Trials@uspto.gov
Tel: 571-272-7822

Paper 69
Entered: May 4, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,
Patent Owner.

IPR2019-00109
Patent 9,795,761 B2

Before JOSIAH C. COCKS, MITCHELL G. WEATHERLY, and TIMOTHY J. GOODSON, *Administrative Patent Judges.*

COCKS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Summary

C.R. Bard, Inc., ("Petitioner") filed a Petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 1–19 and 22–25 ("challenged claims") of U.S. Patent No. 9,795,761 B2 (Ex. 1001, "the '761 patent"). 35 U.S.C. § 311. Medline Industries, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 15. We instituted trial to determine whether the challenged claims were unpatentable as follows:

Claims Challenged	35 U.S.C. §	References
1, 2, 4–11, 13–19, 23, 25[1]	103	Solazzo,[2] Serany,[3] Franks-Farah[4]
3, 12, 22, 24	103	Solazzo, Serany, Franks-Farah, Disston[5]

Paper 17 ("Institution Decision" or "Inst. Dec."). Patent Owner filed a Patent Owner Response. Papers 34, 35.[6] Petitioner filed a Reply. Papers 51, 52 ("Reply").[7] Patent Owner filed a Sur-Reply. Papers 57, 58

[1] Although the Petition initially indicates that the ground of unpatentability based on Solazzo, Serany, and Franks-Farah is applied to claims "1–9, 10–19, 23–25," (Pet. 31) review of the Petition reveals that claims 3, 12, and 24 are not discussed as a part of this proposed ground. *See generally*, Pet.

[2] Solazzo, U.S. Patent No. 7,278,987 B2 issued Oct. 9, 2007 (Ex. 1005).

[3] Serany, U.S. Patent No. 3,329,261 issued July 4, 1967 (Ex. 1006).

[4] Franks, Farah, U.S. Patent No. 6,840,379 B2 issued Jan. 11, 2005 (Ex. 1007).

[5] Disston, U.S. Patent No. 3,166,189 issued Jan. 19, 1965 (Ex. 1008).

[6] Paper 34 is a sealed version of the Patent Owner Response. Paper 35 is a redacted, public version.

[7] Paper 51 is a sealed version of the Reply. Paper 52 is a redacted, public version.

("Sur-Reply").[8] As was authorized by the panel, the parties also filed briefs directed to discussing the impact of *Fox Factory v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019) on this proceeding. Papers 64, 65. Oral argument was heard on February 5, 2020. A transcript of the hearing is in the record. Paper 68 ("Tr.").

B. Related Proceedings

The parties identified as a related proceeding the co-pending district court proceeding of *Medline Industries, Inc. v. C. R. Bard, Inc.*, Case Number 1:17-cv-07216 (N.D. Ill.) ("*Medline III* Litigation"). Pet. 88; Paper 4, 2. The parties also identify petitions for *inter partes* review of claims of the U.S. Patent No. 9,745,088 patent (IPR2019-00035 and IPR2019-00036) as related matters. Pet. 88; Paper 4, 3. Patent Owner further identifies as related matters U.S. Patent Application Nos. 15/703,514; 15/684,787; 15/803,383; 13/374,509; and 15/640,224, which are continuations or continuations-in-part of the application leading to issuance of the '761 patent. Paper 4, 2. Patent Owner further identifies U.S. Patent Application Nos. 14/265,920; 15/804,520; and 15/051,964 as related matters because those applications "share similar disclosures and claim language" with the claims of the '761 patent. *Id*. at 2.

C. The '761 Patent

The '761 patent is titled "Medical Kit, Packaging System, Instruction Insert, and Associated Methods." Ex. 1001, code [54]. The Specification

[8] Paper 57 is a redacted, public version of the Sur-Reply. Paper 58 is a sealed version.

describes tray 200 shown in Petitioner's annotated and colorized version of Figure 4 (Pet. 17), which we reproduce below.

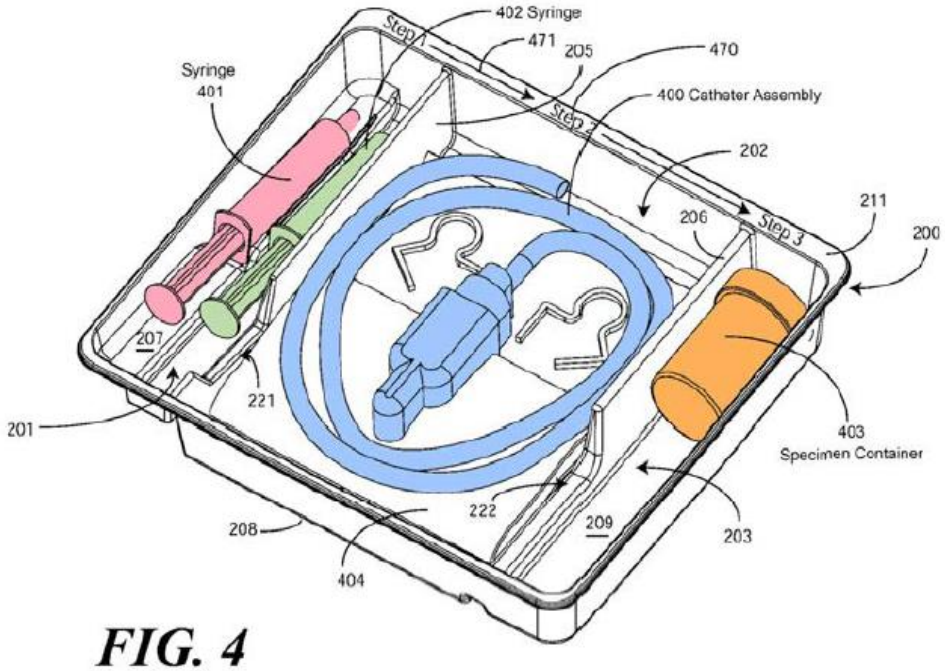


FIG. 4

Figure 4 "illustrates a medical procedure kit configured for a catheterization procedure in accordance with one or more illustrative embodiments of the invention." Ex. 1001, 2:14–16. Tray 100 includes three compartments 201, 202, 203 adapted to accept various items used in a catheterization procedure. *Id*. at 7:54–64. First compartment 201 accommodates syringes 401, 402 (red, green) containing sterile water or lubricants. *Id*. at 11:21–23. Second compartment 202 accommodates catheter assembly 400 (blue). *Id*. at 11:23–25. Third compartment 203 accommodates specimen container 403. *Id*. at 11:25–26. Additional objects can be included with the tray, including one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, swab sticks, a securement device, printed instructions, and so forth. *Id*. at 11:26–45.

Figure 10 of the '761 patent is reproduced below.

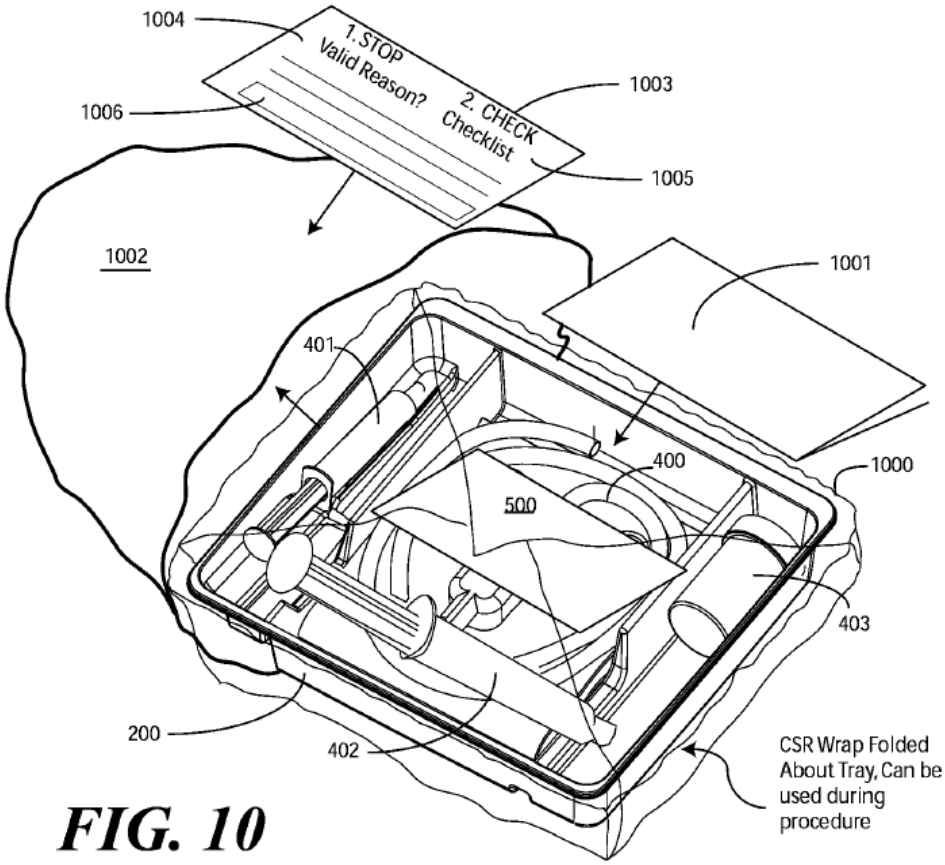


FIG. 10

Figure 10 shows an "illustrative packaging arrangement for a medical procedure kit" including tray 200. *Id.* at 15:29–32. A Central Sterile Reprocessing (CSR) wrap 1000 may be folded around tray 200, and may be unfolded for use in providing a sterile field in which tray 200 may sit during its use. *Id.* at 16:25–33. Figure 10 also shows that "patient aid" 500 may be contained within tray 200. *Id.* The content of patient aid 500 may include the following:

> educational information corresponding to a medical procedure, patient care information corresponding to a medical procedure, information relating to a medical device, such as a urinary catheter, peripherally inserted central catheter, or wound dressing, that is applied to the patient, an illustrated guide

> depicting patient care for medical device, or combinations thereof.

Id. at 12:22–29.

Figure 19 of the '761 patent is reproduced below.

