

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,
Patent Owner.

IPR2019-00035
Patent 9,745,088 B2

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

WEATHERLY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a), 37 C.F.R. § 42.73

I. INTRODUCTION

A. BACKGROUND

C.R. Bard, Inc. (“Petitioner”) filed a petition (Paper 2, “Pet.”) to institute an *inter partes* review of claims 1, 2, 6–10, 16–19, and 25–44 (the “challenged claims”) of U.S. Patent No. 9,745,088 B2 (Ex. 1001, “the ’088 patent”). 35 U.S.C. § 311. Medline Industries, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 12 (“Prelim. Resp.”). Based on

our review of the record at that preliminary stage, we concluded that Petitioner was reasonably likely to prevail with respect to at least one of the challenged claims, and we therefore instituted *inter partes* review of all challenged claims on all the grounds set forth in the Petition. *See* Paper 18, 26–27.

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 103 based on the following grounds (Pet. 23–87):

Claims challenged	35 U.S.C. §	References
1, 2, 6–10, 16, 17, 25–32, 36–41	103	Solazzo, ¹ Serany ²
18, 19, 35	103	Solazzo, Serany, Franks-Farah ³
33, 34, 42	103	Solazzo, Serany, Disston ⁴
43, 44	103	Solazzo, Serany, Disston, Franks-Farah

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition. Paper 36 (“PO Resp.”). Petitioner filed a Reply in support of the Petition. Paper 55 (“Reply”). Patent Owner filed a Sur-reply. Paper 64 (“Sur-reply”). With our authorization, each party filed a brief addressing a recent decision from our reviewing court, *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019). Papers 69, 70. Patent Owner did not move to amend any claim of the ’088 patent.

¹ U.S. Patent No. 7,278,987 B2 (Ex. 1005, “Solazzo”).

² U.S. Patent No. 3,329,261 (Ex. 1006, “Serany”).

³ U.S. Patent No. 6,840,379 B2 (Ex. 1007, “Franks-Farah”).

⁴ U.S. Patent No. 3,166,189 (Ex. 1008, “Disston”).

We heard oral argument on January 6, 2020. A transcript of the argument has been entered in the record (Paper 71, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons expressed below, we conclude that Petitioner has failed to demonstrate by a preponderance of evidence that claims 1, 2, 6–10, 16–19, and 25–44 are unpatentable.

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. 90; Paper 4, 2. The parties also identify IPR2019-00036, in which Petitioner challenges claims 45–58, 60–74, 76–90, and 92 of the ’088 patent, as a related matter. *Id.* Patent Owner further identifies as related matters U.S. Patent Application Nos. 15/684,787 and 15/803,383, which are continuations of the application leading to issuance of the ’088 patent. Paper 4, 2. Patent Owner further identifies U.S. Patent Application Nos. 14/265,920; 15/804,520; 15/051,964; 13/374,509; 15/640,224; and 15/703,514 as related matters because these applications “share similar disclosures and claim language” with the ’088 patent. *Id.*

C. THE ’088 PATENT

The ’088 patent is directed to “storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices.” Ex. 1001,

1:34–37. The Specification describes tray 100 shown in Petitioner’s annotated and colorized version of Figure 7, which we reproduce below.

