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571-272-7822

Paper 9
Entered: 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.

IPR2020-00027
Patent 10,335,584 B2

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

CHERRY, *Administrative Patent Judge*.

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

I. INTRODUCTION

Baxter International Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1–18 of U.S. Patent No. 10,335,584 B2 (Ex. 1001, "the '584 patent"). Becton, Dickinson and Company ("Patent Owner") filed a Preliminary Response. Paper 7.

Pursuant to 35 U.S.C. § 314(a), an *inter partes* review may be instituted only if "the information presented in the petition . . . and any [preliminary] response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

For the reasons given below, on this record Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–18 of the '584 patent. Accordingly, we decline to institute an *inter partes* review of the '584 patent.

II. BACKGROUND

A. Real Parties in Interest

The Petition identifies Baxter International Inc. and Baxter Healthcare Corp. as the real parties-in-interest for Petitioner. Pet. v. Patent Owner identifies Becton, Dickinson and Company as the real party-in-interest for Patent Owner. Paper 4, 1.

B. Related Proceedings

The parties identify the following pending petitions for *inter partes* review involving patents that are related to the '584 patent: IPR2020-00024, Petition for *Inter Partes* Review of U.S. Patent No. 8,740,864, filed on October 18, 2019; IPR2020-00025, Petition for *Inter Partes* Review of U.S.

Patent No. 9,283,367, filed on October 18, 2019; and IPR2020-00026, Petition for *Inter Partes* Review of U.S. Patent No. 10,159,828, filed on October 18, 2019. Pet. v; Paper 4, 2. Petitioner also identifies various District Court proceedings that involved related U.S. Patent No. 8,740,864. Pet. vi. Patent Owner identifies related U.S. Application Serial No. 16/428,083 currently pending. Paper 4, 2.

C. The '584 Patent

The '584 patent is titled "Patient Fluid Line Access Valve Antimicrobial Cap/Cleaner." Ex. 1001, Code [54]. The '584 patent issued from Application Serial No. 15/041,939 ("the '939 application"), filed February 11, 2016. *Id.* at Codes [21], [22]. The '939 application is a continuation of Application Serial No. 14/159,959, filed on January 21, 2014, now Patent No. 9,283,367, which is a continuation of Application Serial No. 11/281,711, filed on November 17, 2005, now Patent No. 8,740,864. *Id.* at Code [63].

The '584 patent relates to devices for antiseptically maintaining patient fluid line access valves. *Id.* at Code [57]. The '584 patent explains that bloodstream infections caused by bacteria/fungi in patients with intravascular catheters are a significant cause of illness and excess medical costs. *Id.* at 1:18–21. Per the'584 patent, a need exists for a way of reducing catheter-related bloodstream infections that is more effective and less expensive than prior art techniques and systems. *Id.* at 1:44–45.

The '584 patent describes a device for antiseptically maintaining patient fluid access valves. *Id.* at 1:49–50. An illustrative embodiment of such a device is depicted in Figure 1, reproduced below.