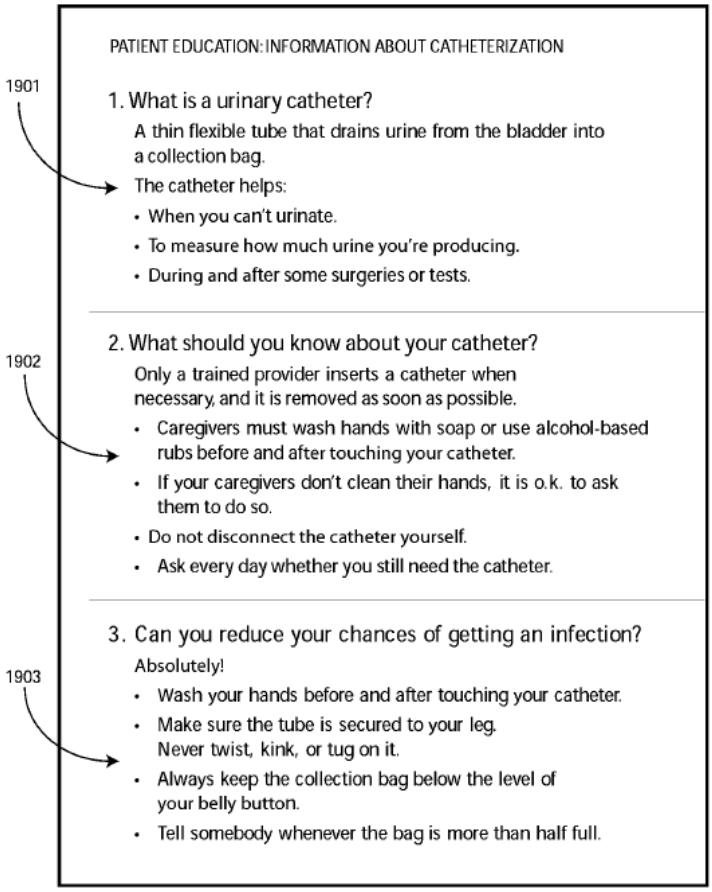


FIG. 19

Figure 19 illustrates an example of patient information that may be provided as a part of a patient aid. *Id.* at 23:8–10. The content of that patient information can include the following:

> [I]nformation 1903 regarding how the patient can reduce the chances of getting an infection. This information 1903 can include a statement that the patient should wash their hands prior to touching the catheter assembly. The information 1903 may also include a statement that the drainage bag should always be

> kept at a level beneath the patient's navel, and that the patient should inform a helper when the bag is more than half full.

Id. at 23:25–33.

Claims 1, 10, 15, and 19 are the independent claims among the challenged claims. *Id*. at 28:11–30:57. Claim 1, which is illustrative, recites:

> 1. A tray configured to accommodate a Foley catheter, the tray comprising:
>
> [a] a surface defining a single layer tray comprising at least two compartments separated by a barrier, the at least two compartments comprising:
>
> [b] a first compartment supporting a first syringe and a second syringe at different heights based upon order of use in a Foley catheterization procedure;
>
> [c] a second compartment to accommodate the Foley catheter; and
>
> [d] the barrier separating the first compartment from the second compartment;
>
> [e] the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter;
>
> [f] further comprising a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient.

Id. at 28:12–29 (with added letter designations a–f to ease discussion).

II. ANALYSIS

A. Claim Construction

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R.

§ 42.100(b) (2018)[9]; *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (affirming that USPTO has statutory authority to construe claims according to Rule 42.100(b)). When applying that standard, we interpret the claim language as it would have been understood by one of ordinary skill in the art in light of the specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'"). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999).

In its Petition, Petitioner contended that "no term or phrase requires specific construction to find that the challenged claims are invalid." Pet. 25. Petitioner, however, noted that Patent Owner, in the related district court proceeding, advanced constructions for three claims terms, which are reproduced below in the following table:

[9] This Rule subsequently was changed to require that claims that are the subject of an *inter partes* review be construed in the same manner used in a civil action under 35 U.S.C. § 282(b). That change, however, does not apply here because the Petition was filed before the effective date of the new Rule, November 13, 2018. *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, 51,344 (Oct. 11, 2018).

Claim Term	Patent Owner Construction
Barrier	structure that separates one compartment from another and prevents or blocks movement between the two
Mnemonic device	feature intended to assist in the memory, such as ordering items left to right or top to bottom
Lubricating jelly application chamber/ compartment	a compartment or channel where lubrication is applied

Pet. 26. The Table above summarizes proposed constructions of claim terms "barrier," "mnemonic device," and "lubricating jelly application chamber/compartment. In our Institution Decision, we observed that there was "no apparent disagreement between the parties that the above-noted terms should take on the above-noted meanings in this proceeding." Inst. Dec. 17. We also determined that it was not "necessary to express an opinion about the meaning of any claim term or phrase" at that time. *Id.* During trial, neither party has raised any issues pertaining to the construction of any claim term. We determine that it is not necessary to address further any matters of claim construction for purposes of this Final Written Decision.

B. Legal Standards

Petitioner challenges the patentability of claims 1–19 and 22–25 on the grounds that the claims would have been obvious in light of various references including: Solazzo, Serany, Disston, Franks-Farah, and Disston. To prevail in its challenges to the patentability of the claims, Petitioner must establish facts supporting its challenges by a preponderance of the evidence.

35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or non-obviousness. *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18). In an *inter partes* review, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Thus, to prevail Petitioner must explain how the proposed combinations of prior art would

have rendered the challenged claims unpatentable. With these standards in mind, we address each challenge below.

C. Level of Ordinary Skill in the Art

The parties generally agree that a person having an ordinary level of skill in the relevant art would have had a bachelor's degree in packaging engineering, mechanical engineering, or industrial design. Pet. 24; PO Resp. 16 (citing 2038 ¶ 37). Alternatively, such a person could have had a degree in another technical field along with about two years of experience designing medical packaging. Pet. 24 (citing Ex. 1002 ¶ 14); PO Resp. 16 (citing Ex. 2038 ¶ 78). Neither party contends that a person of ordinary skill needs to be a medical practitioner, but both parties agree that the person of ordinary skill would have consulted with medical practitioners familiar with catheterization procedures. Pet. 24; PO Resp. 16.

We agree with the parties that the person of ordinary skill would have had a bachelor's degree in packaging engineering, mechanical engineering, or industrial design or, alternatively, a degree in another technical field along with about two years of experience designing medical packaging. Although slight differences exist in the formulation of the level of ordinary skill between the parties, we discern no meaningful difference because none of those differences would affect the outcome of our analysis. To that end, we conclude that it is unnecessary to further define the person having an ordinary level of skill or to formally adopt one party's definition over the other in deciding the issues at hand. We further note that our definition is consistent with the Specification and the cited prior art references, which reflect the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Ground of Unpatentability Based on Solazzo, Serany, and Franks-Farah

In its Petition, Petitioner contends that claims "1–9, 10–19, 23–25" (Pet. 31) are unpatentable over Solazzo, Serany, and Franks-Farah. *See* Pet. 32–77. Patent Owner argues that Petitioner has not shown that any challenged claim is unpatentable based on obviousness. PO Resp. 35–60.

1. Overview of Solazzo

Solazzo is directed to an ergonomic, single layer catheterization/irrigation tray 1 having multiple compartments, including recessed area 3, compartment 27, and wells 31, 33 as shown in Figure 1, which we reproduce on the right. Pet. 32; *See* Ex. 1005, 4:15–25; Fig.1. Solazzo's Figure 1 is a perspective view of the catheterization and irrigation tray illustrating its major features. Ex. 1005, 3:31–33. Divider wall 17 is optional and, when present, divides recessed area 3 into two compartments, with compartment 27 being configured to receive fluid passing over top 25 of wall 17. *Id*. at 4:15–20.

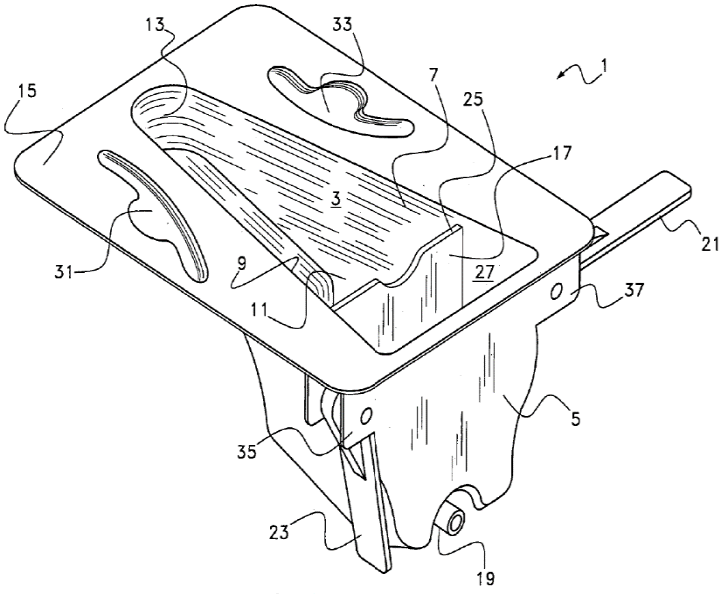


Fig. 1

Figure 2 of Solazzo is reproduced below.

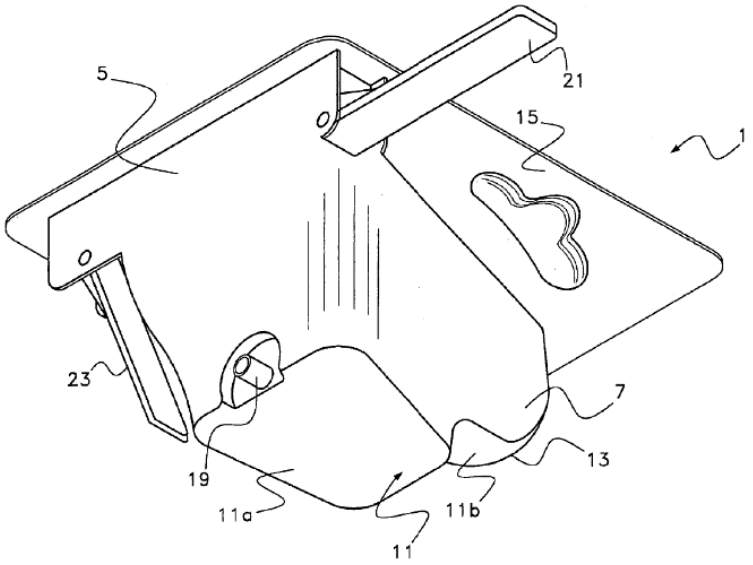


Fig. 2

Figure 2 above is "a bottom oblique view" of the device shown in Figure 1. *Id.* at 3:34–35. Recessed area 3 is trapezoidal-shaped with a "non constant depth" provided by a terraced bottom 11 having low area 11A and shallow area 11B. Ex. 1005, 3:61–66; Fig. 5. Recessed area 3 and compartment 27 store medical devices of tray kit 100, including Foley catheter 120, urinary tract lubricant 140, surgical gloves 130, inflation syringe 110, irrigation syringe (not shown), evacuation tubing, and antiseptic solutions as shown in Solazzo's Figure 8, which is a top view of kit 100 that we reproduce below. *Id*. at 4:1–8; Fig. 8.