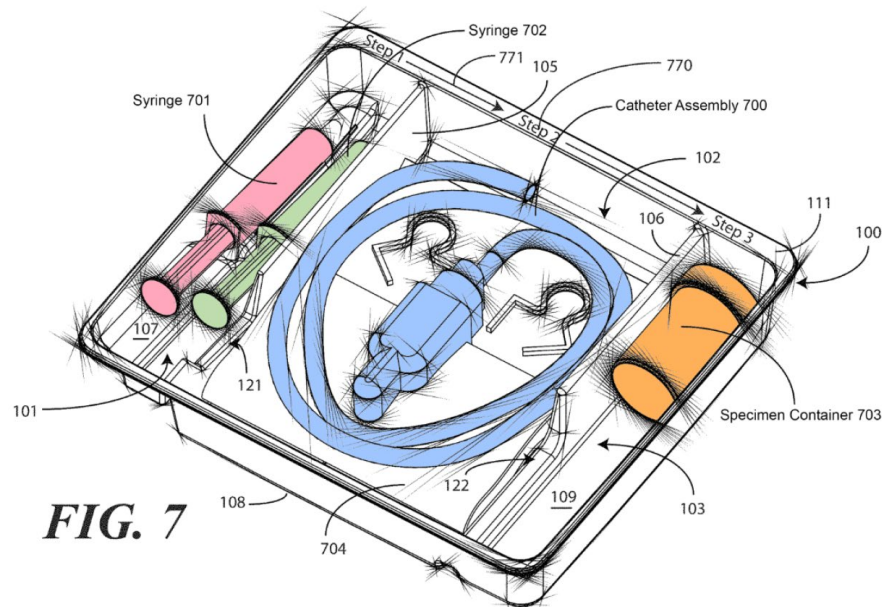


Figure 7 illustrates a catheter, two syringes, and a specimen bottle located within single-level tray 100. *Id.* at 2:45–49.

Before use, tray 100 is double-wrapped to ensure that components in the tray remain sterile up to and through their initial use with tray 100 being wrapped in CSR wrap 1000 and then outer sterile wrap 1002. *Id.* at 11:45–46; 11:51–52; Fig. 10. Tray 100 includes three compartments 101, 102, 103 adapted to receive various items used in a catheterization procedure. *Id.* at 5:12–18. First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. *Id.* at 4:18–21, 9:24–26. Second compartment 102 accommodates catheter assembly 700 (blue) and fluid bag. *Id.* at 9:26–28. Third compartment 103 accommodates specimen container 703 for capturing samples taken from the patient via catheter 700. *Id.* at 4:22–23, 5:64–65. 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 5:46–51.

Claims 1, 25, and 37 are the independent claims among the challenged claims. *Id.* at 27:47–30:57. The text of each independent claim is reproduced below in Parts II.E–II.G below respectively.

II. ANALYSIS

A. CLAIM INTERPRETATION

“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)⁵; *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 be 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

⁵ Our recently changed version of this Rule, which requires that we interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b), 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).

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).

Although Petitioner separately and expressly addresses various claim terms including: “catheter assembly” and “lubricating jelly application chamber,” Pet. 20, “medical assembly,” Reply 3–4, we do not express an opinion about the meaning of these phrases because we determine that the controversy between the parties does not require it.

B. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1, 2, 6–10, 16–19, and 25–44 on the grounds that the claims are obvious in light of various references including: Solazzo, Serany, Disston, and Franks-Farah. 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); 37 C.F.R. § 42.1(d). “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 nonobviousness. *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 a bachelor’s degree in packaging engineering, mechanical engineering, or industrial design. Pet. 18 (citing Ex. 1002 ¶¶ 14–16); PO Resp. 15 (citing Ex. 2026 ¶ 38). Alternatively, such a person could have an engineering degree in another technical field along with about two years of experience designing medical packaging. Pet. 18 (citing Ex. 1002 ¶¶ 14–16); PO Resp. 15 (citing Ex. 2026 ¶ 38). 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 consult with medical practitioners familiar with catheterization procedures. Pet. 18; PO Resp. 15 (citing Ex. 2027 ¶ 78).

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. Accordingly, we apply the level of skill set forth in the preceding paragraph.

D. OVERVIEW OF PERTINENT PRIOR ART

1. *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 below. 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. *Id.* at 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.