FIG. 1

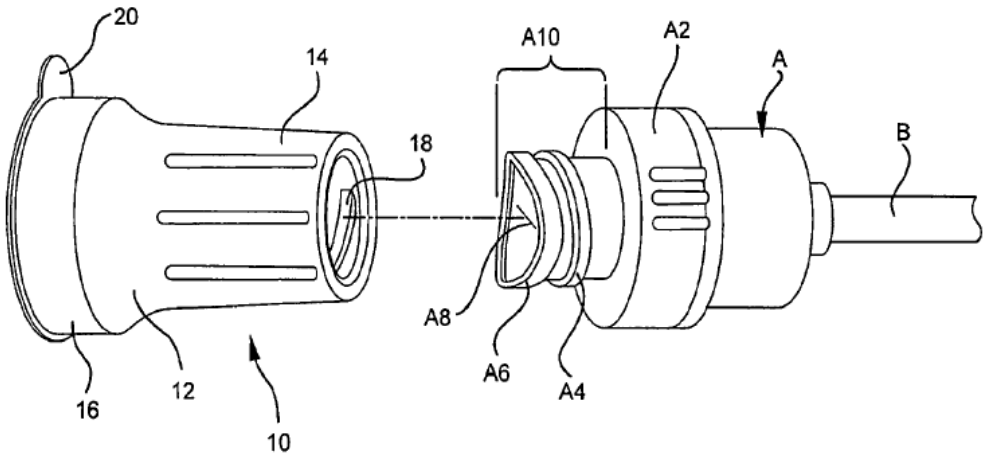

Figure 1 is an exploded view of cap/cleaner 10 with patient fluid line access valve A. *Id.* at 2:15–17. Cap/cleaner 10 includes housing 12 having cap end 14 and cleaning end 16 with lid 20. *Id.* at 2:17–19. Cap end 14 attaches to access valve A at access portion A10, which includes thread A4 and septum A6. *Id.* at 2:19–20, 27–29. Cleaning end 16 includes a chamber having a wet pad impregnated with a cleaning agent, and, optionally, an antimicrobial agent. *Id.* at 3:31–34. To disinfect access valve A, lid 20 is removed and cleaning end 16 is placed over access portion A10 so that the wet pad contacts septum A6. *Id.* at 4:1–2, 11–12.

Another embodiment of the cap and cleaning device is depicted in Figure 10B, reproduced below.

FIG. 10B

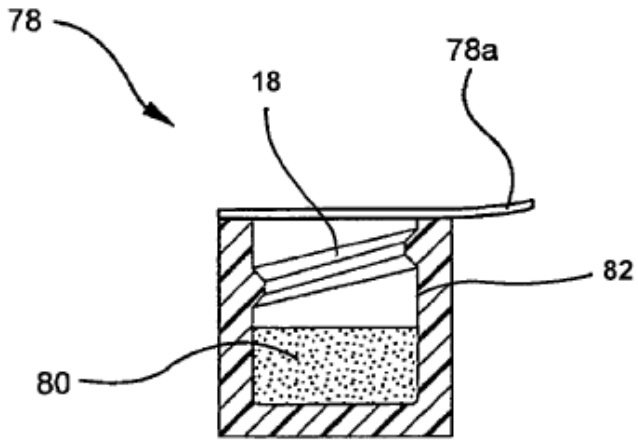

Figure 10B is a cross-sectional view of cap device 78 including threading 18, lid 78a, and pad 80. *Id.* at 5:13–16, 27. Pad 80 may be wet and impregnated with cleaning solution so that cap device 78 functions to both clean and cap access portion A10 of access valve A. *Id.* at 5:18–20. Twisting cap device 78 to thread it on and off access portion A10 provides friction for cleaning. *Id.* at 5:20–22.

D. Illustrative Claim

Of the challenged claims, claims 1, 12, and 15 are independent. Claim 1, reproduced below, is illustrative:

> 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 inner cavity, wherein an opening to the inner cavity is configured for receiving the access portion of the patient fluid tine access valve;
>
> a material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient fluid line

access valve, wherein the material is disposed in the inner cavity;

threading protruding inwardly into the inner cavity from an inner wall of the housing near the opening, the threading configured to engage the external threads of the access portion of the patient fluid line access valve as the housing is placed over the access portion of the patient fluid line access valve to contact the material with the distalmost end face of the access portion of the patient fluid line access valve, and configured to disinfect the distalmost end face and at least a portion of the external threads of the access portion of the patient fluid line access valve with the liquid antimicrobial agent from the material,

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

Ex. 1001, 5:44–6:4.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–18 of the '584 patent on the following grounds:

References	Basis	Claims challenged
Menyhay[1] and Genatempo[2]	§ 103(a)	1–18
Menyhay, Genatempo, and Raad[3]	§ 103(a)	5, 8–11, 14, 18
Menyhay, Genatempo, and Miyahara[4]	§ 103(a)	13, 16
Connell,[5] Raulerson,[6] and Genatempo	§ 103(a)	1–18
Connell, Raulerson, Genatempo, and Raad	§ 103(a)	5, 8–11, 14, 18
Connell, Raulerson, Genatempo, and Miyahara	§ 103(a)	13, 16

Petitioner supports its Petition with a Declaration by Richard Meyst, dated October 11, 2019. Ex. 1002. Patent Owner supports its position with the Declaration of Michael Plishka, dated January 21, 2020. Ex. 2002.