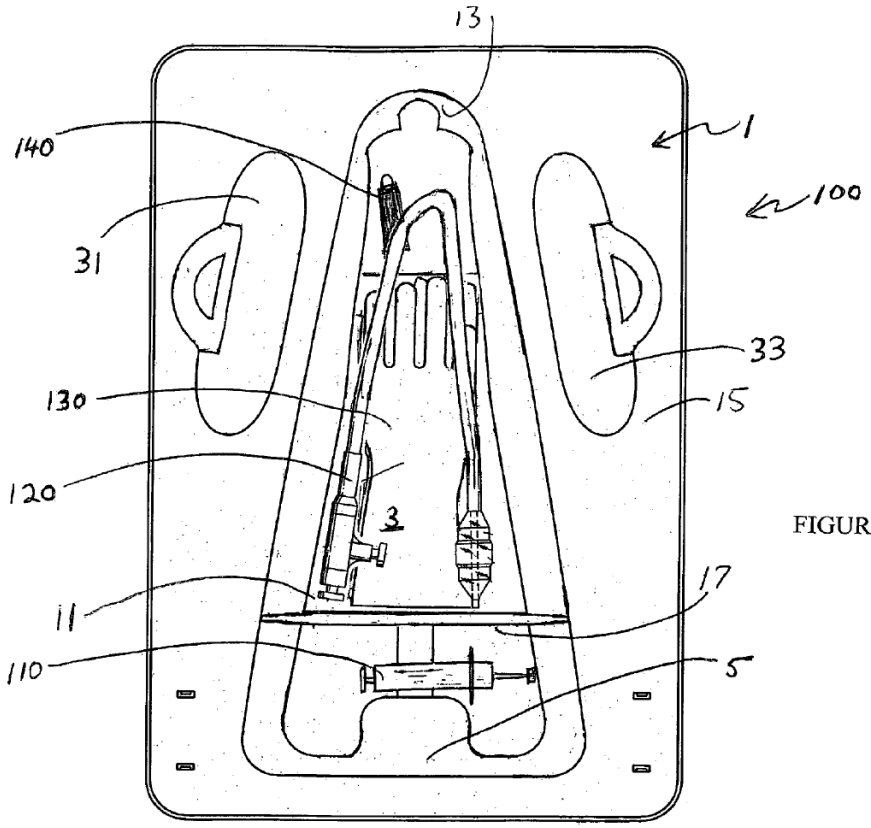
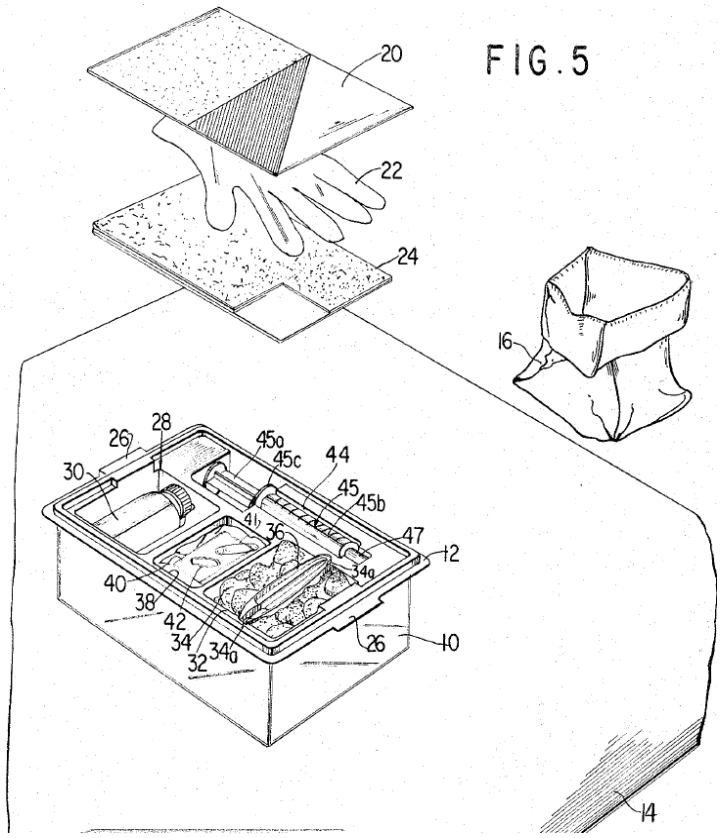


FIGURE 8

Solazzo's Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id.* at 4:41–48. Inflation syringe 110 is stored at low area 11A (shown in Figure 2), and lubricant 140 is stored at shallow area 11B (also shown in Figure 2). *Id*. at 4:41–45; Fig. 8. In use, recessed area 3 and compartment 27 (shown in Figure 1) fit between the legs of a "patient requiring an urological procedure" while flange 15 and wing supports 21, 23 (shown in Figure 2) rest atop the legs while the patient is seated. *Id*. at 1:8–12, 3:66–4:10, 4:26, 4:32–33; Fig.1. A surgeon proceeds to "evacuate the bladder of its contents, urine and/or clots" using kit 100, e.g., by wearing the gloves, lubricating and inserting the catheter, and inflating it with inflation syringe 110. *Id*. at 4:32–33, 4:46–48.

2. Overview of Serany

Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. The package includes multi-compartment single-layer tray 12 mounted on box 10 and enclosed with sealed outer envelope 16 and inner wrap 14 that unfolds to provide a sterile field work area. *Id*. at 1:60–72, 2:17–20; Figs. 1–5. Serany's Figure 5 (reproduced at right in pertinent part) is an exploded view illustrating how various compartments are positioned within Serany's box 10. Pet. 36.



Prefilled syringe 45 of sterile water is positioned in depression 44, which includes indentations 44d (not shown) along the sides to accommodate the syringe's flange. Ex. 1006, 2:40–41, 3:6–22; Figs. 6–7. Serany's package further includes a waterproof underpad 20, gloves 22, fenestrated drape 24, cleansing solution bottle 30, rayon balls 34, forceps 36, lubricating jelly pouch 40, safety pin 41, and rubber band 42. Serany describes its package as containing "all the essential equipment . . . for a complete . . .

catheterization procedure. . . . Everything is available in the proper order of use and in a sterile condition." *Id*. at 1:16–25.

Box 10 also includes Foley catheter 48 that is preconnected to a collapsible drainage bottle 46 via tube 49 and "ready for use" as shown in Serany's Figure 6, which is reproduced at right. *Id*. at 2:22–33, 2:57–70, 3:1–5, 3:23–26, Figs. 5–6. The collapsible drainage "bottle 46 is made of flexible plastic material having fold lines 46a . . . so that it may be folded flat for storage . . . and expanded into cube form when in use. The bottle is shown in FIG. 6 partially expanded for illustration purposes." *Id*. at 3:26–31; Fig. 6. Catheter 48 and tubing 49 are coiled in the box about bottle 46 as shown in annotated Figure 6. *Id*. at 3:33–35.

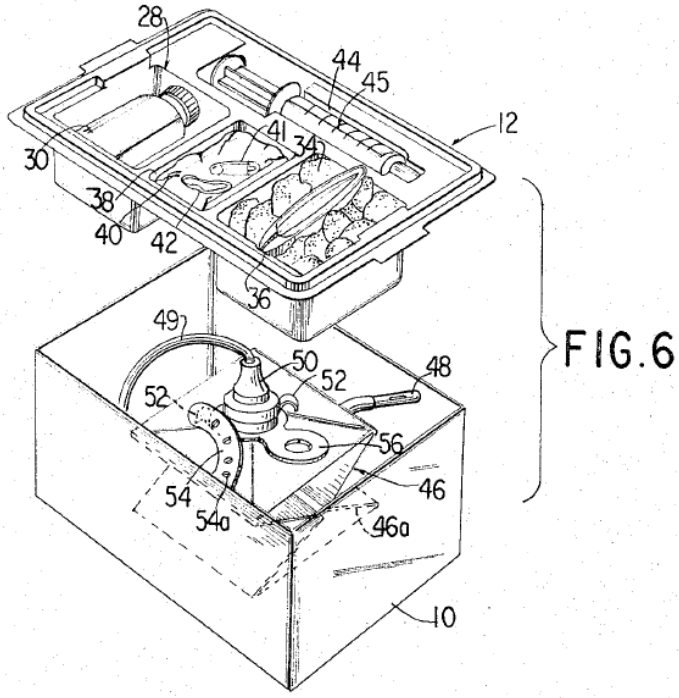


FIG.6

3. Overview of Franks-Farah

Franks-Farah is directed to "[a] method and system for performing intermittent male catheterization by a patient, a patient's caregiver, or a health care provider[.]" Ex. 1007, code (57). Franks-Farah further describes that "[t]he system contains apparatus for at least one intermittent male catheterization and includes at least one male catheter, antibacterial soap, a lubricant, step-by step-instructions, and a container, where the above named

items are positioned inside the container." *Id.* Examples of such step-by-step instructions appear in Figures 2A and 2B, which are reproduced below.

FIG. 2A

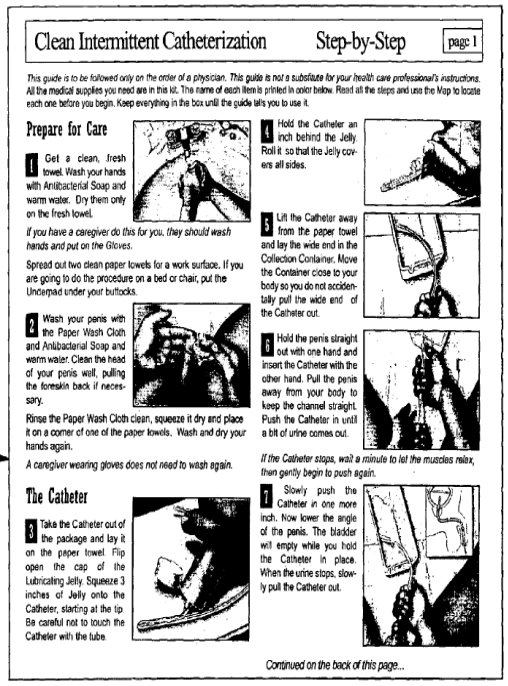
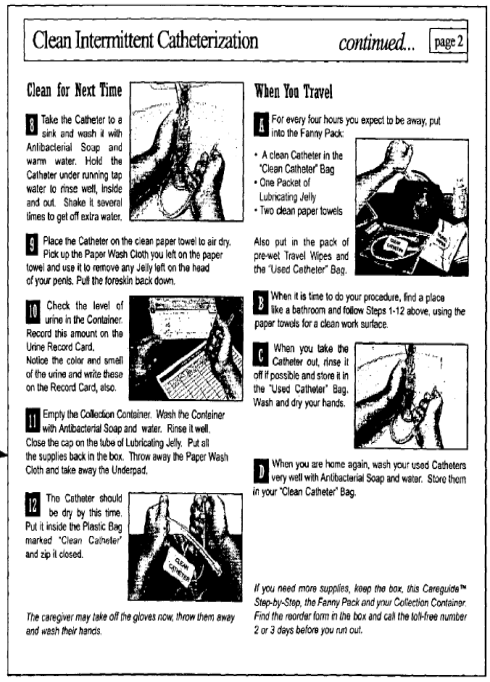


FIG. 2B



Figures 2A and 2B depict top plan views of step-by-step instructions. *Id.* at 3:12–13.

