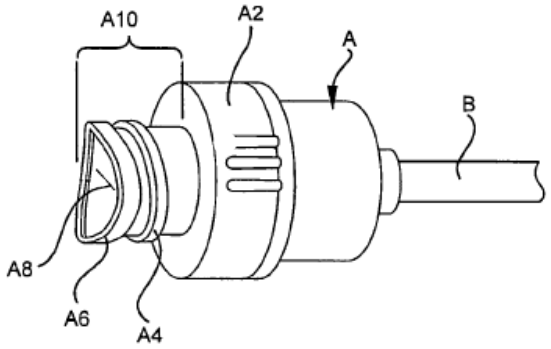
The '367 patent issued March 15, 2016, identifying Minh Quang Hoang and Jonathan Karl Burkholz as joint inventors. Ex. 1001, code (72). The patent relates to "a device for antiseptically maintaining a patient fluid line access valve." *Id.* at 1:49–50.

The '367 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 1:19–23. These infection cause "anywhere from 2,400 to 20,000 death per year." *Id.* at 1:24–25. 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 1:30–32. Addressing this problem by "[i]mpregnating catheters with various antimicrobial agents . . . [has] given less than satisfactory results." *Id.* at 1:33–36. While 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 1:39–43. Thus, according to the '367 patent, "there is a need for an effective and inexpensive way to reduce the number of catheter-related infections." *Id.* at 1:43–45.

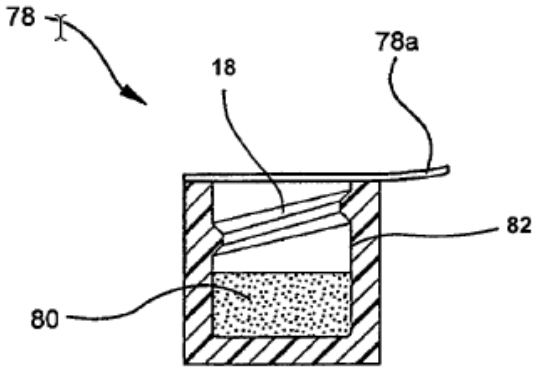
The '367 patent discloses "[c]ap and cleaning devices [that] antiseptically maintain patient fluid line access valves to minimize the risk of infection via catheters." *Id.* at Abstract. "The devices have a hood that contains a wet pad impregnated with a cleaning solution and, optionally, an antimicrobial 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 '864 patent shows a "representative embodiment of cap/cleaner device and a patient fluid line access valve." *Id.* at 1:59–61. The portion of Figure 1 showing the patient fluid 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 2:19–20.

The "patient access valve" depicted in partial Figure 1 above may be cleaned by a cap device. *Id.* at 5:14–16. Figure 10B (reproduced below) shows "a representative embodiment of cap device **78**." *Id.* at 5:9–10.



As shown in Figure 10B, the "cap device" may include "threading **18** having a length that is less than inner circumference **82**." *Id.* at 5:23–24. The "cap device" may also include a "lid **78*a*** and pad **80**." *Id.* at 5:10. The pad may be "either [ ] a wet pad or a dry pad." *Id.* at 5:11–12. "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 5:14–18.

C. Challenged Claims

Petitioner challenges claims 1–20 of the '367 patent. Claim 1 is representative and is reproduced below.

> 1. A device for maintaining a patient fluid line access valve having an access portion with a distalmost end face that includes a septum and external threads on the access portion proximate the distalmost end face, the device comprising:
>
> a housing having an opening to an inner cavity for receiving the access portion of the patient fluid line access valve;
>
> a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve;
>
> threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access

> portion of the patient fluid line access valve to contact the wet pad with the distalmost end face of the access portion of the patient fluid line access valve, and to disinfect the distalmost end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the cleaning solution from the wet pad, wherein the threading receives the external threads of the access portion of the patient fluid line access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad; and
>
> a removable lid enclosing the inner cavity to maintain the wet pad and the cleaning solution in the inner cavity prior to receiving the access portion of the patient fluid line access valve.

Ex. 1001, 5:40–68.

D. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–20 of the '864 patent on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–20	§ 103(a)	Menyhay,[3] Genatempo[4]
7, 12, 20	§ 103(a)	Menyhay, Genatempo, Raad[5]
10, 15	§ 103(a)	Menyhay, Genatempo, Miyahara[6]
1–20	§ 103(a)	Connell,[7] Raulerson,[8]

[3] Menyhay, U.S. Patent No. 5,554,135, issued Sep. 10, 1996 ("Menyhay").
[4] Genatempo et al., U.S. Patent No. 4,440,207, issued Apr. 3, 1984 ("Genatempo").
[5] Raad, U.S. Patent Publication No. 2005/0013836 A1, published Jan. 20, 2005 ("Raad").
[6] Miyahara, U.S. Patent Publication No. 2004/0111078 A1, published June 10, 2004 ("Miyahara").
[7] Connell et al., U.S. Patent Publication No. 2003/0153865 A1, published Aug. 14, 2003 ("Connell").
[8] Raulerson et al., U.S. Patent Publication No. 2006/0030827 A1, published Feb. 9, 2006 ("Raulerson").

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
		Genatempo
7, 12, 20	§ 103(a)	Connell, Raulerson, Genatempo, Raad
10, 15	§ 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.

E. 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 be "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. 8–9 (citing Ex. 1002, ¶¶26-28). According to Petitioner, "[s]uch a person would have had knowledge of design considerations known in the fluid line industry, including patient safety considerations, and would have been familiar with then existing products and solutions, and would

have understood how to search available literature for relevant publications." *Id.* At this stage in the proceeding, Patent Owner does not challenge Petitioner's identification of the qualifications for a POSA. 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).

F. 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). Therefore, we construe the 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)). For purposes of this decision, we determine that no claim terms require express construction.

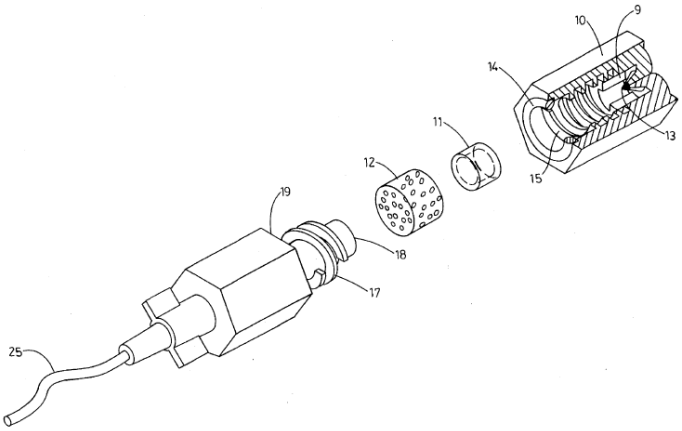
II. OBVIOUSNESS OVER MEYHAY AND GENATEMPO

Petitioner asserts that claims 1–20 of the '367 patent would have been obvious over the combination of Meyhay and Genatempo. Pet. 21–48. 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 1–20 of the '367 patent would have been obvious over the combination of the combination of Meyhay and Genatempo.

A. Disclosures of the Asserted Prior Art

Menyhay

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, Menyhay's apparatus includes "a cylinder **10** that is open on one end." *Id.* at 6:38–39. The cylinder includes "a set of screw threads **15** on the inside" and "[a]n inwardly pointing projection **13**." *Id.*

6:39–42. "A breakable capsule **11**" "filled with . . . an antiseptic, bactericidal and virucidal solution" "is disposed inside cylinder **10** immediately adjacent to projection **13**" and a "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 an "[e]xternal injection port **19**" that includes "a thick septum **18**" and "[a] set of screw thread **17**." *Id.* at 6:53–55As the "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 6:68–7:3. This can be seen in Figure 3 (reproduced below).