F. Level of Ordinary Skill

Petitioner proposes that a person of ordinary skill

> would have had an undergraduate degree, or equivalent thereof, in mechanical engineering or biomedical engineering with at

[1] U.S. Patent No. 5,554,135, issued September 10, 1996 (Ex. 1007, "Menyhay").
[2] U.S. Patent No. 4,440,207, issued April 3, 1984 (Ex. 1006, "Genatempo").
[3] U.S. Patent Application Publication No. US 2005/0013836 A1, published (Ex. 1016, "Raad").
[4] U.S. Patent Application Publication No. US 2004/0111078 A1, published June 10, 2004 (Ex. 1009, "Miyahara").
[5] U.S. Patent Application Publication No. US 2003/0153865 A1, published Aug. 14, 2003 (Ex. 1010, "Connell").
[6] U.S. Patent Application Publication No. US 2006/0030827 A1, published Feb. 9, 2006 (Ex. 1011, "Raulerson").

> 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 (citing Ex. 1002 ¶¶ 26–28; Ex. 1005, 150). Patent Owner does not dispute this definition of a person of ordinary skill. *See generally* Prelim. Resp. For purposes of this Decision, we adopt Petitioner's proposed level of ordinary skill as it appears to be consistent with the level of skill reflected Specification and in 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).

G. Claim Construction

We interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b) "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2019).[7] Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

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

We discern no terms in need of express interpretation to determine whether to institute *inter partes* review. At this stage of the proceeding, we apply the legal standards set forth above when reading the claims.

III. DISCUSSION

A. Obviousness Based On Menyhay and Genatempo

Petitioner challenges claims 1–18 of the '584 patent under 35 U.S.C. § 103 as unpatentable over Menyhay and Genatempo. Pet. 21–47. 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 claims 1–18 of the '584 patent would have been obvious over the combination of Meyhay and Genatempo.

We begin our analysis with an overview of Menyhay and Genatempo, and then discuss the Petitioner's contentions as to how the teachings of the combination render the challenged claims obvious.

1. Overview of Menyhay

Menyhay is entitled "Sterile Medical Injection Port and Cover Method and Apparatus." Ex. 1007, [54]. Menyhay discloses a cover for an external injection port. *Id.* at 4:9–10. Figure 1, reproduced below, is an exploded cut away perspective view of an external injection port cover. *Id.* at 6:11–13.

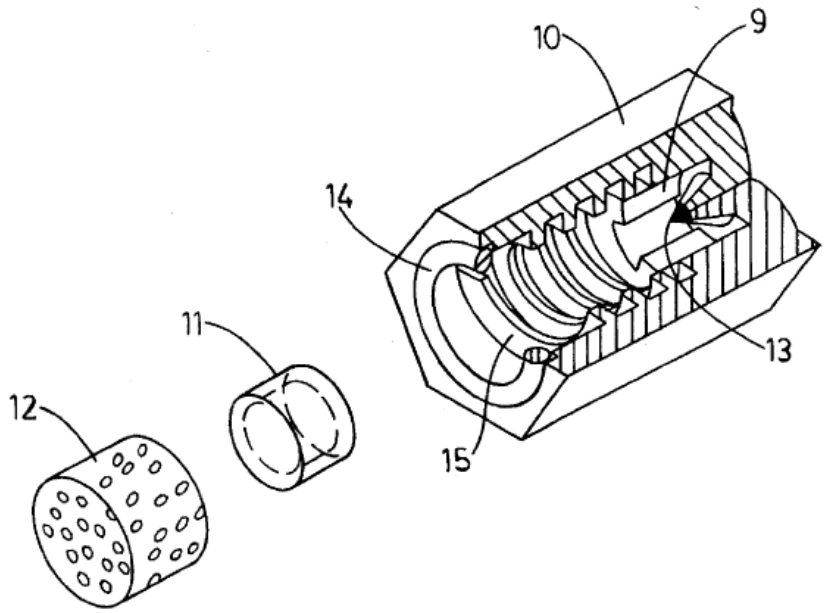

FIG. 1

Figure 1 shown above depicts an external injection port cover including cylinder 10 having an open end with screw threads 15 on the inside and a closed end with projection 13 pointing inwardly. *Id.* at 6:38–42. Breakable capsule 11 is filled with an antiseptic solution and is positioned inside cylinder 10 immediately adjacent projection 13. Id. at 6:45–46. Sponge 12 is positioned on the opposite side of breakable capsule 11. *Id.* at 6:47–48. The cover is screwed onto an injection port and tightened to create pressure between projection 13 and breakable capsule 11, such that the capsule ruptures and releases the antiseptic solution to soak sponge 12. *Id.* at 6:59–64. Completely tightening the cover causes the antiseptic-soaked sponge 12 to make contact with the injection port membrane. *Id.* at 6:67–7:2.

