

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BAXTER INTERNATIONAL INC.,  
Petitioner,

v.

BECTON, DICKINSON AND COMPANY,  
Patent Owner.

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Case IPR2020-00025  
Patent 9,283,367

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**PATENT OWNER'S PRELIMINARY RESPONSE  
UNDER 37 C.F.R. §42.107**

Pursuant to 37 C.F.R. § 42.107, Patent Owner Becton, Dickson and Company (“Patent Owner”) submits this Preliminary Response to the above-captioned Petition (“Pet.,” Paper 1) for *inter partes* review (“IPR”) of claims 1-20 (“Challenged Claims”) of U.S. Patent No. 9,283,367 (“the ’367 patent”), which should be denied institution for failure to show a reasonable likelihood of prevailing on any asserted Grounds.

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## EXHIBIT LIST

Exhibit	Description
2001	Declaration of Keyna Chow ISO <i>Pro Hac Vice</i>
2002	Declaration of Michael Plishka
2003	S. Menyhay, RN, BSN <i>et al.</i> , “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.
2004	Plastics International - Chemical Resistance Chart
2005	Overview of Clearances of Section 510(k) of the Food, Drug and Cosmetic Act
2006	Declaration of Crena Pacheco in Support of Patent Owner’s Preliminary Response

## **I. INTRODUCTION**

This Petition follows a previous IPR petition<sup>1</sup> that challenged the parent of the '367 patent (stemming from an earlier dispute with a different petitioner). Shortly after institution, that dispute settled. While the earlier IPR was instituted, it was done so without the benefit of Patent Owner's arguments on the merits.<sup>2</sup> As explained herein, the Petition grounds are fatally flawed as a matter of fact, and as a matter of law.

In its first set of proposed grounds (Grounds 1-3), Petitioner modifies the operating principle of its capsule-release, primary reference to substitute a systemically different antimicrobial solution (pre-wetted sponge). This unfounded modification would render the entirety of the capsule-release structure superfluous. Petitioner's declarant provides no evidentiary support whatsoever for this theory. This is because, aside from hindsight reconstruction of Patent Owner's claims, there would be no reason for such an illogical modification. From there, Petitioner sets out to solve problems its irrational combination creates in the interest of meeting the Challenged Claims, but these solutions only aggravate the problems identified.

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<sup>1</sup> IPR2014-00880, challenging U.S. Patent No. 8,740,864 (the "'864 patent").

<sup>2</sup> The earlier POPR addressed only discretionary issues under 35 U.S.C. §325(d), and other procedural deficiencies on how the grounds were presented. (IPR2014-00880, Paper 11).

The second set of grounds (Grounds 4-6) fare no better than the first. Here Petitioner simply lists components and leaves it to the Patent Owner and the Board to figure out the actual combinations proposed. For the few modifications that are explained, just like Grounds 1-3, these systemic changes make no technical sense. As a starting point, Petitioner proposes to add a sponge to its capsule-based primary reference that is specifically designed to avoid absorbent materials. Its reason for doing so is that the sponge that the primary reference does not have, and seeks to avoid, may “dry out.” Even if these grounds could be followed in any logical manner, they overlook clear requirements of the claims, and rely on structure of a secondary reference that the Office has already determined does not provide such a claim feature. For at least these reasons, institution of this Petition should be denied.

## **II. THE '367 PATENT**

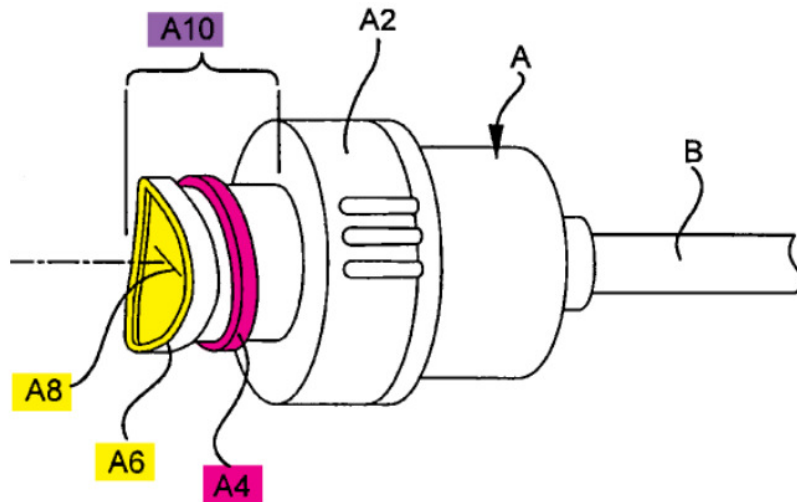
The '367 patent claims a novel solution to the problem of catheter related bloodstream infections caused by the use of Intravenous (“IV”) access valves. The claimed device is a cleaning cap for disinfecting an IV access valve (such as Luer activated valves (“LAV”)). Ex. 2002, ¶19.

In these types of access valves, the septum is the only barrier between the patient’s bloodstream and outside contaminants. Ex. 2003, 1. As typically used, the injection ports remain exposed until use. Ex. 1007, 1:61-2:3. Any septal-surface contaminants present on the septum-surface would be forced into the patient and



could trigger a potentially fatal bloodstream infection. Ex. 2003, 1. This is of particular concern when the connectors are frequently accessed and handled. *Id.*, 2. To prevent this, disinfection protocols are employed. *Id.*, 1-2; *see also* Ex. 1001, 1:19-33 (describing CDC guidelines for preventing bloodstream infections including hand hygiene, catheter site care, and admixture preparation); Ex. 1007, 2:25-3:6 (describing typical cleaning procedures followed each time the injection port is accessed and cleaned). Consistently following these multi-step procedures is, however, difficult, even for experienced medical professionals attending to a patient in an intensive care unit. *Id.* In a study accepted by the American Journal of Infection Control, 67% of the connectors cleaned with alcohol wipes still showed transmission of bacterial contaminants. Ex. 2003, 4. The '367 patent describes one way to reduce these contaminants. Ex. 2002, ¶20.

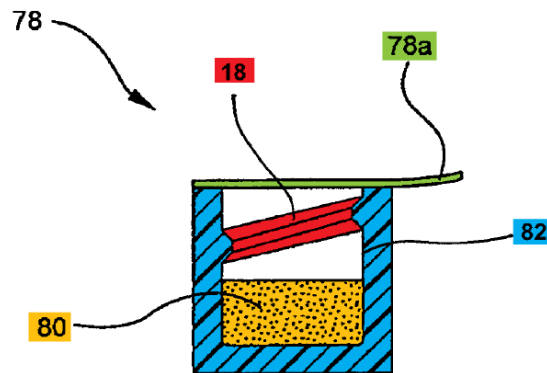
As shown in the color-annotated partial Figure 1, the patient fluid line access valve (A) has an **access portion (A10)** with an **end face** that includes a **septum (A6)**, and **external threads (A4)** on the access portion of the valve proximate the septum:



(see also Ex. 1001, 2:19-25). Cleaning of the end face is critically important because the septum of the end face provides a port for insertion of a needle or a male luer taper that would have access to a patient fluid line. (Ex. 1001, 2:52-57). Ex. 2002, ¶21.

The color-annotated Figure 10b illustrates the claimed device, which is a cleaning cap that includes **a housing**, **a wet pad (80)**, **internal threads (18)**, and **a removable lid (78a)**:

FIG. 10B



The **housing** has a cavity for covering the access portion of the access valve. (Ex. 1001, 1:50-51). The **wet pad (80)** is used to clean the access portion of a patient fluid line access valve. (Ex. 1001, 5:14-16). The **wet pad (80)** is impregnated with a cleaning agent, such as an alcohol-based solution, and optionally, an antimicrobial agent. (Ex. 1001, 3:30-51). The cap also has **internal threads (18)**, which engage external threads on the patient fluid line access valve, advancing the end face of the valve into the cavity. (Ex. 1001, 3:5-12, 5:21-24). When the **internal threads (18)** of the cap are engaged with the external threads (A4) of the access valve (A), the end face of the valve contacts the **wet pad (80)**. (Ex. 1001, Fig. 3). The contact between the pad and the end face of the access portion allows the antiseptic condition of the surface to be maintained, thereby minimizing the risk of microbes penetrating into the access valve (A). (Ex. 1001, 2:59-61, 3:16-24). The cap (78) also has a

**removable lid (78a)**, which “is typically made of foil or similar type material” and which “completely seals the opening” of the cap before use, providing a moisture barrier to maintain the wet pad and cleaning solution in the cavity, and keep them from drying out. (Ex. 1001, 2:34-38, 5:9-10). Ex. 2002, ¶22.

### **III. CLAIM CONSTRUCTION**

Terms of claims subject to IPR are to be construed according to the *Phillips* standard applied in district court. §42.100(b). Only terms necessary to resolve the controversy need to be construed. *Nidec Motor v. Zhongshan Broad Ocean Motor*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Due to the numerous technical deficiencies of the grounds discussed below, no particular claim terms need to be construed at this stage of the proceeding. Patent Owner reserves further discussion of claim construction as may be appropriate for its §42.120 Patent Owner Response if any trial is instituted.

### **IV. GROUNDS 1-3 ARE ILLOGICAL AND UNSUPPORTED**

Petitioner’s proposed Grounds 1-3 attempt to modify the capsule-release system of Menyhay with the systemically different wetted sponge solution of Genatempo. Pet., 11. Menyhay (Ex. 1007) discloses a vascular catheter cover that upon insertion and tightening of the injection port 19 operates to break a capsule 11 to release the aseptic solution contained therein. Ex. 2002, ¶¶24-26. When the capsule 11 is ruptured, the aseptic solution is absorbed by the sponge 12 in

accordance with its porosity such that the sponge bathes the septum 18 of the port in the aseptic solution. Ex. 1007, 6:67-7:3; Ex. 2002, ¶¶26-27. In this way, the sponge cleans the septum of the catheter when fully engaged (tightened to rupture the capsule 12 of aseptic solution). Ex. 1007, 7:4-6; Ex. 2002, ¶¶27, 29. Fig. 3 of Menyhay (below) depicts the arrangement when the capsule 11 is broken by projection 13 to release aseptic agent into the **sponge 12**. Ex. 2002, ¶29.