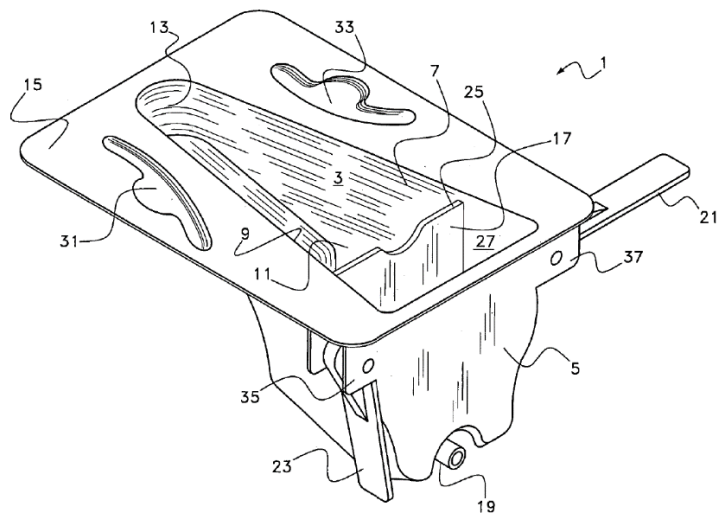
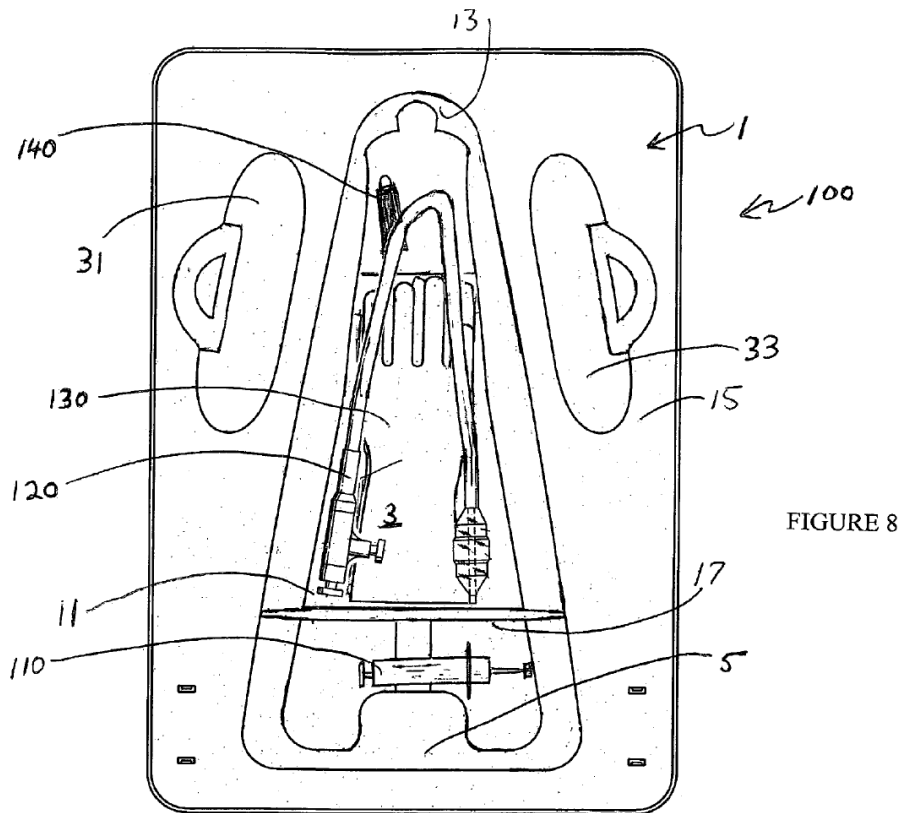
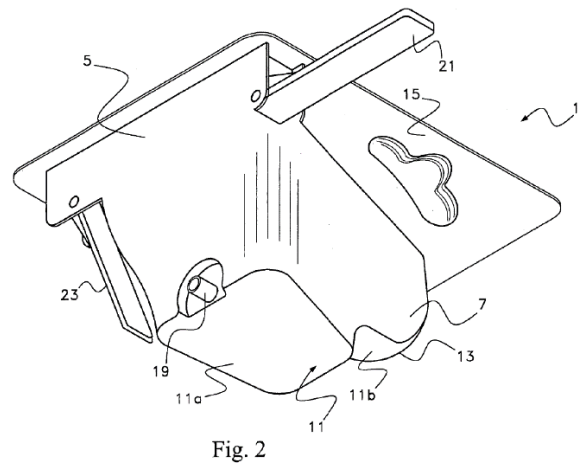