4. Independent Claim 1

Independent claim 1 recites:

> 1. A tray configured to accommodate a Foley catheter, the tray comprising:
>
> [a] a surface defining a single layer tray comprising at least two compartments separated by a barrier, the at least two compartments comprising:
>
> [b] a first compartment supporting a first syringe and a second syringe at different heights based upon order of use in a Foley catheterization procedure;
>
> [c] a second compartment to accommodate the Foley catheter; and

> [d] the barrier separating the first compartment from the second compartment;
>
> [e] the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter;
>
> [f] further comprising a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient.

Ex. 1001, 28:12–29 (with added letter designations a–f to ease discussion).

Petitioner argues that the combined teachings of Solazzo, Serany, and Franks-Farah render claim 1 unpatentable as obvious. Pet. 38–54. Patent Owner disagrees. In view of the record now developed during trial, and for the reasons that follow, we agree with Patent Owner and conclude that Petitioner has failed to prove by a preponderance of evidence that the combination of Solazzo, Serany, and Franks-Farah teaches all the required elements of claim 1. We discuss the basis for that conclusion below in connection with elements 1[b], 1[c], and 1[e].

a) Elements 1[b] and 1[c]

Elements 1[b] and 1[c] collectively require the following features: (1) two syringes residing within a first compartment; (2) a Foley catheter accommodated in a second compartment; and (3) the two syringes are arranged at different heights based upon their order of use in a Foley catheterization procedure. Petitioner relies primarily on the combined teachings of Solazzo and Serany to account for those requirements. *See* Pet. 41–47.[10] Petitioner also alternatively points, in somewhat general and

[10] Petitioner does not rely on the teachings of Frank-Farah in attempting to account for elements 1[b] and 1[c].

brief fashion, to an additional reference characterized as "Imai" that was not presented as the basis of any of Petitioner's proposed grounds of patentability. Pet. 43, 46. We find that Petitioner has not shown that the cited reference teach the subject matter of elements 1[b] and 1[c].

(1) Solazzo and Serany

Although Solazzo describes a kit that contains an inflation syringe and an irrigation syringe, Solazzo does not describe precisely how these two syringes are arranged in its kit. Ex. 1005, 3:12–24. Serany describes a single syringe, its syringe 45 in its depression 44, but Serany does not describe a second syringe. Ex. 1006, 3:6–22, Fig. 5. Both Solazzo and Serany disclose a catheter assembly in a compartment of a tray. Ex. 1005, catheter 120; Ex. 1006, Foley catheter 48. Neither reference, however, expressly describes two syringes in one compartment and a Foley catheter in another compartment, where the two syringes are supported in the first compartment at different heights based upon the order of use of the syringes in a Foley catheterization procedure.

Figure 4 of the '761 patent, which is reproduced below, illustrates how syringes are supported at different heights in a first compartment based upon their order of use, and a Foley catheter placed within a second compartment.

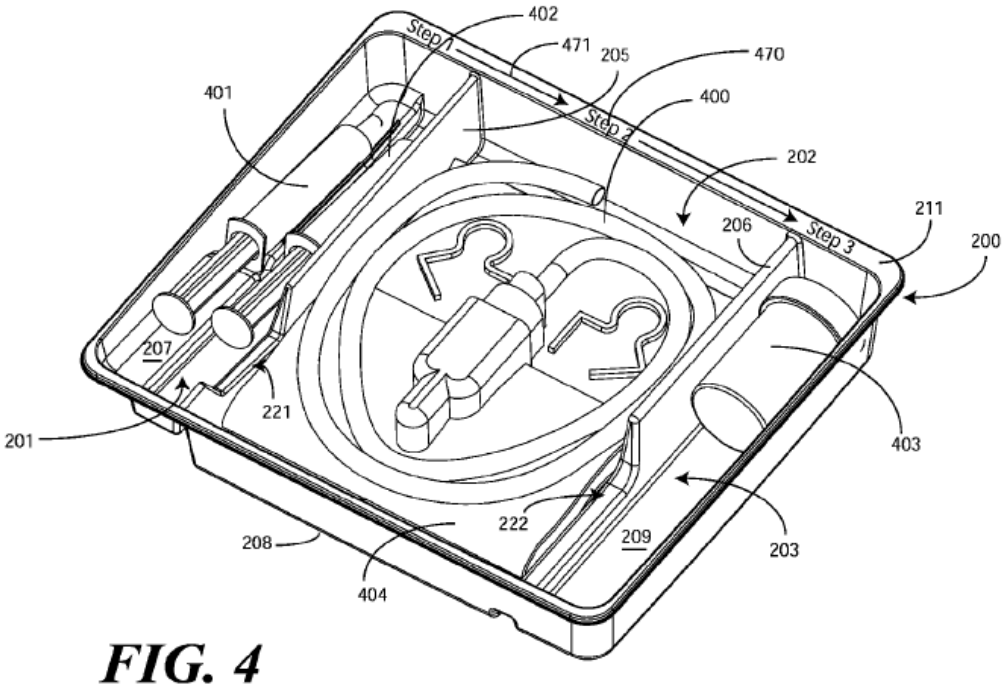
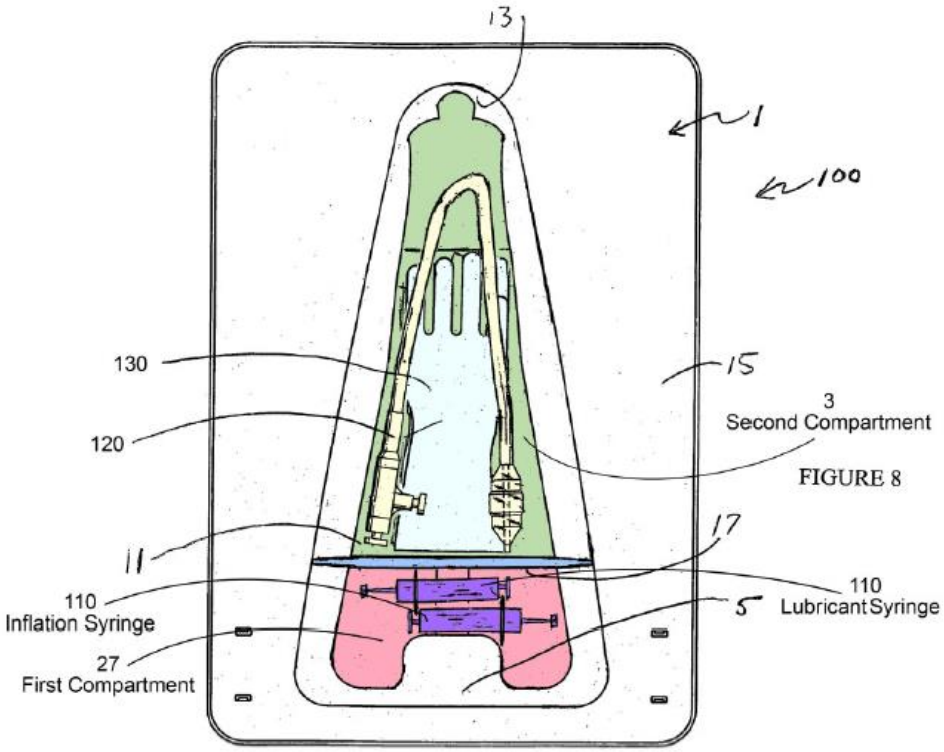


FIG. 4

Figure 4 illustrates tray 200 with first compartment 201 supporting syringes 401, 402, and second compartment 202 holding Foley catheter 400. Ex. 1001, 11:17–21. Syringes 401, 402 are supported at different elevations with syringe 401 positioned at a higher elevation within tray 200 than syringe 402. *Id*. at 11:46–54.

In its proposed combination of the teachings of Solazzo and Serany as they apply to element 1[b], Petitioner points to Solazzo's bottom 11 of tray 1 having a "terraced arrangement" with low area 11a and shallow area 11b. Pet. 44–45 (quoting Ex. 1005, 3:63–66). Relying on the testimony of Mr. Michael Plishka (Ex. 1002), Petitioner contends that the following modified and annotated version of Solazzo's Figure 8 conveys what a person of ordinary skill in the art would have been "motivated" to do when it comes to syringe placement within a compartment. *Id.* at 45.



Petitioner's modified, annotated, and colorized version of Solazzo's Figure 8 was created by Mr. Plishka and is a plan view of Solazzo's catheterization kit as modified based purportedly on teachings from Serany. *Id*.; Ex. 1002 ¶¶ 180–183; *see also* Ex. 1001, Fig. 3 (original version). Petitioner's modified figure includes "lubricant fluid 140, modified to be a syringe" which is shown in the same location as tube 140 of lubricant illustrated in Solazzo's Figure 8. *Compare* Pet. 45 (Petitioner's figure), *with* Ex. 1005, 4:44–45, Fig. 8 (reproduced below) (showing "tube of lubricant fluid 140").