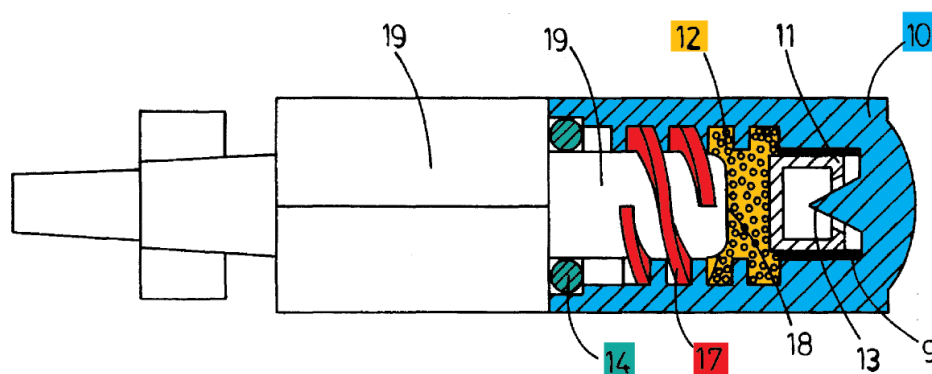


FIG. 3

Menyhay's **cover 10** does not require a sealed lid, or the added practitioner step of removing such, because aseptic solution is retained in breakable capsule 11 until ruptured. Ex. 2002, ¶33. That is, since the **sponge 12** remains dry until rupture, the **cover 10** can remain open ended. Ex. 2002, ¶¶31-34. The aseptic solution is released when the septum 18 of the port 19 applies sufficient pressure onto **sponge 12** to break capsule 11 against projection 13. Ex. 1007, 6:61-64; Ex. 2002, ¶¶25-26,

31. Once broken, the solution is absorbed by the **sponge 12** in correspondence to its designed porosity and the septum 18 of the port 19 is bathed in the aseptic fluid. Ex. 1007, 6:59-7:3; Ex. 2002, ¶¶26, 31. In clinical studies accepted by the American Journal of Infection Control, only 1.6% of the tested connectors indicated any transmission of bacterial contaminants, confirming the reliability of Menyhay's design. Ex. 2003, 4; Ex. 2002, ¶35.

Unlike Menyhay, Genatempo (Ex. 1006) does not describe an open-ended, capsule-release system, but rather a sealed, wetted sponge solution. Ex. 2002, ¶36. Fig. 3 of Genatempo (below) depicts how a portion of the **cap** is lined with **absorbent material 24** that is "filled with an antiseptic." Ex. 1006, 3:22-23; Ex. 2002, ¶36.

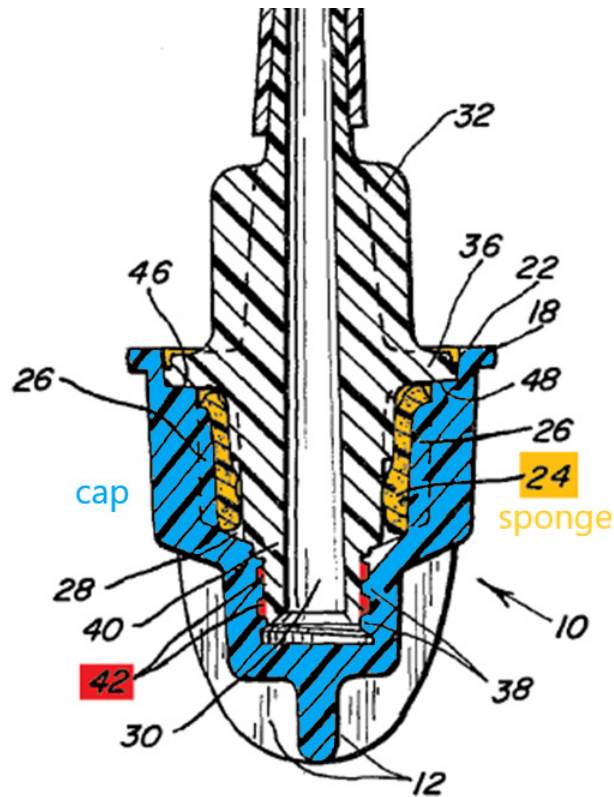


FIG. 3

When inserted, **threads 42** of the connector 32 engage with internal threads 38 of the **cap 10** after passing the **absorbent material 24**. Ex. 1006, 3:36-39; Ex. 2002, ¶38. As Fig. 3 shows, the **absorbent material 24** contacts and provides antiseptic agent to the tubular portion 40 of the connector 32. Ex. 1006, 3:40-45; Ex. 2002, ¶38. The threads 42 are also provided with antiseptic agent as the antiseptic flows downward. *Id.*

Petitioner's grounds modify Menyhay's open-ended capsule system with the **pre-wetted sponge 24** of Genatempo. According to Petitioner's declarant, a POSITA "would have known to preload [the otherwise dry] sponge 12 of Menyhay

with the antiseptic solution as suggested by Genatempo 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., 21-22 (citations omitted).

This proposed modification is driven only by a hindsight interest in meeting the claims of the '367 patent. Simply stated, Menyhay describes bathing its sponge, and selecting the absorption capacity and porosity of the sponge to ensure such bathing. Ex. 1007, 7:51-56; Ex. 2002, ¶31. To the extent the speculative problem of inconsistent bathing was an actual concern, and clinical studies accepted by the American Journal of Infection Control indicate it was not, a POSITA would have done exactly as Menyhay teaches to address such — adjust the porosity of the sponge and/or the material of the capsule. *Id.*; *see also* Ex. 2002, ¶¶42-46. To argue that instead of following the explicit teachings of Menyhay on sponge absorption and capsule properties, a POSITA would modify Menyhay to include a systemically different solution, such that Menyhay's capsule is now superfluous, is unsupported and illogical. *See In re Gardner*, 449 Fed. Appx. 914, 916 (Fed. Cir. 2011) (citing *In re Ratti*, 270 F.2d 810 (CCPA 1959)) (“[I]f a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”). Simply stated, if the sponge is already wet



with aseptic, there is no reason to provide for a capsule to provide the very same aseptic to the sponge.

Grounds 1-3 are predicated on a modification that would change the operating principle of Menyhay. This is because:

- Pre-wetting the sponge renders the capsule-release structure and design of Menyhay (*i.e.*, its operating principle) entirely superfluous; and
- Pre-wetting the sponge no longer allows Menyhay to be an open-ended, one step connection.

**A. Menyhay Provides an Open-Ended, Capsule-Release Solution**

Menyhay describes a “unique external injection port cover” that protects and sterilizes vascular injection ports. *See, e.g.*, Ex. 1007, 3:66-4:4, 4:8-11, 4:46-49, 4:50-67; Ex. 2002, ¶24. Menyhay explains that typically, injection ports remained completely uncovered and exposed, and required numerous steps to sterilize. Ex. 1007, 1:61-2:1, 2:25-3:14; Ex. 2002, ¶25. To address this problem, Menyhay provides a one-step, breakable capsule containing sterilization agents, and a projection that breaks the capsule when an appropriately firm and absorbent sponge applies sufficient pressure to rupture the capsule against the projection. Ex. 1007, 4:8-19, 6:50-52; Pet., 12-13; Ex. 2002, ¶¶25-26. Menyhay states that the capsule can be formed of acrylic or another thin-layered brittle plastic that ruptures under nominal pressure, but “should not be made of glass.” Ex. 1007, 7:47-51; Ex. 2002,

¶30. A **sponge 12** is included in the cover that is specifically selected to have an absorption capacity “roughly equal to or slightly less than the volume of the fluid contained in the capsule” while being “firm enough to transmit pressure to the capsule” placed between the projection 13 and the flat face of a septum 18. Ex. 1007, 7:51-56 (emphasis added); Ex. 2002, ¶¶26-27. Fig. 3 of Menyhay depicts the **cover 10** tightly screwed onto the port 19 and after the capsule 11 has ruptured.

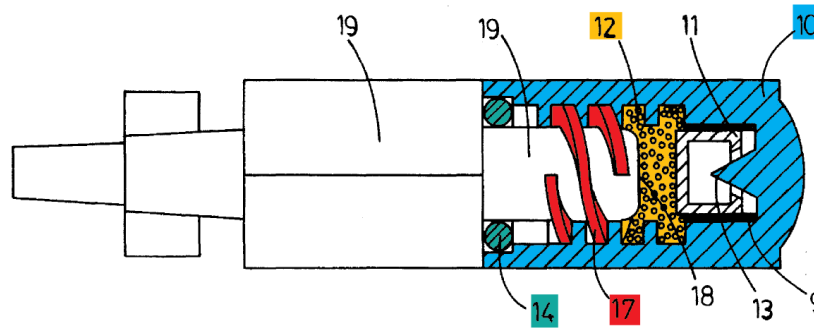


FIG. 3

With these features, Menyhay’s vascular catheter cover can both protect and sterilize critical surfaces including the flat face of the septum 18. Ex. 2002, ¶33. Because the flat septum 18 of the port 19 is contacting the **sponge 12** that is infused with aseptic agents, the flat septum 18 is cleaned of contaminants as the Menyhay cover is tightened. Ex. 2002, ¶¶27-29. By retaining the aseptic solution in the capsule 11, the Menyhay cover can remain open-ended as there is no danger of the aseptic evaporating, spilling, or becoming contaminated. Ex. 2002, ¶32. Since a lid

is not necessary to retain the aseptic, Menyhay's cover can protect the port septum from the elements and prevent the latex of the port septum from degrading or being contaminated. *See* Ex. 1007, 1:61-2:10; Ex. 2002, ¶¶32-33. And as Menyhay explains, this open-ended design avoids the need to perform a time-consuming cleaning procedure consisting of eighteen steps and involving two medical professionals. *See* Ex. 1007, 2:25-3:6 (describing typical cleaning procedures followed each time the injection port is accessed and cleaned); Ex. 2002, ¶34. Menyhay replaced an eighteen step process with a **one-step**, capsule release connection. *Id.*

In addition, capsule based designs provide haptic feedback and audible confirmation of when the aseptic liquid is released as the capsule fractures. Manufacturing a cap without a lid is also simpler because there is no need to develop and validate that the lid is providing an airtight seal. *Id.*

**B. Petitioner Proposes Changing the Operating Principle of Menyhay to Render its Capsule Superfluous**

Petitioner proposes modifying Menyhay so that its sponge is pre-wetted like Genatempo's pre-wetted sponge. Pet., 22-23. But, the purpose of Menyhay's capsule 11 is to "releas[e] the antiseptic agents inside to be soaked up by sponge 12." Ex. 1007, 6:61-64. Projection 13 is immediately adjacent to the capsule 11 and serves to break the capsule under nominal pressure. *Id.*, 6:45-46, 7:47-51. These

features have no other purpose than to break the capsule and wet the otherwise dry sponge. Ex. 2002, ¶41.