2. Overview of Genatempo

Genatempo is entitled "Antibacterial Protective Cap for Connectors." Ex. 1006, [54]. Genatempo discloses "a protective cap for a connector

which securely receives and provides an antibacterial effect to the connector." *Id.* at 1:55–57. Figure 1, reproduced below, is a perspective view of a protective cap. *Id.* at 2:45–46.

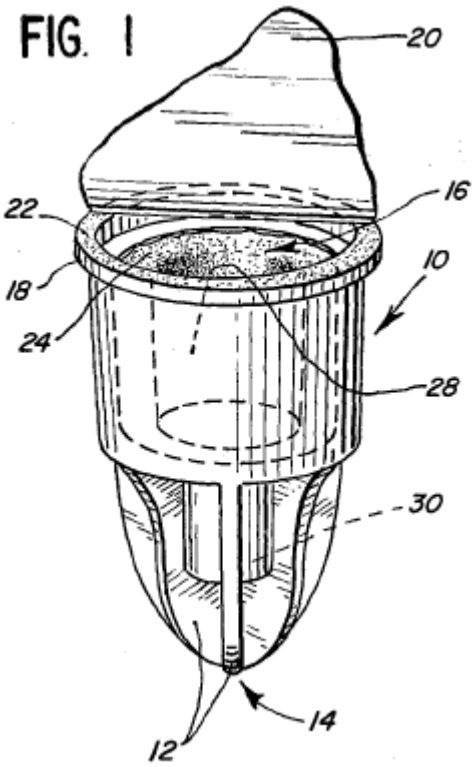

Figure 1 shown above depicts protective cap 10 having opening 16 and closed end 14 with exterior gripping fins 12. *Id.* at 2:57–62. Removable lid 20 covers opening 16, and the inside of protective cap 10 is lined with absorbent material 24 filled with antiseptic. *Id.* at 2:66–68, 3:22–23. Threading protective cap 10 onto a connector causes absorbent material 24 and antiseptic to contact the connector and produce an antibacterial effect. *Id.* at 3:36–42.

3. Analysis

Independent Claim 1 recites, in part, "a material impregnated with a liquid antimicrobial agent prior to receiving the access portion of the patient

fluid line access valve." Ex. 1001, 5:52–55. Independent claim 12 similarly recites, in part, "a material impregnated with a liquid antimicrobial agent prior to attachment of the housing to the access portion of the patient fluid line access valve." *Id.* at 6:44–46. Independent claim 15 recites, in part, "a material within the housing and impregnated with a liquid antimicrobial agent prior to contacting the patient fluid line access valve." *Id.* at 7:6–8.

Petitioner asserts that Menyhay teaches a sponge 12 that is impregnated with antiseptic agents from capsule 11. Pet. 28. Petitioner contends that Genatempo discloses cap 10 with a pad that is impregnated with antiseptic before receiving connector 32. *Id*. (citing Ex. 1006, 3:22–23, Fig. 3; Ex. 1002 ¶¶ 35–36). Petitioner asserts that, "[b]efore using protective cap 10 of Genatempo, removable lid 20 is removed, exposing the wet pad and antiseptic solution." *Id.* (italics omitted) (citing Ex. 1006, 2:64–68; Ex. 1002 ¶ 36). Petitioner relies on the same arguments and evidence for the corresponding limitations in claims 12 and 15. *See id.* at 72, 75–76.

The Petition includes two passages addressing how the allegedly obvious combination meets the requirement that material be impregnated 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 thus 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). The compression of these pre-wetted sponges would allow the

> stored antiseptic liquids to flow across exposed surfaces. (Ex. 1002, 77).

Pet. 22.

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

Pet. 29.

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 that the effectiveness of capsule/release disinfection. Ex. 2003[8], 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 (citing Ex. 1002 ¶¶ 75–76)), but the cited testimony

[8] Steve Z. Menyhay & Dennis G. Maki, "Preventing central venous catheter associated bloodstream infections: Development of an antiseptic barrier cap for needleless connectors," *American Journal of Infection Control*, Dec. 2008, Vol. 36, Issue 10, pp. S174.e1-e5.

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 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. While we recognize that providing an additional sponge location *might* provide additional disinfection, Petitioner has provided insufficient explanation to establish sufficiently that preloading Menyay'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, and Petitioner has provided insufficient persuasive explanation, how a preloaded sponge would provide additional disinfection of Menyhay's port as compared to a sponge described as "aseptically bathing" the port.