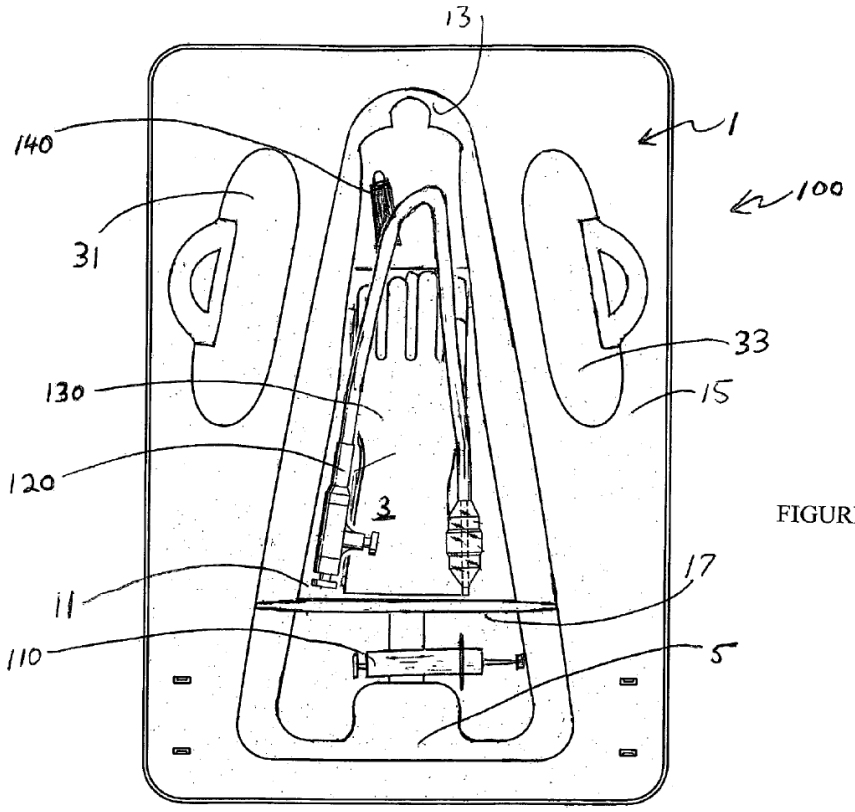


FIGURE 8

Solazzo's Figure 8 is a top view of kit 100 with syringe 110 and tube 140 in tray 1. Ex. 1005, 4:41–45, Fig. 8. Petitioner relies upon Mr. Plishka's testimony stating that it would have been obvious to an ordinarily skilled artisan "to provide a *syringe* of lubricant fluid in place of the *tube* of lubricant fluid." Pet. 40–41 (citing Ex. 1002 ¶¶ 165–167).

Petitioner further argues that the positions of the "first syringe (lubricant fluid 140, modified to be a syringe)" and "inflation syringe" shown in Petitioner's modified version of Solazzo's Figure 3 demonstrates two syringes that are "ordered . . . in accordance with their use" as recited in element 1[b]. Pet. 44–45. Petitioner relies upon Mr. Plishka, who opines, without meaningful analysis, explanation, or citation to objective evidence, that, because of the "terraced arrangement" of bottom 11 of compartment 27,

the modified version of Solazzo "presents the lubrication tube 110 and inflation syringe 140 at different heights." Ex. 1002 ¶ 178.[11]

On reply, Petitioner argues that an expert proffered by Patent Owner, Ms. Lori Chiappetta,[12] "admitted" that Solazzo discloses an order of use during her cross-examination. Reply 9 (citing Ex. 1073, 180:2–18 but quoting only 180:2–14, 180:16–18).[13] The entire cited passage reads as follows:

> Q Sure. Okay. So as we discussed earlier, at least some nurses, based on the video we just watched, were using the lubrication syringe before the water syringe, correct?
>
> A Correct.
>
> Q Okay. So *if* you were performing a Foley catheritization (sic, catheterization) procedure where you were using those devices in that order, and *Solazzo teaches a lubrication tube at a higher point in the tray than the water syringe*, would you agree, then, that those -- that the tube and the syringe are arranged in the tray in accordance with their order of use?
>
> MS. LITTLE: Object to form.
>
> THE WITNESS: I think it's a fluke that it ended up like that; but, yes, you could say that that is it.

Ex. 1073, 180:2–18 (emphases added).

[11] The quoted sentence is reproduced as it appears in Mr. Plishka's Declaration. We discern that Mr. Plishka intended to refer to lubrication tube "140" and inflation syringe "110," rather than vice versa.

[12] Ms. Chiappetta is a registered nurse with 15 years of experience. Ex. 2039 ¶¶ 8–9.

[13] Although the Reply refers to "Ex. 1003," it is clear that Petitioner is intended to refer to Exhibit 1073.

Our review of this testimony reveals that Ms. Chiappetta made no such admission. We note that the question posed to Ms. Chiappetta, to which there was an objection to form, merely proposes a hypothetical in which she is instructed to assume that "Solazzo teaches a lubrication tube at a higher point in the tray than the water syringe" when considering whether the "tube and [] syringe are arranged in the tray in accordance with their order of use." *Id*. Thus, the question does not seek Ms. Chiappetta's own analysis of whether Solazzo's bottom 11 supports a tube and a syringe such that they are arranged in accordance with their use during a catheterization procedure. Petitioner does not persuade us that Ms. Chiappetta "admitted" that Solazzo discloses an order of use. *See* Reply 9.

Whether the modified version of Solazzo meets element 1[b] is informed by the following analysis of Solazzo's tray 1, which is a rather simple structure. Solazzo's Figure 2 (reproduced below) illustrates the shape of Solazzo's bottom 11 (i.e., the claimed base member).

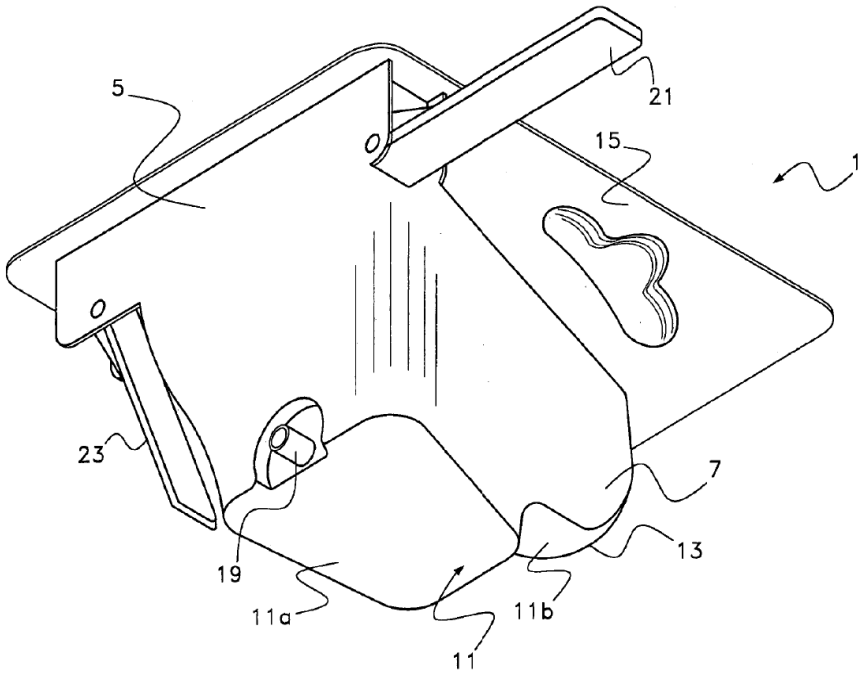


Fig. 2

Solazzo's Figure 2 is a bottom perspective view of its tray 1. Ex. 1005, 3:34–35. Solazzo's recess 3 (not numbered in Figure 2) includes bottom 11 having "a terraced arrangement with low area 11A and shallow area 11B." Ex. 1005, 3:63–66. Solazzo's Figure 5, reproduced below, provides further insight into the shape of bottom 11 of recess 3 (not numbered in Figure 5).

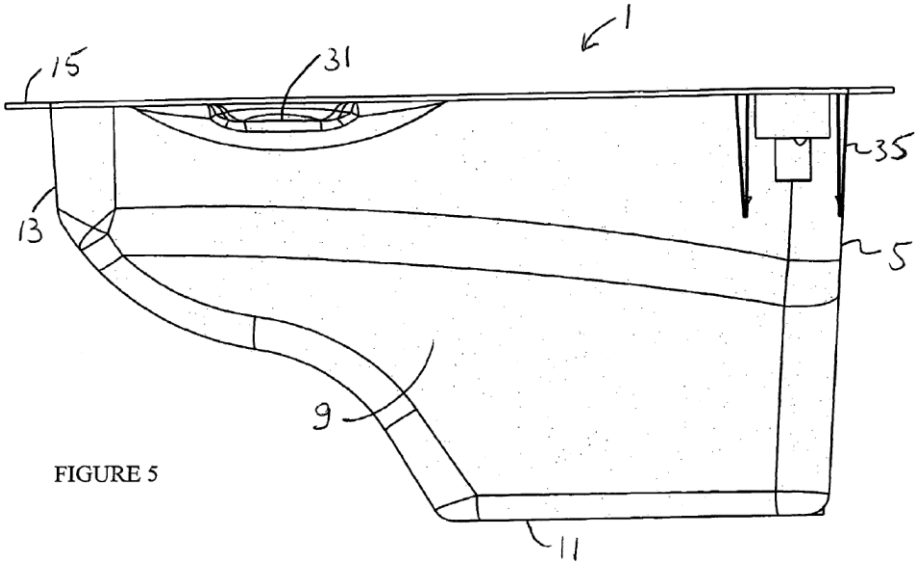


FIGURE 5

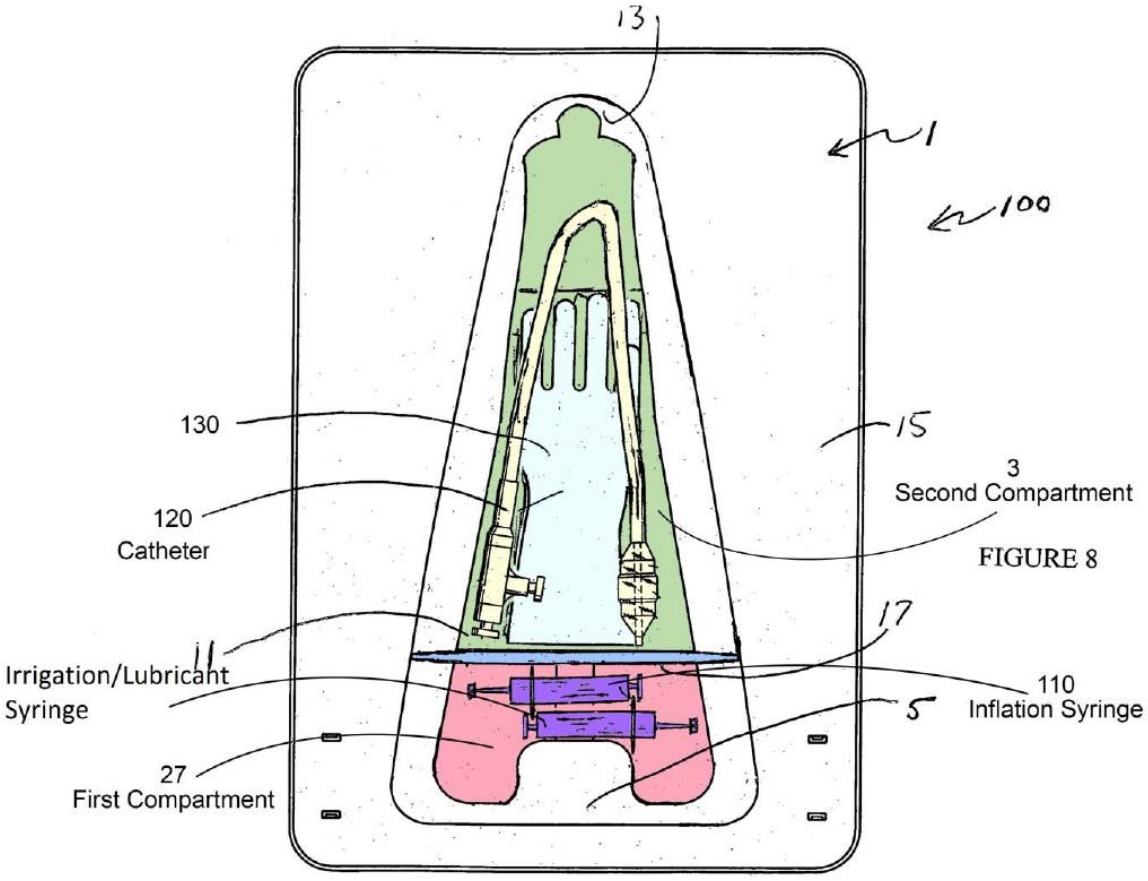
Solazzo's Figure 5 is a side view of the tray shown in Figure 2. *Id.* at 3:40–41. Based upon our review of Solazzo's figures and textual description, we are not persuaded that Solazzo's sloped bottom 11 is configured to support two syringes at different heights within recess 3 based upon the order in which those syringes should be used. Instead, we determine that two syringes placed in Solazzo's recess 3 when tray 1 rests upon bottom 11, without other items, would simply fall to the same elevation, portion 11a of bottom 11. We discern no contour or shape to bottom 11 that would support a syringe at portion 11b absent some other means of support.