Petitioner and its declarant do not address why Menyhay's capsule or structures for rupturing the capsule such as projection 13 would still be needed in the resulting device that includes pre-wetted sponge. Ex. 2002, ¶¶41-42. Petitioner's proposed modification renders Menyhay's capsule-release structure superfluous as it serves no other purpose but to wet the sponge. *Id.* Petitioner, after introducing a wet sponge in place of a dry one, argues that the pre-wetted sponge would dry out prior to use. It then relies upon this manufactured problem to introduce a lid to Menyhay where the capsule structure avoids that extra structure and connection step (*i.e.*, lid removal). *See Plas-Pak Indus. Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 757-59 (Fed. Cir. 2015) ("combinations that change the basic principles under which the prior art was designed to operate or that render the prior art inoperable for its intended purpose may fail to support a conclusion of obviousness") (internal citations and quotations omitted).

**1. Petitioner's Unsupported Declarant Testimony Regarding the Modification is Inconsistent and Ignores the Evidence**

Petitioner's declarant alleges, without evidentiary support, that certain advantages arise from modifying Menyhay in this illogical manner. He first hypothesizes, without evidentiary support of any kind, that Menyhay's sponge may

be partially wet and partially dry because Menyhay's capsule fails to break. Ex. 1002, ¶¶75-76; Ex. 2002, ¶¶44-45. As explained below, there is no evidence in the record that such a problem exists. Rather, the efficacy of Menyhay was touted in clinical studies accepted by the American Journal of Infection Control. Ex. 2002, ¶35. Further, even if such problems could be argued to exist, and they do not, the "obvious" way to address them would be to refine the capsule release structures as suggested by Menyhay, not abandon them in favor of a systemically different solution. Ex. 2002, ¶¶43-46.

The Petitioner's declarant picks and chooses the aspects of Menyhay that he finds subject to failure. On the one hand he argues the Menyhay sponge may have dry spots upon capsule release, but on the other, he credits the capsule release structure as releasing excess antiseptic fluid to flow upward, away from the sponge (due to compression of the sponge) along the channels of the threading to meet other aspects of the claim. Ex. 1002, ¶77. This internally inconsistent testimony is entitled to little, if any, weight. *Bungie, Inc. v. Worlds Inc.*, IPR2015-01268, Paper 44 at 54 (PTAB Nov. 30, 2016) (citing *In re Am. Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004)) (finding a declarant's "inconsistent and unsupported testimony, which contradicts other record evidence, unpersuasive."); *see also* 37 C.F.R. §42.65(a).

**C. Petitioner Ignores Menyhay’s Teachings on Calibrating Sponge & Capsule Characteristics**

Petitioner’s “dry sponge” theory fails to explain why the implementation details of Menyhay’s capsule and sponge structures would be abandoned in favor of its radical departure that would add a pre-wet sponge. Ex. 2002, ¶¶43-46. Very little weight should be accorded to a Petitioner’s declarant’s statements that ignore the disclosures of the prior art. *See Fisher & Paykel Healthcare Ltd. v. Resmed Ltd.*, IPR2017-00501, Paper 41 at 48 (PTAB Oct. 23, 2018) (giving very little weight to testimony failing to address express disclosures in the prior art).

Petitioner speculates that it is possible “the capsule of *Menyhay* fails to break sufficiently to wet sponge 12,” resulting in dry spots. Pet., 22 (citing Ex. 1002, ¶¶75-76). Petitioner’s expert does not identify any evidence that substantiates this failure mode in Menyhay’s device. *See* Ex. 1002, ¶¶75-77; Ex. 2002, ¶¶43-45; *see also TQ Delta, LLC v. Cisco Systems, Inc.*, 942 F.3d 1352, 1358 (Fed. Cir. 2019) (“Conclusory expert testimony does not qualify as substantial evidence”) (citations omitted). Indeed, the literature, as evidenced by a study accepted by the American Journal of Infection Control, confirms Menyhay’s solution was found to be reliable and effective. Ex. 2003, 4; Ex. 2002, ¶35.

Just two paragraphs after alleging sponge dryness is a concern, Petitioner’s declarant contradicts himself when stating Menyhay’s sponge would release excess

aseptic liquid “that will flow along the channels of the threading.” *Compare* Ex. 1002, ¶75 (“the [Menyhay] sponge may be partially wet and partially dry when it comes in contact with the connector face”) *with id.*, ¶77 (“the [Menyhay] sponge will compress, releasing stored antiseptic liquid that will flow along the channels of the threading”). Petitioner’s declarant does not explain how this excess stored antiseptic liquid could exist in the sponge he alleges is partially dry. *Id.* These illogical positions cannot be reconciled.

Petitioner then proceeds to argue that the threads would need further cleaning, alleging that patient safety would be improved by applying Genatempo’s teachings of “additional disinfection of the exposed surfaces.” Pet., 22-23 (citing Ex. 1002, ¶¶75-78). Petitioner appears to be referring to Genatempo’s discussion regarding the cleaning of threading of the connector. Ex. 1002, ¶78. But this alleged benefit is already provided in Menyhay. Petitioner’s expert agrees. He inconsistently argues this very benefit just *one paragraph prior*. That is, in Menyhay’s device, “stored antiseptic liquid that will flow along the channels of the threading.” *Id.*, ¶77. As such, it is unclear what the Petitioner is arguing with respect to “additional disinfection.”

Petitioner’s declarant also ignores Menyhay’s express disclosure that the sponge has “an absorption capacity roughly equal to or *slightly less* than the volume of fluid contained in the capsule.” Ex. 1007, 7:51-56 (emphasis added); Ex. 2002,

¶46. No explanation has been offered as to how a POSITA would understand this relationship to provide for any part of the sponge being partially dry upon release of the aseptic solution from the capsule. *Id.*

### **1. Menyhay Teaches a Range of Capsule Materials**

Petitioner alleges a benefit of its proposed modification is that dry spots would be avoided “in the event that the capsule of Menyhay fails to break sufficiently to wet sponge 12.” Pet., 22 (citing Ex. 1002, ¶¶75-76). But the cited portions of Petitioner’s expert’s declaration fail to acknowledge the teachings of Menyhay on capsule construction—for example, why such an alleged issue could not be solved as suggested by Menyhay.

Petitioner’s declarant ignores Menyhay’s express identification of capsule materials that “break sufficiently.” Menyhay discloses acrylic as an example of a brittle plastic from which the thin-layered capsule can be formed. Ex. 1007, 7:47-51; Ex. 2002, ¶¶44-45. Clinical studies confirm Menyhay’s device is reliable. Ex. 2003, 4; Ex. 2002, ¶35. Petitioner offers no evidence to the contrary because it cannot. As such, Petitioner’s unsupported speculation of possible benefits cannot be considered as evidence. *Arris Int’l PLC v. Sony Corp.*, IPR2016-00828, Paper 10 at 16-17 (PTAB Oct. 7, 2016) (giving “very little weight” to a declarant’s testimony regarding alleged benefits when the prior art already provides a different solution to the same alleged problem); *see also TQ Delta*, 942 F.3d at 1358



(“Conclusory expert testimony does not qualify as substantial evidence”) (citations omitted).

## **2. Menyhay Teaches Adjusting Absorption Capacities**

Even if Petitioner’s allegation that the Menyhay sponge may not be fully wetted were supported, instead of entirely changing how Menyhay operates, a POSITA would have adjusted the absorption capacity of the sponge so that less aseptic solution is needed to fully wet the sponge. Ex. 2002, ¶¶43, 46. Menyhay discloses how the absorption capacity may be “roughly equal to or slightly less than the volume of fluid contained in the capsule.” Ex. 1007, 7:51-54; Ex. 2002, ¶46.

A POSITA would have had no reason to entirely change Menyhay’s principle of operation when such a solution to possible partial wetting of the sponge is taught. Ex. 2002, ¶¶46. Instead, a POSITA would have noted the suggestion by Menyhay that a smaller absorption capacity may be desirable and made an appropriate adjustment. *Id.* Petitioner offers no explanation as to why a POSITA would not have recalibrated these aspects of Menyhay before jumping to Petitioner’s illogical and systemic redesign. In addition, the time required to obtain the approvals needed to market a systemically redesigned device would have further discouraged a POSITA from implementing Petitioner’s proposed modification.

**D. Even If Changing Menyhay’s Principle of Operation, the Combination Lacks a Reasonable Expectation of Success**

By applying Genatempo’s teachings of a pre-wetted sponge to Menyhay as Petitioner proposes, several factors that Menyhay expressly describes are changed. Menyhay specifies its dry sponge should be “firm enough to transmit pressure to the capsule.” Ex. 1007, 7:54-56. Menyhay states this should be a “nominal pressure.” *Id.*, 7:47-51. But pre-wetting the sponge as Petitioner proposes would change the sponge’s firmness and prevent the capsule from breaking reliably. Ex. 2002, ¶47. Pre-wetting the sponge unnecessarily complicates the system by allowing the sponge to collapse before sufficient force is applied to the capsule. *Id.* This would make the resulting system less reliable and predictable, and hinder translation of the hub and thus the breaking of the capsule. *Id.* As such, Petitioner’s proposed modification aggravates the very problem it is trying to solve with respect to capsule breakage. *Id.*

Petitioner’s expert fails to address this concern of the proposed modification. *See generally*, Ex. 1002. When describing the “resulting combination,” there is no mention of how the wet sponge would still be sufficiently firm to break the capsule. *Id.*, ¶79. Petitioner does not explain how much aseptic solution should be retained in the capsule now that, in the modified device, the sponge is pre-wetted—or, for that matter, what porosity of sponge is required. This is probably because this

discussion would highlight the illogic of competing solutions, and the fact that the operating principle of Menyhay has now been changed. Ex. 2002, ¶¶41-42. Excess fluid would leak from the cap and cause patient discomfort. *See, e.g.*, Ex. 1010, [0066] (“The connector and cap therefore do not create a mess and do not make the user/patient perform special handling in order not to spill the disinfectant contained therein.”); Ex. 2002, ¶¶48-49. Spillage of excess fluid when the cap is unassembled is also possible. Ex. 2002, ¶¶48-49. This excess solution may also interfere with the interfaces between the cap and the connector due to the solution’s incompressibility and contribute to incomplete fractures of the capsule. *Id.* The excess solution could also cause suction between different components, making it difficult to separate the cap and connector. *Id.* It is also possible the aseptic solution may contact components of the catheter that are not as compatible with the aseptic solution, resulting in modified physical properties and causing possible part failure. *Id.*; *see also* Ex. 2004.