Petitioner further submits that "[t]he compression of these pre-wetted sponges would allow the stored antiseptic liquids to flow across exposed surfaces." Pet. 22. 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 wet and 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 sponge becomes saturated. Manyhay's sponge becomes saturated after the capsule ruptures while Genatempo's sponge is saturated from the beginning.

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 its sponge saturation does not 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 "[p]reloading *Menyhay's* sponge as suggested by *Genatempo* . . . would have provided additional disinfection of the exposed surfaces, providing for enhanced patient safety." Pet. 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*, that the sponge not become fully wetted in the time between breaking the seal and the disinfecting process." Pet. 29. We are not persuaded because, as discussed above, the current record does not support that Menyhay's sponge would fail to become fully wetted or that the timing of 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 sponge arrangement 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 Gentampo 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.").

4. Claims 2–11, 13, 14, and 16–18

Claims 2–11, 13, 14, and 16–18 all depend from directly or indirectly from claims 1, 12, and 15. Thus, we determine that Petitioner has also failed to show a reasonable likelihood of prevailing in showing that these claims would have been obvious over Menhay and Genatempo.

B. Remaining Grounds Based on Menyhay and Genatempo

Petitioner challenges claims 5, 8–11, and 14 of the '584 patent under 35 U.S.C. § 103(a) as unpatentable over Menyhay, Genatempo, and Raad. Pet. 47–52. Petitioner challenges claims 13 and 16 of the '584 patent under 35 U.S.C. § 103(a) as unpatentable over Menyhay, Genatempo, and Miyahara. Pet. 52–54. Petitioner relies on the same analysis discussed above to account for the "material impregnated" limitation in claims 1, 12, and 15. Thus, we determine that Petitioner has failed to show a reasonable likelihood of prevailing on these grounds as well.

C. Obviousness Based on Connell, Raulerson, and Genatempo

Petitioner challenges claims 1–18 of the '584 patent under 35 U.S.C. § 103(a) as unpatentable over Connell, Raulerson, and Genatempo. Pet. 55–78. Patent Owner opposes. Prelim. Resp. 27–51. 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 1–18 of the '584 patent would have been obvious over the combination of Connell, Raulerson, and Genatempo.

As Genatempo is discussed above in section III.A.2, We begin our analysis with an overview of Connell and Raulerson, and then discuss the Petitioner's contentions for each of the claims.

1. Overview of Connell

Connell is entitled "Dialysis Connector and Cap Having an Integral Disinfectant." Ex. 1010, [54]. Connell discloses "a connector and a cap that are easily and readily attachable to a dialysate container and a catheter inserted into a patient's peritoneal cavity." *Id.* ¶ 14. Figure 4, reproduced below, is an elevation view showing the use of the connector and cap to transfer medical fluid to or from a patient. *Id.* ¶ 62.

FIG.4

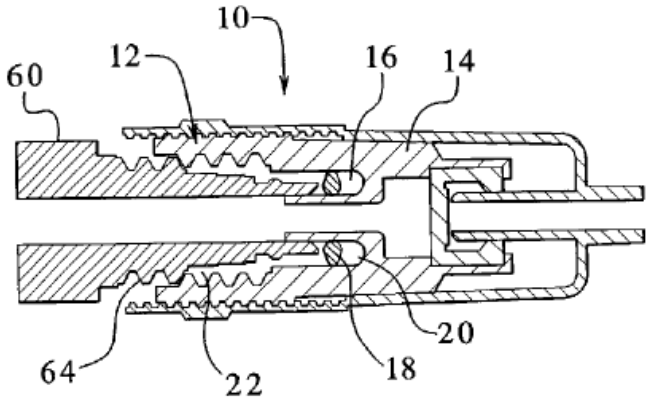

Figure 4 depicts connector 60 ready to be connected to connector 10. *Id.* ¶ 100. Connector 60 threads into body 14 of cap 12 so that the ends of the connector advance against seal 18, rupturing it and releasing disinfectant 20 from receptacle 16. *Id.* ¶ 101. Pressure from the ends of connector 60 drives disinfectant 20 out past seal 18 and over threads 65 of connector 60. *Id.* ¶ 102.

2. Overview of Raulerson

Raulerson is entitled "Luer Cleaner." Ex. 1011, [54]. Raulerson discloses "an apparatus for cleaning a luer connector that is attached to a catheter assembly implanted on a patient." *Id.* ¶ 2. Figure 1, reproduced below, is a perspective view of a luer cleaner according to a preferred embodiment. *Id.* ¶ 7.