Fig. 1

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 as shown in Figure 2, reproduced at right. *Id.* at 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 3:14–24, 4:1–8; Fig. 8.



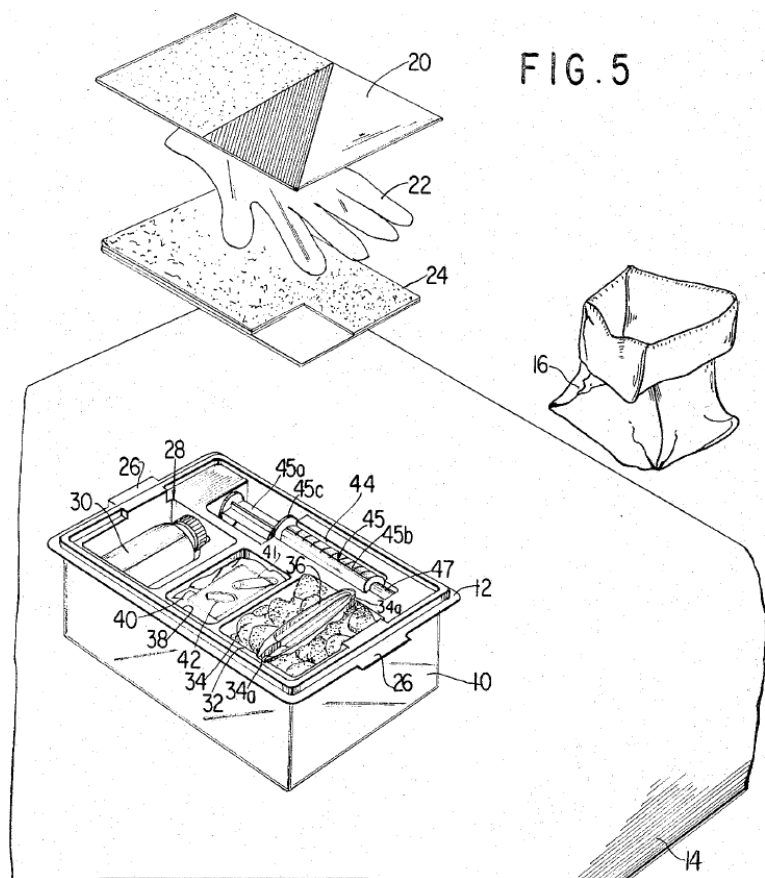
Solazzo’s Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id.* at 4:41–48.

Inflation syringe 110 is stored at low area 11A, and lubricant 140 is stored at shallow area 11B. *Id.* at 4:41–45; Fig. 8.

In use, the recessed area 3 and compartment 27 fit between the legs of a “patient requiring an urological procedure” while flange 15 and wing supports 21, 23 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. Serany

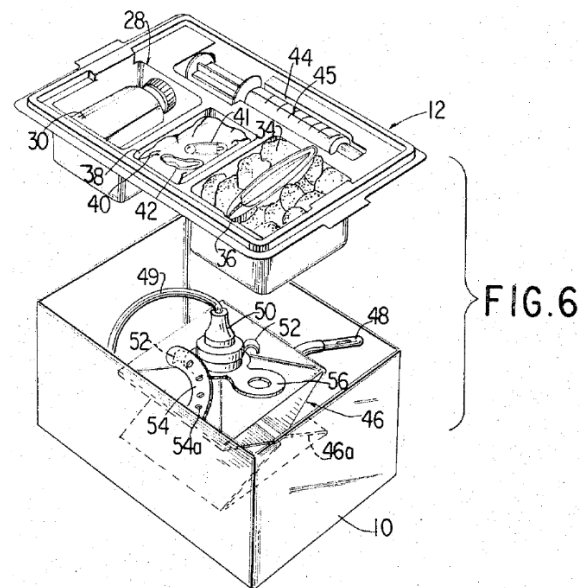
Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. Serany’s Figure 5 (reproduced at right in pertinent part) is an exploded view illustrating how various compartments are positioned within Serany’s box 10. 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.