Solazzo's Figure 8 depicts tube 140 as positioned in upper portion 11b of tray 1. However, tube 140 is held in place, if at all, by catheter 120 and gloves 130 within recess 3. Stated another way, tube 140 is neither supported nor held at an elevated position in portion 11b by bottom 11. Accordingly, we determine that Solazzo's bottom 11 fails to meet the requirements of claim 1 of "a first compartment supporting a first syringe and a second syringe at different heights based upon order of use in a Foley catheterization procedure." We also conclude that the combined teachings of Solazzo and Serany do not account for that requirement.

We also note that the record before us demonstrates that at least one focus of the invention set out in the '761 patent lies in the particular arrangement of components within a catheterization tray. In claim 1, as discussed above, that arrangement includes positioning syringes in a particular manner based on their order of use during a catheterization procedure. The arrangement additionally includes positioning the two

syringes in a compartment that is different from a compartment that receives a Foley catheter.

Petitioner argues that it would have been obvious to place two syringes in Solazzo's compartment 27, and provides its own illustration of such an arrangement in a figure that is modified rather extensively from Solazzo's Figure 8. Pet. 41–42. We reproduce Petitioner's modified figure below.



Petitioner's modified version of Solazzo's Figure 8 illustrates two syringes within compartment 27. *Id.*; Ex. 1002 ¶¶ 168–170. Solazzo, however, never expressly describes placing two syringes or even tube 140 within compartment 27. Petitioner proposes two alternative theories in the creation of the above-reproduced figure. One of those theories involves

modification of Solazzo's tube of lubricant fluid 140 into a syringe and then transferring that tube from compartment 3 to compartment 27. Notably, Solazzo does not itself suggest that the location of tube 140 within compartment 3 is deficient or inadequate. Having considered the record that has developed during trial, Petitioner's proposed placement of the tube, whether in the form of a syringe or a tube, within compartment 27 appears premised on a hindsight biased attempt to account for requirements of claim 1 rather than on what a skilled artisan would have taken from the teachings of the prior art. *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017) ("[W]e cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.")

Petitioner also contends that Solazzo expressly describes that its catheterization/irrigation tray kit includes two syringes, inflation syringe 110 and an irrigation syringe. Pet. 40 (citing Ex. 1005, 3:15–24). Although Petitioner acknowledges that Solazzo does not expressly describe where the irrigation syringe is located within recessed area 3, Petitioner contends that compartment 27 is the "natural place to store the irrigation syringe because it already holds the inflation syringe." *Id*. at 41. That contention amounts simply to argument of counsel without citation to record evidence. Argument of counsel, however, cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). The contention also appears speculative especially given that Solazzo describes placing tube 140 in one compartment (recess 3) while inflation syringe 110 is placed in the other compartment (overflow compartment 27) of Solazzo's "divider wall" embodiment. Ex. 1005, Fig. 8.

In view of the above, it appears that Petition's contention is a product of hindsight bias rather than being based on what a skilled artisan would have understood from the teachings of the prior art.

(2) Imai

At the outset, we observe that no reference characterized as "Imai" is presented as a part of any ground of unpatentability proposed by Petitioner to claims of the '761 patent.[14] The Petition limits its brief presentation of Imai to Imai's Figure 1 showing what appears to be three syringes grouped together. Based on Imai's Figure 1, Petitioner contends that a person of ordinary skill in the art would have derived motivation to group two syringes together in a compartment separate from a Foley Catheter (Pet. 43) and also to support the syringes "at different heights based upon order of use in a Foley catheterization procedure" as required by claim 1. *Id.* at 46 (emphasis omitted). Petitioner provides no further citation to Imai's teachings and instead cites solely to the testimony of Mr. Plishka (Ex. 1002 ¶¶ 173–174, 185–187) and Dr. Edward Yun (Ex. 1003 ¶ 28) to support the above-noted contentions. To convey how syringes would be arranged in a catheterization kit, Mr. Plishka simply points to the same teachings in Serany pertaining to arranging components generally in a "logical step-by-step order" that we found unpersuasive above. Dr. Yun makes no mention of Imai and provides no citation to record evidence to support his testimony.

Patent Owner contends the following:

[14] Evidently, the reference to "Imai" on pages 43 and 46 of the Petitioner is to Japanese Patent No. JP-A-2007-229520 (Ex. 1011 with an English translation at Ex. 1012).

> Imai's disclosure has nothing to do with catheterization trays but instead relates to an epidural anesthesia kit that would be used by an anesthesiologist, not a nurse placing a urinary catheter. The disclosed syringes are not used in a catheterization procedure, but for aspirating antiseptic solution of injecting anesthetic into the patient, and in any case Imai does not describe any arrangement relating to order of use.

PO Resp. 27–28 (citing Ex. 1012 ¶ 29, Abstract; Ex. 2038 ¶¶ 106, 107, 118).

Like Patent Owner, we question why Figure 1 of Imai depicting particular components of an epidural anesthesia kit would have provided motivation or reason to configure the tray of a catheterization kit such as to arrange components within it in a particular manner. We find credible the testimony of Patent Owner's declarant, Dr. Sher Paul Singh (Ex. 2038) discounting Petitioner's basis for relying on Imai. *See* Ex. 2038 ¶¶ 106, 107, 118. We conclude that Petitioner's reliance on Imai is vague, inadequately supported, and does not explain persuasively why or how Imai's teachings would have suggested to a person of ordinary skill in the art to arrange syringes in a compartment distinct from a Foley catheter with the syringes positioned at different heights based upon their order of use. We are not persuaded that Petitioner accounts appropriately for elements 1[b] and 1[c] through its references to Imai.

b) Element 1[e]

Element 1[e] requires "the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter." We conclude that Petitioner has not carried its burden to prove that element 1[e] would have been obvious based on the teachings of Solazzo, Serany, and Franks-Farah.

In the context of claim 1 as a whole, the first compartment must be configured to support two syringes and also define a lubricating jelly

application chamber. Thus, because Petitioner takes the approach that compartment 27 would receive two syringes, Petitioner must also rely on that compartment as forming a lubricating jelly application chamber. As seen, for instance, in Solazzo's Figures 1 and 5 (reproduced below), divider wall 17 defines two compartments within recess 3, one of which is compartment 27.

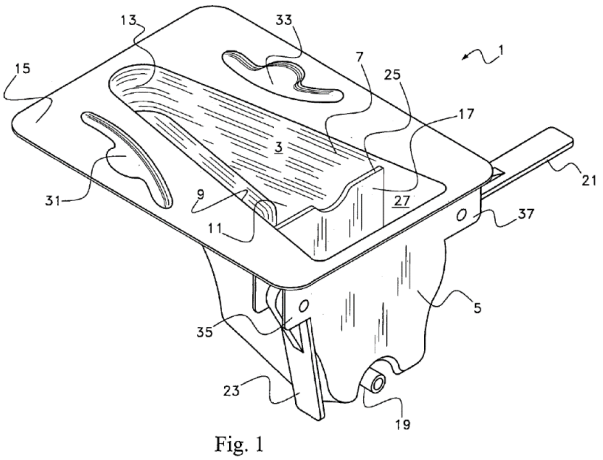


Fig. 1

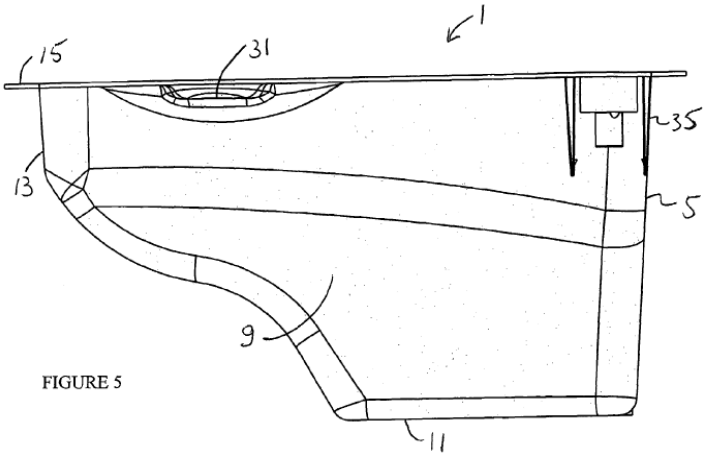


FIGURE 5

Figures 1 and 5 above depict, respectively, a top perspective view and a side elevation view of a catheterization/irrigation tray. Ex. 1005, 3:31–33. Solazzo provides no description of compartment 27 as being configured to apply lubricating jelly. Instead, Solazzo describes that "fluids will over flow into compartment 27 rather than spill over flange 15." *Id*. at 4:18–20. To accomplish that purpose of serving as an overflow receptacle, compartment 27 is structured to be notably deeper than the other formed compartment and includes bottom 11 with access to drain 19. *Id.* at 4:10–15; Figs. 1, 5. Solazzo also expressly describes areas for applying lubricating jelly as follows:

> Optional Foley catheter lubricating wells 31 and 33 are available for right handed and left handed users so that lubricating material could be applied to the catheter or other

> insertion device by filling the well with lubricant and then sliding the device through the lubricant in the well.