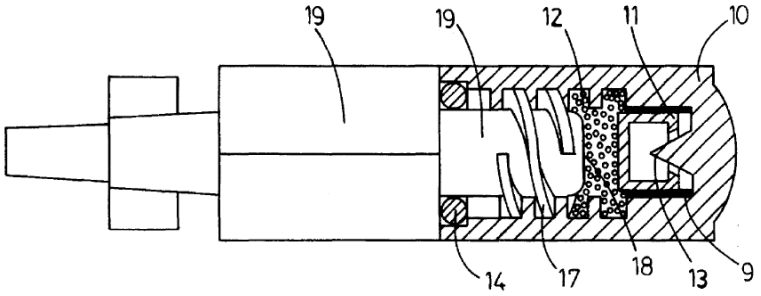
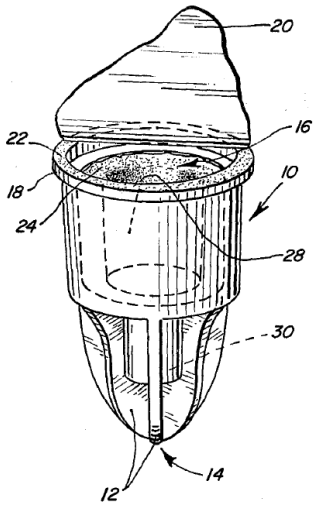


Figure 3 is a "partially cut away side view showing the cover and port of the present invention after the cover has been tightly screwed over the port and the antiseptic capsule ruptured." *Id.* at 6:18–21.

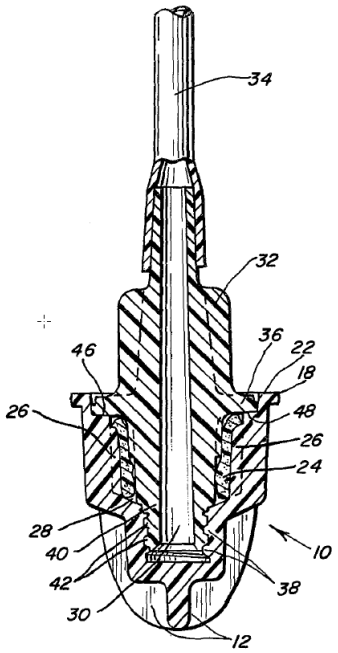
Genatempo

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.



Ex. 1006 at Fig. 1. As shown in Figure 1, "[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 cross sectional view of Genatempo's cap covering a connector.



In Figure 3, "connector **32[**,**]** **. . .** a typical connector used with CAPD tubing sets," "is shown engaged by protective cap **10**." *Id.* at 3:30–31. 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

B. Analysis

The challenged claims all recite a "wet pad" "holding" (claim 1 and its dependents) or "impregnated with" (claims 9 and 14 and their dependents) a "cleaning solution" *before* the patient fluid access valve is attached to the housing. *Id.* at 5:47–48 (claim 1 reciting, "a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve"); 6:29–30 (claim 9 reciting, "a wet pad impregnated with a cleaning solution prior to attachment of the housing to the access portion of the patient fluid line access valve"); 6:64–65 (claim 14 reciting, "a wet

pad within the housing and impregnated with a cleaning solution prior to contacting the threaded patient fluid line access valve").

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

> [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 sufficiently to wet sponge 12. (Ex. 1002, ¶¶75-76). A POSA would have also understood that preloading *Menyhay's* sponge as suggested by *Genatempo*, along with the additional sponge location of *Genatempo* would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety. (Ex. 1002, ¶¶75-78).

Pet. 22–23. The second passage appears in Petitioner's analysis of claim 1, under the subheading "Part [b]." 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, Abstract) to ensure full-wetting of the sponge and thus avoiding dry spots in the event that the capsule of *Menyhay* fails to break sufficiently to wet sponge 12." Pet. 22. 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 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 (Pet. 22–23 (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 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 22–23. While 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 (Pliskha 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 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. 22–23.

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*, that the sponge not become [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 of 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 Gentampo as an alternative to 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.").

III. OBVIOUSNESS OVER MENYHAY, GENATEMPO, AND RAAD

Petitioner asserts that claims 7, 12, and 20 of the '367 patent would have been obvious over the combination of Menyhay, Genatempo, and Raad. Pet. 48–52. In this ground, Petitioner applies Menyhay and Genatempo as discussed above, and relies on Raad to address the additional limitations in claims 7, 12, and 20 regarding the composition of the cleaning solution. *Id.* As Petitioner does not rely upon Raad to address the deficiency discussed above, we find that Petitioner has not carried its burden

to establish 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.