Given the Petitioner has studiously avoided any discussion of these issues, there can be no reasonable expectation of success. *See In re O’Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988) (holding a reasonable expectation of success is required for obviousness) (citations omitted).

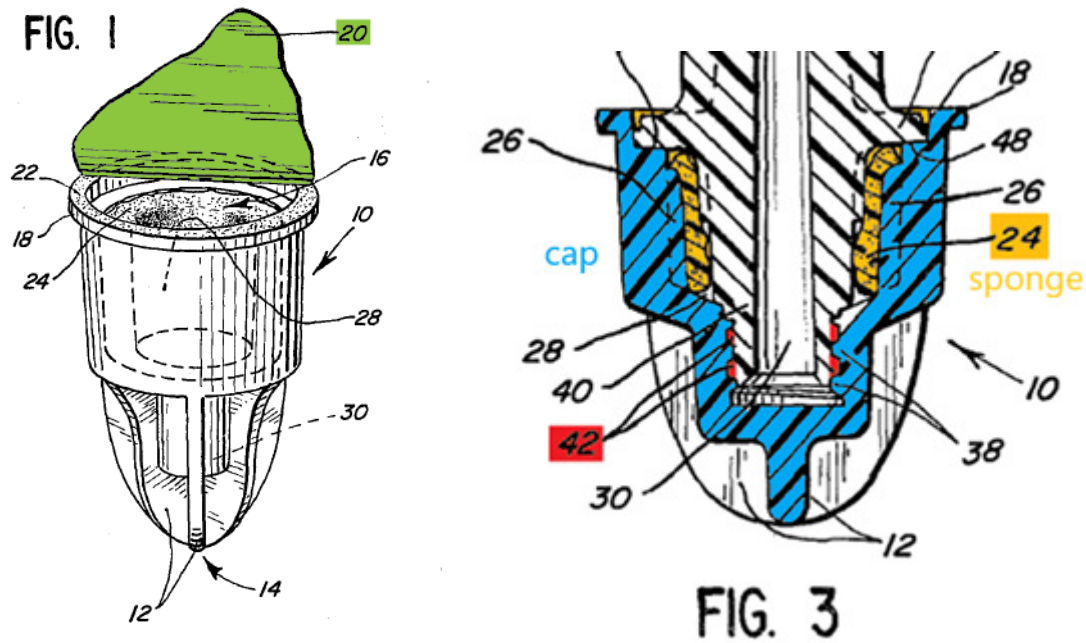
**E. Petitioner Adds a Lid to Menyhay's Open-Ended Solution to Remedy a Problem its Combination Creates**

In addition to changing Menyhay's operating principle (capsule-release) by rendering the capsule entirely superfluous, Petitioner urges adding a lid as taught from Genatempo along with the preparation step of peeling away a lid in its combination. Pet., 23. But Petitioner admits the only reason to perform this further modification is a *result* of its proposed combination. Pet., 23 (citing Ex. 1002, ¶¶76, 79). This additional modification is evidence of the non-obviousness of Petitioner's proposal. *See Fox Factor, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 59 at 20 (PTAB, April 2, 2018) (finding "the accumulating number of apparently necessary changes suggests that the modifications may not have been as simple and routine as [Petitioner's expert] implies"). Adding an extra step where the focus is to reduce practitioner roles relative to sterile ports is the antithesis of obviousness. *See* Ex. 1007, 3:7-65.

**1. Genatempo's Pre-Wetted Sponge Necessitates the Lid**

Genatempo is a peritoneal dialysis catheter cap that uses a systemically different solution to capsule release solutions. Genatempo's cap contains an aseptically impregnated (*i.e.*, pre-wetted) **absorbent material 24**. Ex. 1006, Fig. 3; Pet., 29-30, 35; Ex. 2002, ¶36. Prior to use, a **peelable lid 20** is removed from Genatempo's cap 10. Ex. 2002, ¶37. The **peelable lid 20** serves to reduce the

evaporation of the antibacterial agent retained in the **absorbent material 24**. *Id.*, 3:1-5; Ex. 2002, ¶37.



As the excerpt of Fig. 3 of Genatempo shows, when the port 32 is inserted into the cap 10, **pre-wetted absorbent material 24** is arranged along the tubular sides of the port 32. *Id.*, 3:30-51, Fig. 3; Ex. 2002, ¶38. Genatempo explains that any antibacterial effect from the **pre-wetted material 24** that is provided to threads 42 would occur through migration of the antiseptic. *Id.*

Petitioner admits there would be a “need to modify the configuration to include a lid or seal” as a *result* of its proposed application of Genatempo’s teachings to Menyhay’s device. Pet., 23 (citing Ex. 1002, ¶¶76, 79). Petitioner’s expert attempts to justify this by alleging the lid would prevent the spilling or contamination

of the solution prior to use. Ex. 1002, ¶79. But none of these alleged problems would even exist *but for* Petitioner's illogical modification of Menyhay. Ex. 2002, ¶50.

Menyhay encases the aseptic solution in a breakable capsule, eliminating the possibility of evaporation, spillage, or contamination. Ex. 1007, 7:51:56; Ex. 2002, ¶¶30, 32, 33, 50. Only through the introduction of a pre-wetted sponge, as suggested by Petitioner, can there be evaporation, spillage or contamination of aseptic fluid. Ex. 2002, ¶50. This argument only serves to highlight the benefit of Menyhay's open-ended capsule release solution, and the systemically different solutions of Menyhay and Genatempo. Ex. 2002, ¶¶50-52.

## **2. Genatempo's Lid Complicates Usage**

One reason Menyhay's capsule-based solution was developed was to address the intricate cleaning procedures that would be followed by two medical professionals. *See* Ex. 1007, 2:25-3:6; Ex. 2002, ¶51. As Menyhay explains, two medical professionals are needed to ensure a sterile environment because the outsides of packages containing iodine and alcohol swabs are not sterile. Ex. 1007, 2:16-20; Ex. 2002, ¶¶51-52. Consequently, the second person opens the packages for the first person to remove the contents. Ex. 1007, 2:20-24; Ex. 2002, ¶¶51-52. Menyhay's cap simplifies this procedure to a one-step process that can be executed by anyone, including the patients themselves. Ex. 1007, 4:46-49; Ex. 2002, ¶¶51-

52. Including a lid also requires additional time to implement due to the need to determine and validate the optimum bonding parameters for the medical device. Ex. 2002, ¶¶51-52; Ex. 2005.

By further modifying Menyhay to include Genatempo's lid, Petitioner adds a step to a simple one-step process. *Id.* In addition, by necessitating the removal of the peelable lid, the added step reintroduces the possibility of contamination that Menyhay's design sought to reduce. *See* Ex. 1007, 2:16-24; Ex. 2002, ¶¶51-52. The relatively small size of the cap and the need to remove a lid of such a small device is an additional burden in a high-stress environment. Ex. 2002, ¶¶51-52; *see also* Ex. 1010, [0066] ("The connector and cap therefore do not create a mess and do not make the user/patient perform *special handling* in order not to spill the disinfectant contained therein.") (emphasis added).

#### **F. Grounds 1-3 Fail**

Petitioner's proposed modification of Menyhay would changes the operating principle of Menyhay to render its capsule-release superfluous, and omit its one-step, open-ended structure. Such a change can only be motivated by hindsight reconstruction to meet the claims of the '367 patent. To the extent the Menyhay solution was unreliable, and there is no evidence demonstrating such, a POSITA would adjust the sponge porosity as Menyhay teaches, not opt for a competing solution such as Genatempo that would render its structure unnecessary in the first

instance. Moreover, even if modified as suggested, the changed properties of the wetted sponge may actually lead to further problems breaking the capsule, the very straw-man problem that the Petitioner argues drives its use of such an arrangement in the first instance. Finally, by its own admission, Petitioner's proposed modification relies upon motivations that are necessitated only by its illogical modifications.

Petitioner has failed to offer *any* evidence regarding Menyhay's modified operating principle, why Menyhay's explicit teaching of adjusting capsule and sponge characteristics is completely ignored, or how its suggested solution would overcome the significant, additional drawbacks/problems it introduces. As Petitioner's evidence stands alone on these fundamental issues, there can be no factual dispute to construe in Petitioner's favor. As such, the preliminary proceeding should be resolved in favor of Patent Owner, and institution denied. *See BASF Corp. v. Ingevity South Carolina LLC*, IPR2019-00202, Paper 13 at 6 (PTAB Oct. 17, 2019) (“[37 C.F.R. §42.108(c)] only applies to *disputed* issues of material fact, and does not simply require us to accept every bare assertion made in a Petition.”) (emphasis original). Petitioner has failed to demonstrate a reasonable likelihood of prevailing on base claims 1, 9, and 14, and at least by virtue of dependency, any claim depending therefrom.