Id. at 4:21–25.

Thus, Solazzo depicts and explains that lubricating wells 31, 33 are shallow compartments arranged on the surface of flange 15 at the top of the tray and are structured to permit a Foley catheter to be "slid[]" through so as to apply lubrication. There is a clear incongruity in Petitioner's approach that sees a lubricating jelly application chamber emerge, not from either of the dedicated wells 31, 33, which were expressly disclosed and configured to serve as lubrication chambers, but instead from compartment 27, which was designed specifically to receive overflow of fluids, such as urine.

The '761 patent also provides insight into the type of structure the inventors associated with a lubricating jelly application chamber. Figure 2 of the '761 patent is reproduced below.

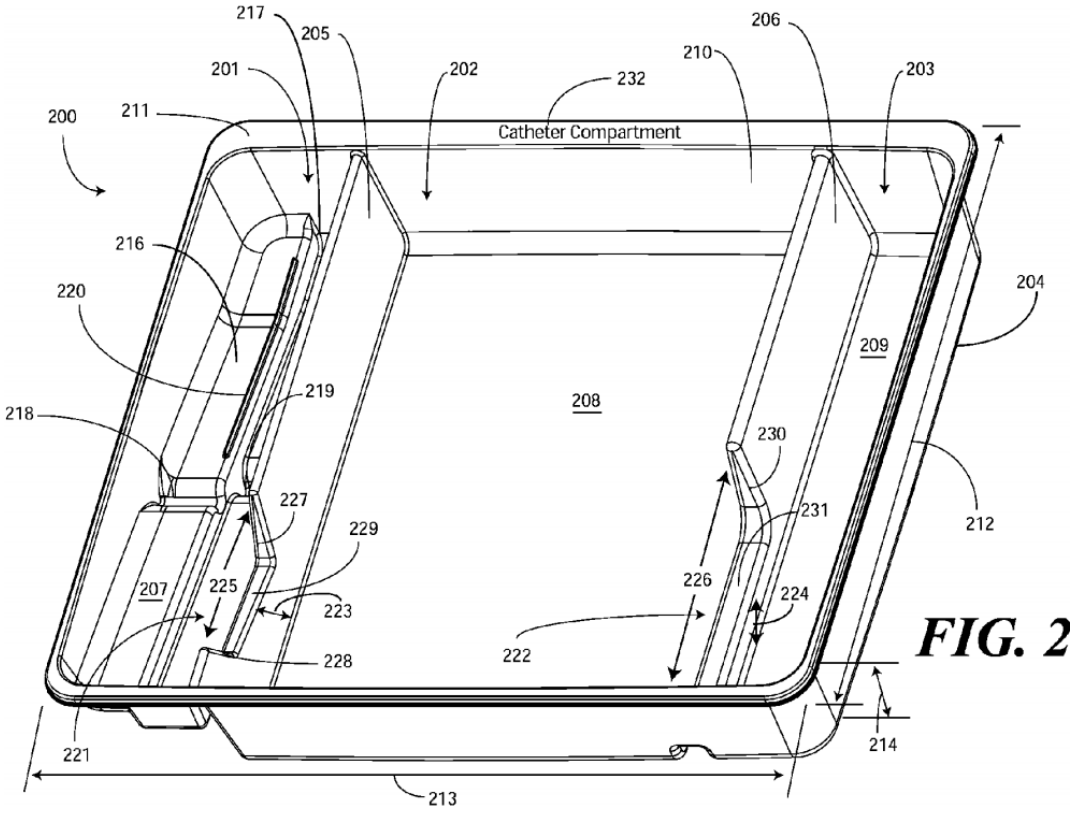


FIG. 2

Figure 2 above "illustrates an embodiment of a tray for use in a catheter procedure kit." Ex. 1001, 2:9–11. Tray 200 includes first compartment 201 separated from second compartment 202 by barrier 205. *Id.* at 7:9–13. Compartment accommodates syringes and includes a stair-stepped contour 215 (not numbered in Figure 2) with first step portion 216 and second step portion 217, with the step portions arranged at different heights. *Id.* at 8:1–7. The '761 patent further explains the following:

> [T]he medical services provider may dispense the lubricating jelly along the second step portion 217. As the second step portion 217 is lower in the tray 200 than the first step portion 216, the second step portion 217 serves as a channel in which the lubricating jelly may spread. A health care services provider may then pass the catheter through the first opening 221, through the channel formed by the second step portion 217, i.e., along the second step portion 217 through the dispense lubricating jelly to the catheter when compared to prior solutions.

Id. at 9:36–45.

Thus, the '761 patent describes a type of lubricating jelly application chamber (step portion 217) as being configured as a "channel" through which a catheter is passed before catheterizing the patient. In our view, such description suggests a lubricating application chamber with structural characteristics of a shallow channel near the top portion of the tray that is easily accessible and facilitates easy transmission of a catheter through lubricating jelly to a patient.

We are mindful of Dr. Yun's testimony (Ex. 1003 ¶¶ 21–22) on which Petitioner relies in advocating that "practitioners place lubricant in many different locations on a tray depending on user preference." Pet. 49. Dr. Yun's testimony, however, is general in nature, and he does not testify that a person of ordinary skill in the art would have regarded the bottom of a

deep compartment for collecting urine overflow (such as Solazzo's compartment 27) as a location suitable for, or a compartment configured to permit, application of lubricating jelly to a catheter. We also are mindful that Petitioner bases its position in large part on Solazzo's use of the term "[o]ptional" in describing lubricating wells 31, 33. Pet. 49 (citing Ex. 1005, 4:21–25). In Petitioner's view, that expression of "[o]ptional" means that both wells can be omitted entirely. We consider a more natural reading to be that the "[o]ptional" nature of "lubricating wells 31, 33 [that] are available for right handed and left handed users" means that a user of the tray would use either well 31 *or* well 33 depending on whether the user is right or left handed. Our reading undermines Petitioner's position that Solazzo's overflow compartment 27 forms a lubricating jelly application compartment.

In any event, irrespective of how one reads the above-discussed "optional" term, we consider that, in the context of catheterization procedures and components used in such procedures, it is unreasonable to view any given chamber of a catheterization tray as forming a lubricating jelly application chamber regardless of its structural configuration. Patent Owner points to testimony of its declarant, Ms. Chiappetta, (PO Resp. 37), who testifies that a skilled artisan would not have regarded Solazzo's compartment 27 as a lubricating jelly application chamber because of its structural dissimilarity to Solazzo's expressly disclosed lubrication wells 31, 33 and because compartment 27 is structured to be "relatively deep for collection of urine." Ex. 2039 ¶ 174. Patent Owner also relies on Ms. Chiappetta's testimony (PO Resp. 37) that compartment 27 would not have been viewed as lubricating jelly application chamber because "a clinician often needs to either test the urine or fluid collected in a catheterization

process or measure the collected fluid's volume. Having lubrication in the portion of the tray that collects the urine will contaminate the urine, invalidating the test, and potentially ruining the volume measurement." Ex. 2039 ¶ 176. The testimony of Dr. Singh, on which Patent Owner also relies (PO Resp. 38), is in accord with that of Ms. Chiappetta. To that end, Dr. Singh is also of the view that the nature of the use of divider wall 17 to form Solazzo's compartment 27 and its purpose to accommodate urine overflow renders it unsuitable as a lubricating jelly application chamber. Ex. 2038 ¶ 125. We find the testimony of Ms. Chiappetta and Dr. Singh to be persuasive.

Accordingly, Petitioner does not persuade us that Solazzo's compartment 27 constitutes "the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter" required by claim 1.

c) Summary — Claim 1

For the foregoing reasons, we conclude that Petitioner has not demonstrated by a preponderance of evidence that the combined teachings of Solazzo, Serany, and Franks-Farah describe or suggest elements 1[b], 1[c], and 1[e]. Thus, we are not persuaded that Petitioner has met its burden to show by a preponderance of evidence that claim 1 is unpatentable.

5. Independent claim 10

Independent claim 10 recites:

10. A Foley catheter container, comprising:

[a] a single layer tray comprising a surface defining at least two compartments separated by a barrier, the at least two compartments comprising:

> [b] a first compartment comprising a first compartment base member, the first compartment to accommodate a first syringe and a second syringe;
>
> [c] a second compartment comprising a second compartment base member;
>
> [d] the Foley catheter, situated in the second compartment;
>
> [e] the barrier separating the first compartment from the second compartment;
>
> [f] the first compartment base member situated at a different height within the tray than the second compartment base member;
>
> [g] the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray;
>
> [h] further comprising a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter applied to a patient.

Ex. 1001, 28:61–29:16 (with added letter designations a–h to ease discussion).

Claim 10 shares some similar limitations with claim 1. As with claim 1, Petitioner contends that claim 10 is unpatentable over Solazzo, Serany, and Franks-Farah. Pet. 66–71. Patent Owner disagrees. PO Resp. 39 (referencing in-part arguments made in connection with elements 1[b], 1[c], and 1[e]). Similar to claim 1, claim 10 requires a tray with at least two compartments, one to accommodate two syringes and one in which a Foley Catheter is situated (elements 10[b] and 10[c]). For reasons discussed above with respect to those similar features of elements 1[b], 1[c], and 1[e], we are not persuaded that Petitioner has carried its burden to prove

that the proposed combination of Solazzo, Serany, and Franks-Farah teaches all the elements required by claim 10.[15]

Claim 10 further requires that the "first compartment defin[es] a lubricating jelly application chamber to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray" (element 10[g]). Petitioner does not provide a persuasive explanation as to how Solazzo's structure permits passing a catheter from compartment 3 into compartment 27 in order to lubricate the catheter at the bottom of compartment 27. Divider wall 17 serves to divide these two compartments. *See* Ex. 1005, Fig. 1. Petitioner argues that because divider wall 17 has a lower height than flange 15 and includes a notch, the catheter could pass from compartment 3 to compartment 27 and rest on the notch. Pet. 70. But we are not persuaded that the relatively narrow and deep compartment 27 would permit lubrication of a tube that is passing over divider wall 17. For that reason also, we are not persuaded that Petitioner's proposed combination of Solazzo, Serany, and Franks-Farah teaches all the elements of claim 10. Accordingly, we are not persuaded that Petitioner has shown by a preponderance of evidence that claim 10 is unpatentable as obvious.