IV. OBVIOUSNESS OVER MENYHAY, GENATEMPO, AND MIYAHARA

Petitioner asserts that claims 10 and 15 of the '864 patent would have been obvious over the combination of Menyhay, Genatempo, and Miyahara. Pet. 52–54. In this ground, Petitioner applies Menyhay and Genatempo as discussed above, and relies on Miyahara to address limitations in claims 2, 11, and 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 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

V. OBVIOUSNESS OVER CONNELL, RAULERSON, AND GENATEMPO

Petitioner asserts that claims 1–20 of the '367 patent would have been obvious over the combination of Connell, Raulerson, and Genatempo. Pet. 55–78. Patent Owner opposes. Prelim. Resp. 27–49. 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 1–20 of the '367 patent would have been obvious over the combination of Connell, Raulerson, and Genatempo.

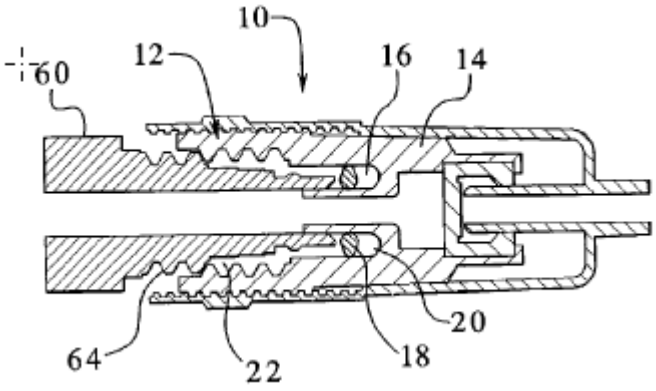
A. Disclosures of the Asserted Prior Art

Connell

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, Abstract. "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.



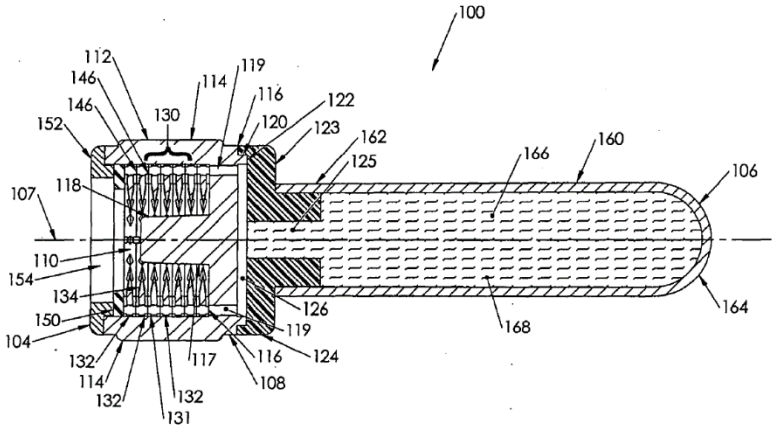
Id. at Fig. 4. As shown in Figure 4, :[t]he connector . . . **60** includes external threads **64** that mate[] with the internally facing threads **22** of the body **14** of the cap **12**." *Id.* ¶ 100. The cap includes **"**disinfectant **20"** that is held in place by seal **18**. *Id.* "When the 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 the seal **18** moves or ruptures, "the disinfectant **20** runs out over the external threads **64** of connector **60.**" *Id.*

Raulerson

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 roatated "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, "the 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 a "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.* "The bristles **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.*

"The closed 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.

Genatempo

Genatempo's disclosure is discussed *supra* p. 11–12.