## V. GROUNDS 4-6 ARE INCOMPLETE

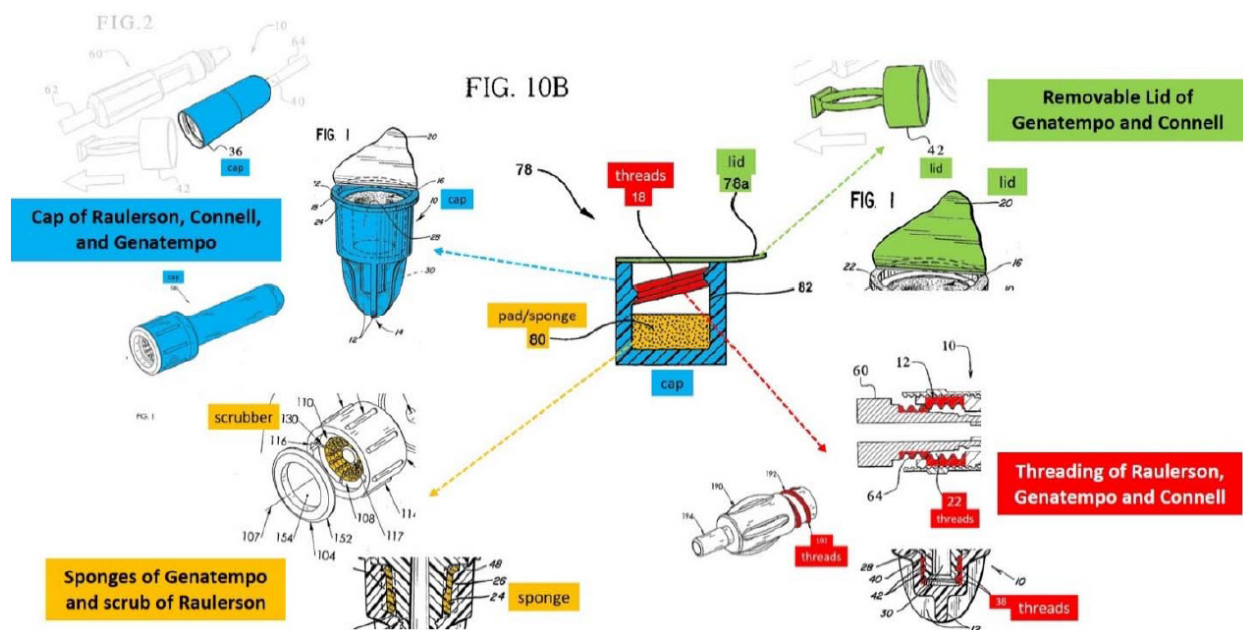
Petitioner hopes to convince the Board that if individual patent claim elements can be demonstrated as old, any claimed *combinations* of those elements may be considered obvious. But, a proper obviousness showing requires far more. The Federal Circuit has soundly rejected such piecemeal obviousness analyses since its inception:

That all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is however, simply irrelevant. Virtually all inventions are combinations and virtually all are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art.

*Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983).

Petitioner's proposed combinations of art fail to show that the claimed inventions would have been obvious to one of ordinary skill in the art.

Further, Petitioner's rationale for its proposed combinations falls well short of the "convincing line of reasoning" necessary to support its proposed, and often systemically inconsistent changes. (*See* MPEP §2144(I)-(II).) Petitioner's proposed combinations are shown in its parts-list info graphic below:



(Pet. 57-58). Thus, while individual elements of the claims may be found in the art, Petitioner fails to demonstrate why one of ordinary skill would have arrived at the claimed arrangements of the '367 patent. Petitioner's rationale appears to be that since the parts existed, any combination of them is obvious. But Petitioner bears the burden of providing a coherent ground and an articulable rationale for modifying the references as proposed. Ex. 2002, ¶¶53-54.

For the few modifications that are explained, the proposed combinations require altering the operating principle of the primary reference. Petitioner proposes to add a sponge to its capsule-release primary reference that is specifically designed to avoid absorbent materials. (Ex. 1010, [0053] (explaining an "advantage of the present invention is to provide a cap for use... that... does not require an absorbent material to hold the disinfectant"). Petitioner's reason for making this modification

is that the sponge that the primary reference does not have, and seeks to avoid, may “dry out.” These grounds, like those discussed above, are illogical.

Even if the proposed combinations could be followed in any logical manner, they overlook clear requirements of the claims. Grounds 4-6 fail for not disclosing or suggesting, alone or in combination, a sponge of any kind against the end face of a connector, let alone a specific type of connector, as required by the claim limitation “contact[ing] the wet pad with the distalmost end face of the access portion of the patient fluid line access valve.”

Even if Petitioner’s arguments could be accepted, they urge a technical issue relative to the Genatempo reference that was explicitly rejected by the examiner during prosecution of both the parent ’864 patent and the ’367 patent. Accordingly, Grounds 4-6 should be additionally denied under § 325(d) for presenting the same prior art arguments previously presented to the Office. *See Becton, Dickinson, and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17 (PTAB, Dec. 15, 2017) (precedential).

**A. Petitioner’s Proposed Combinations of Connell, Raulerson, and Genatempo Are Ambiguous.**

Petitioner explains little with respect to Grounds 4-6 other than providing the above parts-list, info-graphic of references—Connell, Raulerson, and Genatempo.

(Pet. 57-58). As shown in Petitioner's parts-list, Grounds 4-6 all modify the cap, threading, and removable lid of Connell, with the cap, threading, and scrub of Raulerson, and further with the cap, threading, sponges, and removable lid of Genatempo. (*Id.*); Ex. 2002, ¶¶65-66.

Petitioner fails to provide articulable rationales for many of its proposed modifications, for example, what structure it is taking from which reference, and where and how to modify the base references. For example, as shown in the parts-list, Petitioner relies on the threading from all three references. In this regard, it is unclear where the combined system would begin or end. It is also unclear where the threads would be located relative to the cap, for example, whether the threads would be located closer to the opening of the cap as disclosed in Connell, or closer to the inside bottom of the cap as disclosed in Genatempo. (Pet. 57-58). As another example, Petitioner seeks to adopt "sponges of Genatempo" in its proposed combinations. But other than stating that the sponges are wet and impregnated with an antiseptic cleaning solution, it does not explain where the sponges would be positioned in its proposed combination. (Pet. 57-58); Ex. 2002, ¶¶67-68. Because Petitioner leaves its proposed combinations ambiguous, the Board should resolve these ambiguities in favor of Patent Owner as to all grounds. *Adaptics Ltd. v. Perfect Co.*, IPR2018-01596, at 15-24 (PTAB March 6, 2019) (Paper 20) (denying

institution because Petitioner's grounds suffer from a lack of particularity and indefinite scope under 35 U.S.C. § 312(a)(3)).

Grounds 4-6 should be rejected for lacking the required specificity. Patent Owner is left guessing as to Petitioner's arguments. Ex. 2002, ¶69.

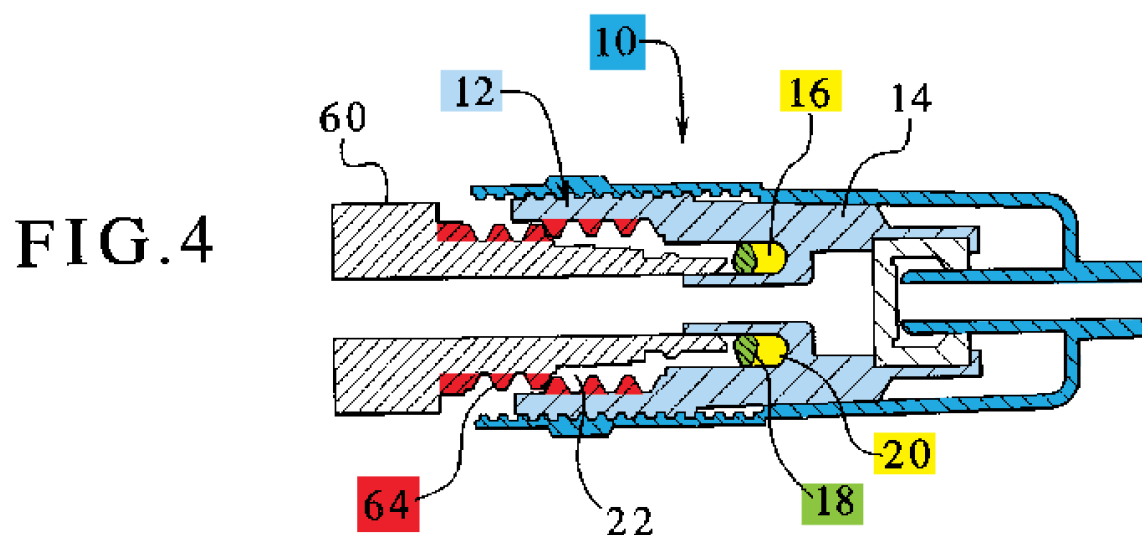
**1. Connell Provides a Capsule-Release Design.**

Connell describes a connector cap that “easily and readily attaches to a dialysate container and a catheter inserted into a patient's peritoneal cavity.” (Ex. 1010, Abstract). The connector cap has disinfectant in a capsule (*i.e.*, a sealed receptacle) that is not released until it is ready to be used to clean a connector. Ex. 2002, ¶55.

The operating principle of Connell is its capsule-release design, thereby avoiding the mess of sponge-based systems. Specifically, such design does not “create a mess” or “make the user/patient perform special handling in order not to spill the disinfectant.” (Ex. 1010, [0066]). Connell also states that the advantage of its capsule-release design is that it “does not require an absorbent material to hold the disinfectant.” (Ex. 1010, [0053]). With this design, Connell explains that its connector cap provides “a safe and easy connection” for “introducing a disinfectant for a user/patient.” (Ex. 1010, [0066]). Ex. 2002, ¶57.

As shown in color-annotated Figure 4 below, the connector cap (10) includes a **shell** that encloses a **cap (12)**. The **cap (12)** includes a disinfectant receptacle (16)

that houses the **disinfectant (20)**. (Ex. 1010, [0016], [0071]). A **seal (18)** is also included to cap off the receptacle (16). (Ex. 1010, [0071]). The connector cap (10) has **internal threads (22)** that can mate with the **external threads (64)** of connector (60). (Ex. 1010, [0100]). Ex. 2002, ¶55.



In operation, the connector (60) is inserted into the connector cap (10) by engaging the **threads (22) and (64)** together, such that the ends of the connector (60) would press against the **seal (18)** causing it to move or rupture, thereby releasing the **disinfectant (20)**. The **disinfectant (20)** would then run out to clean the **external threads (64)** of the connector (60). (Ex. 1010, [0101]). Ex. 2002, ¶56.