[15] Although there are some differences in claim language, we conclude that claim elements 10[b], 10[c], and 10[e] correspond to elements 1[b], 1[c], and 1[e] with the exception that the requirement in 1[b] pertaining to supporting syringes at different heights based on their order of use is missing from element 10[b].

6. Dependent claims 2–9, 11, 13, and 14

Claims 2–4 and 6–9 ultimately depend from claim 1. Claims 11, 13, and 14 ultimately depend from claim 10. Petitioner also identifies where it believes all the added features of those dependent claims are found in the prior art. Pet. 54–60, 62–65, and 71. Because we conclude that Petitioner has failed to demonstrate obviousness by a preponderance of evidence for either of independent claims 1 or 10, we reach the same conclusion with respect to dependent claims 2–9, 11, 13, and 14. *See Mylan Pharms. Inc. v. Research Corp. Techs., Inc.*, 914 F.3d 1366, 1376 (Fed. Cir. 2019) ("Dependent claims, with added limitations, are generally not obvious when their parent claims are not.") (citing *W.L. Gore & Assocs., Inc., v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983)).

7. Claims 15–18

Independent claim 15 reads as follows:

15. A tray for a Foley catheter, comprising:

[a] A single-layer surface defining at least two compartments separated by a barrier, the at least two compartments comprising:

[b] a first compartment comprising a base member, the first compartment accommodating a first syringe and a second syringe;

[c] a second compartment accommodating the Foley catheter; and

[d] the barrier separating the first compartment from the second compartment;

[e] the base member defining a mnemonic device indicating which of the first syringe or the second syringe should be used to dispense lubricating jelly disposed in one of the first syringe or the second syringe into the first compartment;

> [f] the first compartment defining a lubricating jelly application compartment to lubricate the Foley catheter with the lubricating jelly from the one of the first syringe or the second syringe when at least a portion of the Foley catheter is passed from the second compartment into the first compartment while remaining within a perimeter defined by the single-layer surface;
>
> [g] further comprising information, disposed on a first portion of a patient aid, for caring for the Foley catheter when applied to a patient.

Ex. 1001, 29:33–58 (with added letter designations a–g to ease discussion).

Petitioner argues that claims 15–18 are unpatentable over Solazzo, Serany, and Franks-Farah. Like claim 1, claim 15 requires a tray including at least two compartments with one compartment accommodating a first and second syringe and a second compartment accommodating a Foley catheter (elements 15[b] and 15[c]). Claim 15 also requires "the first compartment defining a lubricating jelly application compartment to lubricate the Foley catheter with the lubricating jelly from the one of the first syringe or the second syringe when at least a portion of the Foley catheter is passed from the second compartment into the first compartment . . ." (element 15[f]). For reasons discussed above with respect to claim 1, we are not persuaded that Petitioner has carried its burden to demonstrate that the proposed combination of Solazzo, Serany, and Franks-Farah teaches elements 15[b], 15[c], and 15[f].[16] Also, similar to claim 10, the lubricating jelly application

[16] Although there are some differences in claim language, we conclude that claim elements 15[b], 15[c], and 15[f] correspond to elements 1[b], 1[c], and 1[e] with the exception that the requirement in 1[b] pertaining to supporting syringes at different heights based on their order of use is missing from element 15[b]. As discussed below, however, claim 15[e] includes a related requirement in connection with a "mnemonic device" feature.

compartment of claim 15 must facilitate lubrication of the Foley catheter when at least a portion of it "is passed from the second compartment into the first compartment." For the reasons discussed in connection with claim 10, such requirement further distinguishes the structure recited in claim 15 from the structure of Solazzo's compartment 27.

Claim 15 additionally requires that the base member of the first compartment "defin[es] a mnemonic device indicating which of the first syringe or the second syringe should be used to dispense lubricating jelly disposed in one of the first syringe or the second syringe into the first compartment" (element 15[e]). Petitioner contends that such "mnemonic device" limitation is met based on the teachings of Solazzo and Serany, which, according to Petitioner, convey that Solazzo's "syringes could be ordered by height in the first compartment 27 due to that compartments inclined nature." Pet. 73. It is apparent that Petitioner likens the "mnemonic device" (element 15[e]) aspect of claim 15 to the syringes "at different heights based upon order of use" (element 1[b]) aspect of claim 1. *Id*. For reasons discussed above with respect to element 1[b], we are not persuaded that Petitioner carried its burden to establish that element 15[e] is taught by the cited art.

Accordingly, we conclude that Petitioner has not shown by a preponderance of evidence that claim 15 or its dependent claims 16–18 are unpatentable based on the combined teachings of Solazzo, Serany, and Franks-Farah.

8. Claim 19

Claim 19 recites:

19. A single-layer tray, comprising:

> [a] a surface defining at least two compartments separated by a barrier, the at least two compartments comprising:
>
> [b] a first compartment to support a first syringe and a second syringe, the first compartment comprising one or more recesses for accommodating flanges of one or more of the first syringe or the second syringe;
>
> [c] a second compartment to accommodate a Foley catheter;
>
> [d] the first syringe and the second syringe, situated in the first compartment;
>
> [e] the Foley catheter, situated in the second compartment;
>
> [f] the barrier separating the first compartment from the second compartment;
>
> [g] the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter;
>
> [h] further comprising pose-procedure information for caring for the Foley catheter when applied to a patient, wherein the post procedure information is disposed on a first portion of a patient aid.

Ex. 1001, 30: 14–33 (with added letter designations a–h to ease discussion).

Claim 19 requires features similar to those discussed above with respect to claim 1. Claim 19 requires a tray with two syringes situated in a first compartment and a Foley catheter situated in a second compartment (elements 19[b], 19[c], 19[d], and 19[e]). Claim 19 also requires that the first compartment defines a lubricating jelly application chamber (element 19[g]). Thus claim 19, like claim 1, requires two syringes situated in one compartment and a Foley catheter situated in a different compartment. Claim 19 also requires that the first compartment define a lubricating jelly application chamber. For reasons discussed above with respect to those similar features of elements 1[b], 1[c], and 1[e], we are not persuaded that

Petitioner has carried its burden to prove that the proposed combination of Solazzo, Serany, and Franks-Farah teaches all the elements required by claim 19.[17] Thus, we are not satisfied that Petitioner has shown by a preponderance of evidence that claim 19 is unpatentable based on the combined teachings of Solazzo, Serany, and Franks-Farah.

9. Claims 23–25

Claims 23–25 ultimately depend from claim 19. Petitioner also contends that those claims are unpatentable over Solazzo, Serany, and Franks-Farah. *See*, *e.g*., Pet. 31. Petitioner has not demonstrated obviousness by a preponderance of evidence for independent claim 19, and we reach the same conclusion with respect to dependent claims 23–25. *See Mylan Pharms. Inc.*, 914 F.3d at 1376.

10. Objective Indicia of Non-Obviousness

Our evaluation of the first three *Graham* factors leads us to determine that Petitioner has not demonstrated that the challenged claims would have been obvious in view of the cited art. The Federal Circuit has found it unnecessary to consider arguments relating to objective indicia of non-obviousness when the patent challenger failed to establish obviousness. *See Otsuka Pharmaceutical Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("Because we agree with the district court that the Defendants failed

[17] Although there are some differences in claim language, we conclude that claim elements 19[b] and [d], 19[c] and [e], and 19[g] correspond to elements 1[b], 1[c], and 1[e] with the exception that the requirement in 1[b] pertaining to supporting syringes at different heights based on their order of use is missing from element 19[b].

to prove that claim 12 of the '528 patent would have been prima facie obvious over the asserted prior art compounds, we need not address the court's findings regarding objective evidence of nonobviousness."); *Palo Alto Networks, Inc. v. Finjan, Inc.*, 748 F. App'x 317, 324 (Fed. Cir. 2018) ("The Board, having found that Finjan had failed to carry its burden of showing that the instituted prior art disclosed [a particular] limitation, did not reach the issue of secondary considerations of nonobviousness. Therefore, it was not necessary for the Board to consider Dr. Bims's testimony, which was limited to the issue of secondary considerations of nonobviousness.").

Accordingly, although we have considered the entirety of the record before us, we conclude that it is unnecessary in this proceeding to address Patent Owner's objective indicia of non-obviousness.

E. Obviousness in View of Solazzo, Serany, Franks-Farah, and Disston

Petitioner challenges dependent claims 3, 12, 22, and 24 as being unpatentable over Solazzo, Serany, Franks-Farah, and Disston. Pet. 78–86. Claim 3 ultimately depends from claim 1. Claim 12 ultimately depends from claim 10. Claim 22 depends from claim 19. Claim 24 ultimately depends from claim 19. Petitioner does not rely on Disston to remedy any of the above-discussed deficiencies in connection with Petitioner's challenges to the patentability of claims 1, 10, and 19. Accordingly, for the reasons already discussed, we also are not persuaded that Petitioner has shown by a preponderance of evidence that claims 3, 12, 22, and 24 are unpatentable. *See Mylan Pharms. Inc.*, 914 F.3d at 1376.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not met its burden to show by a preponderance of the evidence that (1) 1, 2, 4–11, 13–19, 23, and 25 are unpatentable over Solazzo, Serany, and Franks-Farah, and (2) claims 3, 12, 22, and 24 are unpatentable over Solazzo, Serany, Franks-Farah, and Disston.

In summary,

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 4–11, 13–19, 23, 25	103	Solazzo, Serany, Franks-Farah		1, 2, 4–11, 13–19, 23, 25
3, 12, 22, 24	103	Solazzo, Serany, Franks-Farah, Disston		3, 12, 22, 24
Overall Outcome				1–19, 22–25

IV. ORDER

For the reasons given, it is:

ORDERED that Petitioner has failed to establish based on a preponderance of evidence that claims 1–19 and 22–25 of U.S. Patent 9,745,088 B2 are unpatentable as obvious under 35 U.S.C. § 103; and

FURTHER ORDERED because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Mehran Arjomand
Nicole Smith (*pro hac vice*)
Dylan James Raife (*pro hac vice*)
MORRISON & FOERSTER LLP
marjomand@mofo.com
nsmith@mofo.com
draife@mofo.com

For PATENT OWNER:

Nicholas T. Peters
Paul B. Henkelmann
Allen E. Hoover
Jon A. Birmingham
Nicole L. Little (pro hac vice)
FITCH, EVEN, TABIN & FLANNERY LLP
NtPete@fitcheven.com
PHenkelmann@fitcheven.com
AHoover@fitcheven.com
Jbirmi@fitcheven.com
NLittle@fitcheven.com

Jeffrey P. Kushan
Nathaniel C. Love (*pro hac vice*)
SIDLEY AUSTIN LLP
jkushan@sidley.com
nlove@sidley.com