A. Analysis

The challenged claims all recite a "patient fluid line access valve" having a "distalmost end face that includes a septum." Ex. 1001, 5:41–42; 6:20–21; 6:58–59. The challenged claims also recite a "wet pad" "holding" (claim 1 and claims depending therefrom) or "impregnated with" (claims 9 and 15 and claims depending therefrom) a "cleaning solution." *Id.* at 5:47–48; 6:29–30; 6:64–65. All of the challenged claims require that the claimed device allow "contact" between the "wet pad" and the "end face" of the "patient fluid line access valve." *Id.* at 5:54–56 (independent claim 1 reciting that the threads of the inner cavity of the housing engage the external thread of the patient fluid line access valve "to contact the wet pad with the distalmost end face of the access portion of the patient fluid line access valve, and to disinfect the distalmost end face"); *see also, id.* at 5:59–63 (independent claim 1 further reciting, "wherein the threading [of the inner cavity of the housing] receives the external threads of the access portion of the patient fluid line access valve thereby causing the distalmost end face to advance into the inner cavity such that the septum contacts the wet pad"); 6:31–34 (independent claim 10, reciting "the wet pad being positioned within the cavity for contacting the distalmost end face of the patient fluid line access valve . . . to reduce the amount of microbes on the access portion"); *id.* at 6:66–7:3 (independent claim 15 reciting, "the wet pad being

configured to contact at least a portion of the threaded patient fluid line access valve and the distalmost end face of the threaded patient fluid line access valve to reduce the amount of microbes on the threaded patient fluid line access valve"); *id.* at 7:6–9 (independent claim 15 further reciting, "the thread for engaging the external threads of the threaded patient fluid line access valve to cause the wet pad to contact the distalmost end face of the threaded patient fluid line access valve").

Petitioner's argument with respect to the requirement for contact between the wet pad and the end face is, in its entirety, as follows:

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

Pet. 66.

In the above argument, Petitioner simply asserts, without support from the record evidence, that in the device suggested by the combination of Connell, Raulerson, and Genatempo, a wetted sponge would contact the septum of the end face. Petitioner, does not explain how or why the art suggests that a wetted sponge would contact the septum of the end face.

Elsewhere in the Petition, Petitioner asserts that cited art teaches disinfecting the threads of medical connectors. *Id.* at 55 ("*Connell* provides a fluid connector cleaner with sealed disinfectant to clean the threading of the connector"); *id.* at 56 ("*Raulerson* teaches a scrubbing mechanism that uses rotational energy to clean the threading of a connector"); *id.* at 56–57 ("By adopting the pre-impregnated sponge of *Genatempo*, . . . 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."). But Petitioner does not identify, and we do not find in the record, persuasive evidence that devices of Connell, Raulerson, or Genatempo disinfect the end face of a connector.

Given that the cleaning components of the cited art – the bristles of Raulerson, the absorbent material of Genatempo, and the sealed disinfectant of Connell – are all positioned to clean the sides rather than the end face of a connector, Petitioner must provide some explanation of how the cited art suggests cleaning the end face in order to render the claimed device obvious. Because Petitioner has not done so, Petitioner has not carried its burden to establish a reasonable likelihood that it will prevail in showing that the challenged claims would have been obvious over the combination of Connell, Raulerson, and Genatempo.

VI. OBVIOUSNESS OVER CONNELL, RAULERSON, GENATEMPO, AND RAAD

Petitioner asserts that claims 7, 12, and 20 of the '367 patent would have been obvious over the combination of Connell, Raulerson, Genatempo, and Raad. Pet. 79–81. In this ground, Petitioner applies Connell, Raulerson, and Genatempo as discussed above, and relies on Raad to address limitations

in claims 7, 12, and 20 regarding the composition of the cleaning solution. *Id.* As Petitioner does not rely upon Raad to address the deficiency discussed above, we find that Petitioner has not carried its burden to establish 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.

VII. OBVIOUSNESS OVER CONNELL, RAULERSON, GENATEMPO, AND MIYAHARA

Petitioner asserts that claims 10 and 15 of the '367 patent would have been obvious over the combination of Connell, Raulerson, Genatempo, and Miyahara. Pet. 82–83. In this ground, Petitioner applies Connell, Raulerson, and Genatempo as discussed above, and relies on Miyahara to address limitations in claims 10 and 15 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 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.

VIII. 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 at least one claim of the '367 patent is unpatentable.

Accordingly, we decline to institute an *inter partes* review of all claims 1–20 of the ’367 patent.

IX. 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 ’367 patent.

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