## 2. Raulerson Employs a Scrubber to Clean the External Threads of a Luer Connector.

Raulerson teaches a luer cleaner having a circular scrubber to clean a luer connector by rotating the luer cleaner about the luer connector to dislodge any debris on the luer connector. (Ex. 1011, [0004]). Figure 1 illustrates a **luer cleaner (100)**

that uses a scrubber for cleaning the **external threads (192)** of a luer connector (190):

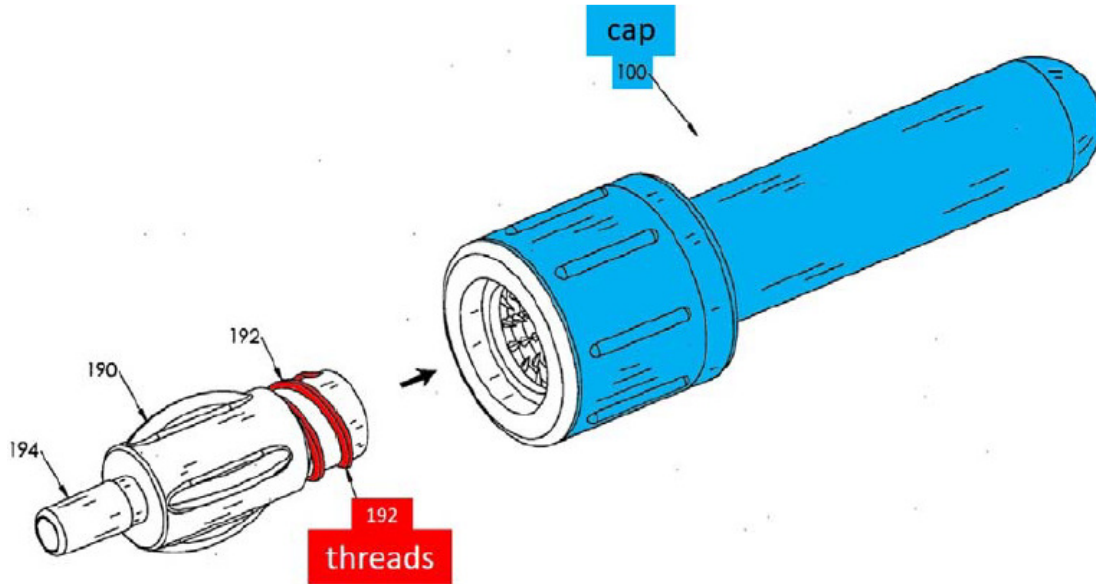


FIG. 1

(Petitioner's annotated Figure 1). Ex. 2002, ¶58. As depicted in color-annotated Figure 3 of Raulerson below, the luer cleaner (100) includes a scrubber (130) having "bristles 134." The bristles (134) of the scrubber (130) line the inner side walls of the luer cleaner (100). When a luer connector (190) is inserted onto the center guide member (117) of the luer cleaner (100), only the side surfaces (where the external threads are located), and not the end surface, of the luer connector (190) would be in contact with the bristles (134) of the scrubber (13). (Ex. 1011, [0021]). Ex. 2002, ¶59.

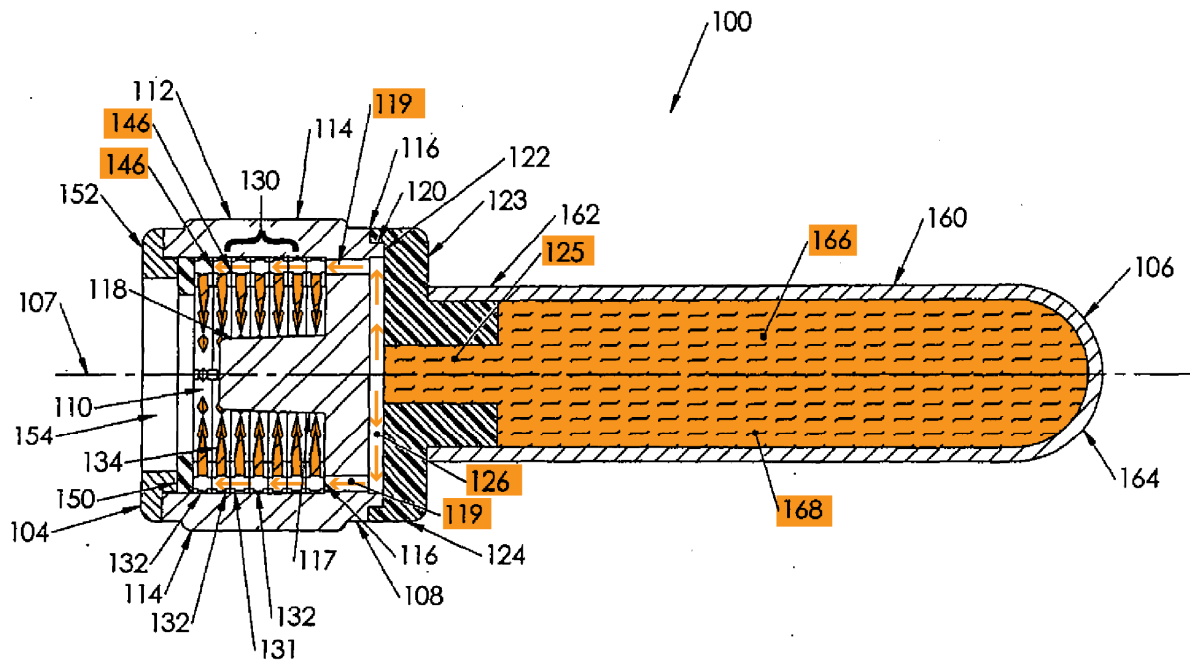


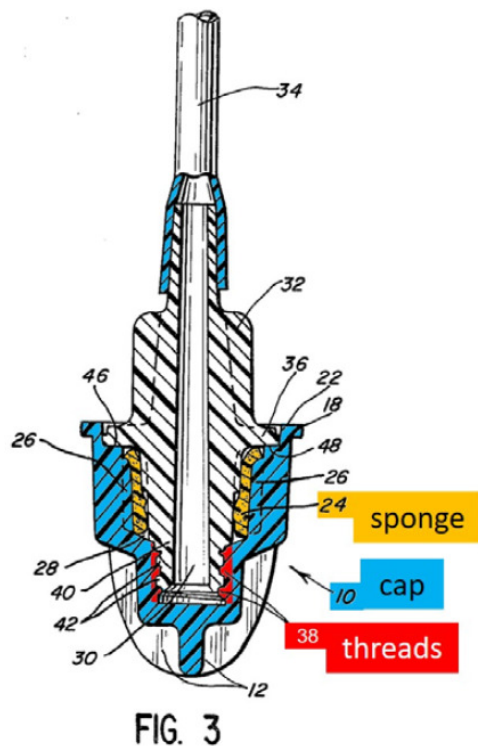
FIG. 3

Raulerson further teaches the use of a large reservoir (166) of antiseptic fluid (168), and discloses multiple passages (*e.g.*, connecting passage 125, circular throughway 126, passage 119, radial passage 146, etc.) that allow the fluid to flow to the scrubber, as shown in the color-annotated Figure 3 above. (Ex. 1011, [0028], [0031]). There is no barrier that separates the disinfectants in the reservoir (166) and the body of the luer cleaner (108). (Ex. 1011, Fig. 3, [0031]). In operation, the reservoir is compressed, forcing the fluid from the reservoir into the passages, and leading the fluid to the scrubber (130) for cleaning the luer connector (190). (*Id.*); Ex. 2002, ¶60.



### 3. Genatempo Employs Sponges on the Inner Sidewalls of a Cap.

As discussed above, Genatempo is a peritoneal dialysis catheter cap that utilizes a pre-wetted sponge to a connector. Ex. 2002, ¶61. As shown in Figure 3, the **cap (10)** includes an **absorbent material (24)** and inner threads (42):



(Petitioner's annotated Figure 3). The **absorbent material (24)** is located closer to the opening of the **cap (10)**; and the internal threads (42) are located near the closed end of the **cap (10)**. In operation to clean a connector (32), the internal threads (42) of the **cap (10)** are engaged with the **threads (38)** of the connector (32). When the threads are engaged, Genatempo discloses that **absorbent material (24)** contacts the main tubular member 40 of the connector 32. (Ex. 1006, 3:43-45). Figure 3

does not show any contact between the **absorbent material (24)** and the end face (*i.e.* the bottom surface) of the connector (32). Figure 3 also does not show any gap between the end face of the connector (32) and the inside bottom of the **cap (10)**. Ex. 2002, ¶¶62-64.

In its proposed combinations, Petitioner relies on Connell's cap for providing sealed disinfectant to clean the threading of a connector. (Pet. 55 (*citing* Ex. 1010 ¶¶101-103)). Petitioner also relies on Connell for disclosing that the cap "threadingly mates" with the connector and "the threading advancement of the cap onto the connector." (*Id.*) Petitioner argues that a POSITA would have been motivated to modify Connell's cap with Raulerson for its teaching of a scrubbing mechanism that would ensure "sufficient distribution of a liquid cleaner on all surfaces" for better cleaning on the threading, and the end face, of the connector. (Pet. 56 (*citing* Ex. 1011, ¶4), 65-66 (*citing* Ex. 1011, ¶¶4, 31)). Petitioner also argues that a POSITA would further "adopt[] the pre-impregnated sponge of Genatempo" in its combinations such that "when the sponge is compressed, [it would] release liquid to flow throughout the threading portions of the coupling." (Pet. 56-57). Petitioner argues that the adoption of the pre-impregnated sponge of *Genatempo* in the combinations would provide the benefit of "sufficient wetting of the sponge in advance" to ensure there would be "no dry spots or other infirmities associated with a failure to break a seal." (Pet. 56-57 (*citing* Ex. 1006, 3:43-45)).

**B. Petitioner's Proposed Modifications Would Change Connell's Operating Principle Specifically Designed to Avoid Sponges**

Petitioner argues that a POSITA would “adopt[] the pre-impregnated sponge of Genatempo” in its combinations to modify Connell’s cap for the benefit of “sufficient wetting of the sponge in advance” to ensure there would be “no dry spots or other infirmities associated with a failure to break a seal.” (Pet. 56). However, such proposed modifications would alter the operating principle in Connell. Ex. 2002, ¶70.

A POSITA would not have been motivated to add a sponge taught in Genatempo to improve Connell’s cap. Connell is a capsule-release design, just like Menyhay. As explained in Grounds 1-3 above, adding a sponge to a capsule-release design renders it superfluous. For example, Petitioner argues that adopting Genatempo’s sponge would ensure “sufficient wetting of the sponge in advance.” (Pet. 56). But Connell does not rely on any sponge for cleaning because the operating principle is to release the disinfectant from the sealed receptacle, allowing it to run through and clean the external threads of the connector. (Ex. 1010, [0101]); Ex. 2002, ¶71.

In fact, Connell explains that not having a sponge is an advantage. Specifically, it states that the “advantage of the present invention is to provide a cap... that... does not require an absorbent material to hold the disinfectant.” (Ex.