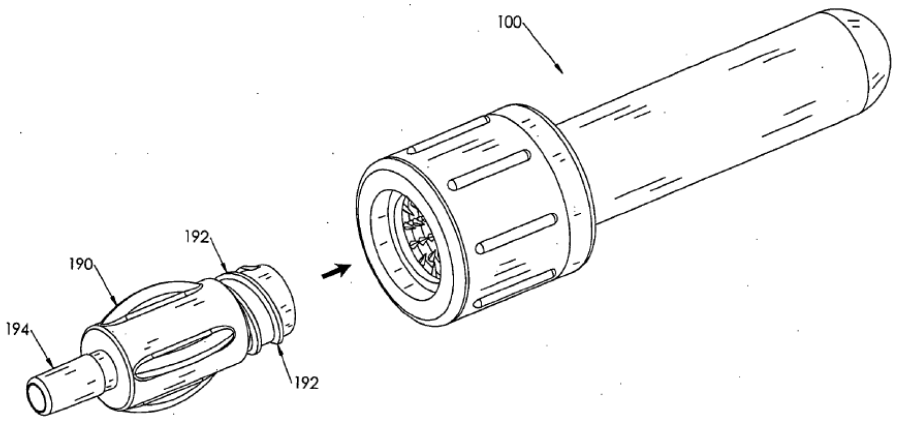

FIG. 1

Figure 1 depicts luer cleaner 100 and luer 190. *Id.* ¶ 14. Luer 190 includes threads 192 at its proximal end, and the proximal end is inserted into the open end of luer cleaner 100. *Id.* Luer cleaner 100 includes antiseptic in a reservoir. *Id.* Luer cleaner 100 is rotated about luer 190, and pressure forces the antiseptic cleaner out of the reservoir to clean luer threads 192. *Id.*

3. Independent Claims 1, 12, and 15

All Challenged Claims of the '584 patent require contact between the claimed material impregnated with a liquid antimicrobial agent and the "distalmost end face" of the access portion of the patient fluid line access valve to be disinfected. Specifically, independent claim 1 recites "contact the material with the distalmost end face of the access portion of the patient fluid line access valve, and configured to disinfect the distalmost end face." Ex. 1001, 5:61–64. Similarly, independent claim 12 recites "the material being positioned within the cavity for contacting the distalmost end face . . . to reduce the amount of microbes on the access portion" (Ex. 1001, 6:46–51); and independent claim 15 recites "the material being configured to contact . . . the distalmost end face of the patient fluid line access valve to reduce the amount of microbes" (*Id.* at 7:8–13).

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).

Pet. 66.

In the above argument, Petitioner simply asserts 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 that provides sealed disinfectant to clean the threading of the connector"); *id.* at 56 ("*Raulerson* teaches a physical 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 any of the devices of Connell, Raulerson, or Genatempo disinfect the end face of a connector, much less a combination of these devices.

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.

4. Claims 2–11, 12, 13, and 14–18

Claims 2–11, 13, 14, and 16–18 all depend from directly or indirectly from claims 1, 12, and 15. Thus, we determine that Petitioner has also failed to show a reasonable likelihood of prevailing in showing that these claims would have been obvious over Connell, Raulerson, and Genatempo.

D. Remaining Grounds Based on Connell, Raulerson, and Genatempo

Petitioner challenges claims 5, 8–11, and 14 of the '584 patent under 35 U.S.C. § 103(a) as unpatentable over Raulerson, Genatempo, and Raad. Pet. 78–82. Petitioner challenges claims 13 and 16 of the '584 patent under 35 U.S.C. § 103(a) as unpatentable over Raulerson, Genatempo, and Miyahara. Pet. 82–84. Petitioner relies on the same analysis to account for the "contacting" limitation considered above with respect to the combination of Connell, Raulerson, and Genatempo. Thus, we determine that Petitioner has failed to show a reasonable likelihood of prevailing on these grounds as well.

IV. CONCLUSION

For the foregoing reasons, on this record, we conclude Petitioner has not demonstrated a reasonable likelihood that it will succeed in showing claims 1–18 of the '584 are unpatentable. Accordingly, we do not institute an *inter partes* review of all challenged claims under all grounds set forth in the Petition.

V. ORDER

For the reasons given, it is:

ORDERED that the Petition is *denied* as to all challenged claims of the ’584 patent; and

FURTHER ORDERED that no *inter partes* review is instituted.

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