1010, [0053]). Connell explains that the use of “absorbent material with disinfectant” was attempted in prior art, but “[a] need still exists however to improve the efficiency, effectiveness and cost of providing sterile connections...” (Ex. 1010, [0012]) Connell also implies that the sponge-based design is messy. (Ex. 1010, [0066] (explaining that its own design does not “create a mess” or “make the user/patient perform special handling in order not to spill the disinfectant.”)). Adopting the “absorbent material, such as that of *Genatempo*” (Pet. 56), as proposed by Petitioner would change Connell’s operating principle of releasing disinfectant from a sealed receptacle to clean a connector. *See Plas-Pak Indus. Inc.*, 600 F. App’x at 757-59. Adding a sponge would also teach away from the stated advantage of Connell’s cap for not needing to use a sponge. *See Millennium Pharm., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1366-67 (Fed. Cir. 2017) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.”). Ex. 2002, ¶72.

Petitioner further argues that “[b]y 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.” (Pet. 56-57) (emphasis added). But, Connell already does exactly that—breaking the seal on the receptacle to release its

disinfectant to spread all over the threads of a connector. (Ex. 1010, *Abstract*, [0055], [0101]). Petitioner has not explained why Connell's solution is insufficient and why it needs to be altered. The fact that something "can" be done does not mean that it is "obvious." *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("obviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention"). The mere ability to modify or replace the sponge to provide for more liquid for the same benefit would not render the claimed feature obvious. *See Arris*, IPR2016-00828, Paper 10 at 16-17 (giving "very little weight" to a declarant's testimony regarding alleged benefits when the prior art already provides a different solution to the same problem).

Because Petitioner has presented no evidence on this point, there is no genuine issue of material fact as to Connell's operating principles that would warrant a finding of facts in Petitioner's favor. *See BASF Corp.*, IPR2019-00202, Paper 13 at 6 ("[37 C.F.R. §42.108(c)] only applies to *disputed* issues of material fact, and does not simply require us to accept every bare assertion made in a Petition.") (emphasis original).

**C. Petitioner’s Proposed Combinations Do Not Disclose or Render Obvious the Limitation “Contact[ing] the Wet Pad with the Distalmost End Face of the Access Portion of the Patient Fluid Line Access Valve.”**

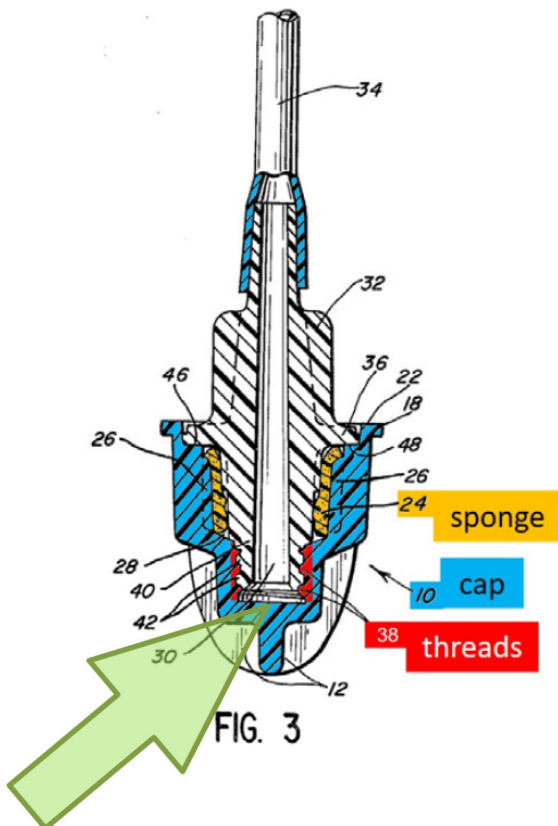
Even assuming *arguendo* that a POSITA would have been motivated to modify Connell with the teachings of Raulerson and Genatempo, the proposed combinations still would not meet all the claim limitations. All Challenged Claims of the ’367 patent require contact between the claimed wet pad and the “distalmost end face” of the access portion of the patient fluid line access valve to be disinfected. Specifically, independent claim 1 recites “contact the 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.” (Ex. 1001, 5:54-56)<sup>3</sup> Ex. 2002, ¶73. But Grounds 4-6 do not disclose or suggest this claimed arrangement. Petitioner offers no argument on how the Connell’s cap would be modified with any wet pad that would provide such required contact. (Pet. 65-66). Indeed, Petitioner’s arguments in Grounds 4-6 for the corresponding claim limitation Part [c.i] do not even mention “contact.” (*Id.*); Ex. 2002, ¶74.

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<sup>3</sup> Similarly, independent claim 9 recites “the wet pad being positioned within the cavity for contacting the distalmost end face ... to reduce the amount of microbes on the access portion” (Ex. 1001, 6:31-33); and independent claim 14 recites “the wet pad being configured to contact... 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.*, 6:66-7:3).

To the extent even understood, Petitioner relies on “[s]ponges of Genatempo and scrub of Raulerson” in its proposed combinations as disclosing the claimed wet pad. (Pet. 57-58 (*citing* Ex. 1002, ¶100)). But Petitioner fails to even identify how the recited “contact” is met in its proposed combinations. (Pet. 64-66). Indeed, neither the “sponges of Genatempo” nor “scrub of Raulerson” in the proposed combinations would be in contact with the end face of any connector, let alone the recited access portion of the patient fluid line access valve. Ex. 2002, ¶75.

Petitioner’s own color-annotated Figure 3 of Genatempo reproduced below (Pet. 14) shows that the sponges are not in contact with the end face of the depicted connector:



Because the **absorbent material (24)** is located closer to the opening of the cap than the internal threads (42) (which are located near the closed end of the cap, in the second, inner chamber (30)), by the time the threads of the cap (42) engage the **threads (38)** of the connector, the **end face** (as indicated by the arrow annotated by Patent Owner) of the connector is not in contact with the **absorbent material (24)**. Ex. 2002, ¶76. Indeed, the specification confirms that “[t]he tube of absorbent material 24 is shown contacting main tubular member 40 of connector 32, as well as threads 42,” and not the recited “distalmost end face” as set forth in the Challenged Claims. (Ex. 1006, 3:43-45). Ex. 2002, ¶77.

In the proposed combinations, Petitioner suggests to “adopt[] the pre-impregnated sponge of *Genatempo*” such that “when the sponge is compressed, [it would] release liquid to flow throughout the threading portions of the coupling.” (Pet. 56 (*citing* Ex. 1002, ¶99)). But Connell already discloses this feature without the use of a sponge. (Ex. 1010, [0101]). Importantly, claim 1 requires “contact the wet pad with the distalmost end face.” Whether the liquid released from the sponge would flow through the threads is irrelevant to whether there is contact between the sponge and the end face because the threads are not situated on the end face. And even if the liquid released from the sponge contacts the end face (it does not, because there is no gap between the end face of the connector and the inside bottom of the cap), there is no physical contact between the sponge and the



end face. Such requirement is simply not met in Petitioner's proposed combinations "adopting the pre-impregnated sponge of *Genatempo*." (*Id.*); Ex. 2002, ¶78.

To the extent Petitioner relies on the scrubber of Raulerson as disclosing the recited contact, the scrubber does not contact the end face of its connector either. Petitioner argues that when the threads of the cap are engaged with the threads of the connector in the resulting combination, "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)." (Pet. 66). But the claims require contact of the wet pad with the end face, not merely "the proximal end of the luer" as argued by Petitioner.

Importantly, as depicted in color-annotated Figure 3 of Raulerson below, the **scrubber 130** of the luer cleaner 100 would not make contact with the **end face** of the luer connector 190 when it is inserted because the scrubber 130 is situated along only the inner side walls of the luer cleaner 100.

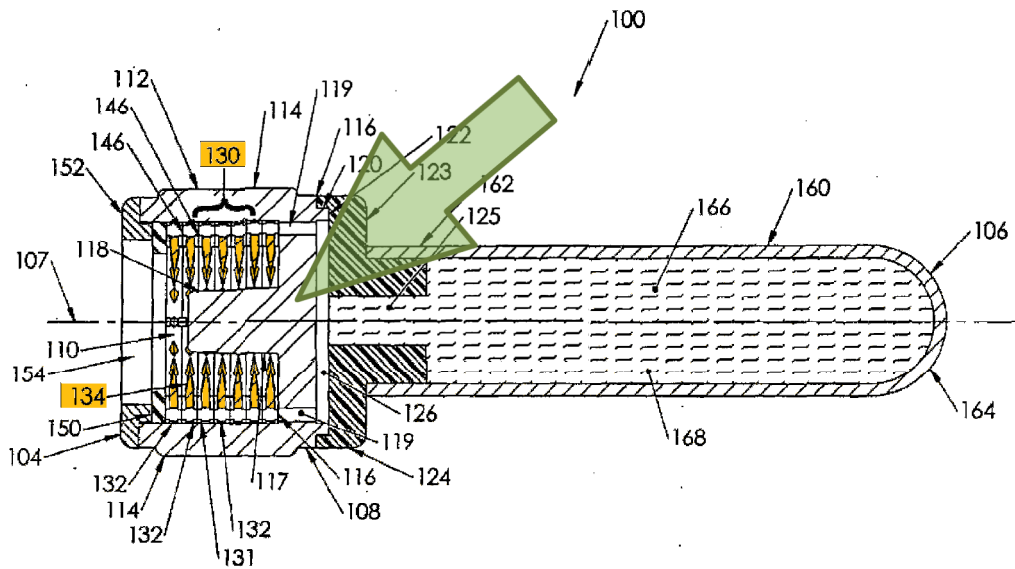


FIG. 3

(color-annotated Figure 3—the green arrow points at the center guide member 117, which is where the end face of the luer connector would make contact when it is inserted into the luer cleaner. (Ex. 1011, [0016])). Indeed, the Raulerson specification confirms that the “bristles 134” of the scrubber 130 “engage the luer threads of the luer,” and not the end face of the luer, “when the luer is inserted into the luer cleaner 100.” (Ex. 1011, [0021]). In any event, bristles of a scrubber are not a wet pad that can hold a cleaning solution, as required by the claims.<sup>4</sup> (Ex. 1001, 5:47-48).

<sup>4</sup> Even Petitioner and its expert recognize that a scrubber, or bristles of the scrubber, taught by Raulerson, is/are not a “pre-impregnated absorbent material,” and thus suggest adopting the sponge of Genatempo in the proposed combinations, for meeting the “wet pad” limitation of the claims. (Pet. 56-57 (citing Ex. 1002, ¶ 99)).

**D. Petitioner Has Not Met its Burden to Show that a POSITA Would Have Been Motivated to Adopt the Sponges from Genatempo in the Proposed Combinations.**

Petitioner's motivation-to-combine arguments are incomplete. Petitioner argues that a POSITA would have been motivated to modify Connell, in view of Raulerson, and in further view of Genatempo, to arrive at the claimed cap. But such proposed modifications would change the operating principle in Connell's cap, as discussed above. Further, the purported motivation is based on hindsight bias relying on manufactured rationales that are untethered to the teachings in the underlying references.

Claim limitation 1[b] requires "a wet pad holding a cleaning solution prior to receiving the access portion of the patient fluid line access valve." (Ex. 1001, 5:47-48). Petitioner argues that there is motivation to modify the combination of Connell and Raulerson with the teachings of Genatempo that allegedly discloses the recited wet pad. (Pet. 56-57, 63-64). Ex. 2002, ¶79.

Specifically, Petitioner argues that a POSITA "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)... in such a combination, there would be no dry spots or other infirmities associated with a failure to break the seal. (Ex. 1002,

¶99)” (Pet. 56-57). Petitioner’s expert parrots the same “rationale” in his declaration. (Ex. 1002, ¶99). Ex. 2002, ¶80.

A POSITA would not have been motivated to add a sponge taught by Genatempo in the proposed combination of Connell and Raulerson because neither of these references is faced with the purported “dry spots” issue or “other deficiencies associated with failure of breaking” that Petitioner relies upon in Grounds 4-6. Connell does not have a sponge at all. Indeed, it identifies the lack of a sponge as an advantage. (Ex. 1010, [0053]); Ex. 2002, ¶¶81-82.

Raulerson teaches the use of a large reservoir (166) of antiseptic fluid (168), and discloses multiple passages (*e.g.*, connecting passage 125, circular throughway 126, passage 119, radial passage 146, etc.) that allow the fluid to flow to the scrubber, as shown in the color-annotated Figure 3. (Ex. 1011, [0028], [0031]).

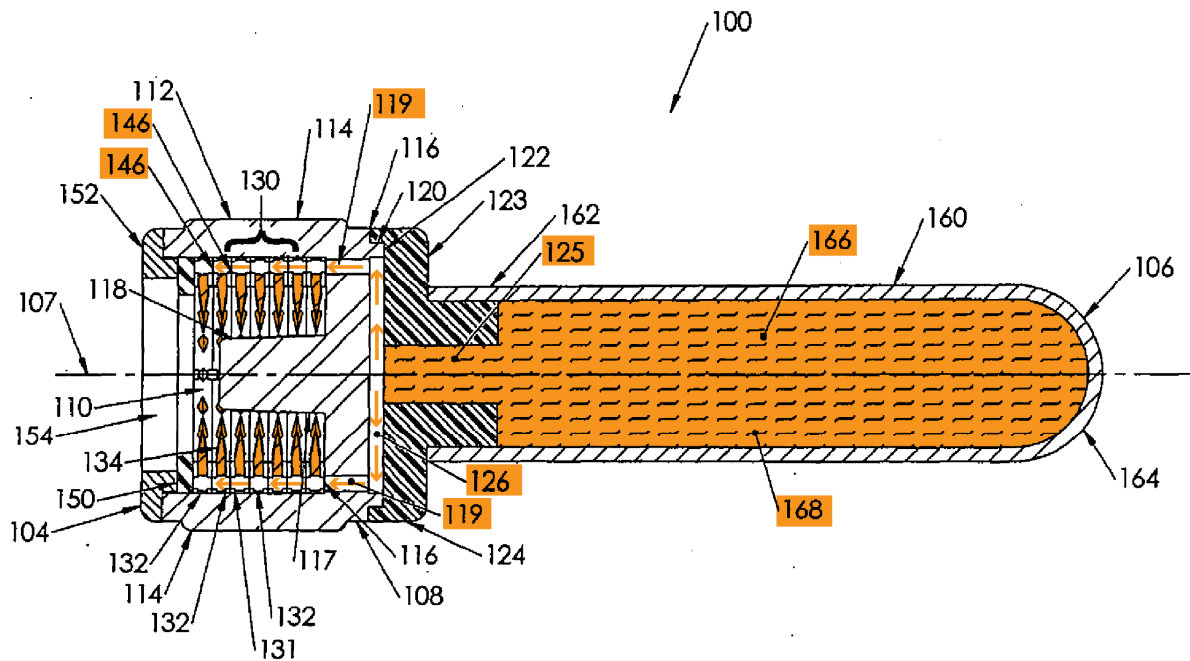


FIG. 3

Raulerson does not mention any “dry spots” issue in its scrubber for failure of the antiseptic fluid to sufficiently wet the scrubber bristles for cleaning the luer connector. To the contrary, the antiseptic fluid is in such abundance that Raulerson is concerned with the fluid entering “the interior of the luer 190” after it has been released from the reservoir. (Ex. 1011, [0016]). Ex. 2002, ¶83.

Similarly, there is no issue to be solved for “failure of breaking” the sealed portion with disinfectant either. Connell discloses a “seal 18” that “compresses against the walls of the receptacle 16, so that the disinfectant 20 residing within the receptacle 16... cannot initially escape...” (Ex. 1010, [0073]). Connell further discloses that when the cap 12 is in use, the “seal 18” would be ruptured or

displaced to release the disinfectant 20. (Ex. 1010, [0100]-[0101]). Connell does not disclose any problem with breaking the “seal 18” to release the disinfectant 20. Rather, Connell discloses the “seal 18” to be “thin or otherwise frangible” in some embodiments. (Ex. 1010, [0074]). Indeed, Connell was concerned with the opposite of that problem—that the seal would be loose or destroyed during shipment prior to using the connector 10. (Connell, [0095]). Ex. 2002, ¶84.

The issues of “dry spots” or “other infirmities associated with a failure to break the seal” would not motivate a POSITA to adopt “the pre-impregnated sponge of Genatempo” because those issues are not applicable to Connell or Raulerson. Petitioner has not provided any other rationale that would have motivated a POSITA to adopt Genatempo’s sponge in the proposed combination of Connell and Raulerson. Ex. 2002, ¶85.

Accordingly, Petitioner fails to meet its burden to demonstrate that a POSITA would have been motivated to modify Connell, in view of Raulerson’s teaching, and in further view of Genatempo’s teaching, to arrive at the claimed cap of the ’367 patent absent hindsight. *See In re NTP, Inc.*, 654 F. 3d 1279, 1299 (Fed. Cir. 2011) (“Care must be taken to avoid hindsight reconstruction by using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.”) (Internal quotations and citations omitted).

Petitioner has failed to offer *any* evidence regarding Connell's operating principle, or its alleged problems in capsule-release systems. As Petitioner's evidence stands unchallenged, there can be no factual dispute to construe in Petitioner's favor. As such, the preliminary proceeding should be resolved in favor of Patent Owner and institution denied. *See BASF Corp.*, IPR2019-00202, Paper 13 at 6 (“[37 C.F.R. §42.108(c)] only applies to *disputed* issues of material fact, and does not simply require us to accept every bare assertion made in a Petition.”) (emphasis original). Petitioner has failed to demonstrate a reasonable likelihood of prevailing on base claims 1, 9, and 14, and at least by virtue of dependency, any claim depending therefrom.

**VI. GROUNDS 4-6 SHOULD BE DENIED UNDER 35 U.S.C. § 325(d)**

For Grounds 4-6, Petitioner relies on the same disclosure in the same prior art reference as disclosing the same claim limitation that was considered and explicitly rejected by the examiner during prosecution of both the parent '864 patent and the '367 patent, and fails to address the examiner's findings despite including a § 325 section in its Petition. (Pet. 11). Petitioner's failure to address the very same prior art argument before the Office is a textbook § 325(d) case that warrants denial.

As discussed above, Petitioner relies on “adopting the pre-impregnated sponge of *Genatempo*” in its combinations to disinfect the threads of a connector

as disclosing the claim limitation reciting “contact the wet pad with the distalmost end face of the access portion of the patient fluid line access valve.” However, in its notice of allowance of the ’864 claims, the examiner states:

10. The closest prior art is Genatempo (4440207), which as discussed in the Non-Final office action teaches disinfecting at least a portion of the external threads, however Genatempo fails to teach or suggest an access valve having an end face that contacts the wet pad and is advanced into the cavity via the engagement of the threads. Rather, in Genatempo, by the time the respective threads are engaged, the end face has past the wet pad and is **no longer in contact.**

(Ex. 1021, 273-74 (2014-01-21 Notice of Allowance)). Similarly, in its notice of allowance of the ’367 claims, the examiner states: “Genatempo fails to teach or suggest that the thread engages the external threads on the access portion as the access portion is advanced into the inner cavity so that *the distalmost end face of the access portion contacts the wet pad* to provide the cleaning solution to the septum and at least a portion of the external threads.” (Ex. 1003, 443-445 (2015-11-17 Notice of Allowance)(emphasis added)).

As can be appreciated, the Office has already considered the exact proposition that is presented in Grounds 4-6 and rejected it. Genatempo, fails to disclose an end face that contacts the wet pad when the threads are engaged, as required by the claims of the ’367 patent.



For the reliance on Genatempo as disclosing the recited “contact” in the Challenged Claims, neither the Petitioner nor its expert add any additional insight, evidence or argument not duplicative of what was considered during prosecution. (Pet. 66 (*citing* Ex. 1002, ¶100)). Because the Petition presents the “same or substantially the same prior art or arguments” that were previously presented to the Office, the Proposed Grounds 4-6 should be denied under 35 U.S.C. § 325(d).

## **VII. CONCLUSION**

Because the Petition fails to show that there is a reasonable likelihood that Petitioner will prevail in proving *any* Challenged Claim unpatentable, the Petition should be denied. Pursuant to 35 U.S.C. § 314, no *inter partes* review should be instituted.

Dated: January 21, 2020

Respectfully submitted,

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**CERTIFICATE OF WORD COUNT**

The undersigned certifies that the foregoing PATENT OWNER'S PRELIMINARY RESPONSE UNDER 37 C.F.R. §42.107 complies with the type-volume limitation in 37 C.F.R. §42.24(b)(1). According to the word-processing system's word count, the brief contains 10,080 words, excluding the parts of the brief exempted by 37 C.F.R §42.24(c).

Dated: January 21, 2020

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**CERTIFICATE OF SERVICE**

The undersigned certifies that the foregoing PATENT OWNER'S PRELIMINARY RESPONSE UNDER 37 C.F.R. §42.107 was served in its entirety by filing through the Patent Trial and Appeal Board End to End (PTAB E2E), as well as providing a courtesy copy via e-mail to the following attorneys of record for Petitioner listed below:

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