For example, prefilled syringe 45 of sterile water in depression 44, which includes indentations 44d along the sides to accommodate the syringe's flange. *Id.* at 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–



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 Figure 6. *Id.* at 3:33–35.

E. INDEPENDENT CLAIM 1

Independent claim 1 recites:

1. A medical procedure kit, comprising:
 - [a] a tray having a compartment for receiving a medical assembly;
 - [b] a first syringe and a second syringe disposed within the tray;
 - [c] at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
 - [d] an outer packaging disposed about both the tray and the at least one layer of wrap material, wherein:
 - [e] the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and
 - [f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe; and
 - [g] the first compartment comprising a base member that defines a mnemonic device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure.

Ex. 1001, 27:47–67 (with added letter designations a–g to ease discussion).

Petitioner argues that claim 1 is unpatentable as obvious in view of the combined teachings of Solazzo and Serany. Pet. 31–49. Patent Owner argues that the combination of Solazzo and Serany fails to render independent claim 1 unpatentable as obvious. PO Resp. 16–33. For the reasons that follow, we agree with Patent Owner that Petitioner has failed to prove by a preponderance of evidence that the combination of Solazzo and Serany describes elements 1e and 1g and thus fails to establish that claim 1 is obvious. PO Resp. 24–32.

Collectively, elements 1e and 1g require two syringes that are arranged by their order of use during a catheterization procedure in one compartment that includes a base member that defines a mnemonic device that reminds the user which syringe should be used first.

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 fails to describe a second syringe. Ex. 1006, 3:6–22, Fig. 5. Based upon our review of Solazzo and Serany, we determine that neither reference describes a tray with a base member that defines a mnemonic device indicating which syringe should be used first or arranging two syringes within the tray in accordance with the order in which the syringes are used.

The pertinent portion of Figure 4 of the '088 patent (reproduced at right) illustrates the mnemonic device. Figure 4 is a front elevation view of the claimed tray.

Ex. 1001, 2:36–37. The Specification describes the mnemonic device as follows:

The stair-stepped contour 115 can be used as mnemonic device when multiple syringes are stored within the first compartment 101. For example, it may be intuitive that a syringe placed on a higher step portion may need to be used first. This intuition is further enforced when the higher step portion is disposed farther to the left in a left-to-right usage configuration. Thus, a user receives a mnemonic reminder to use a syringe disposed on the first step portion 116 prior to a syringe disposed

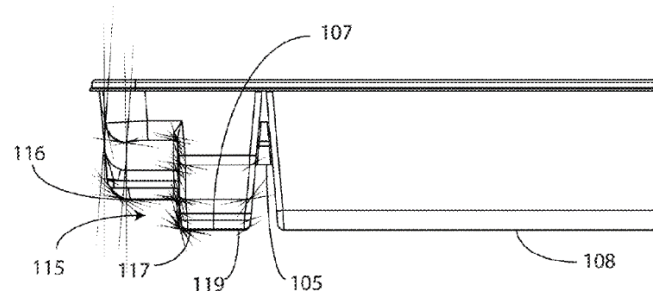


FIG. 4

on the second step portion 117, as it is both higher and farther to the left.

Ex. 1001, 6:16–25.

Figure 7, which is reproduced below, illustrates how syringes are supported in the first compartment on the base member that defines the mnemonic device according to their order of use.

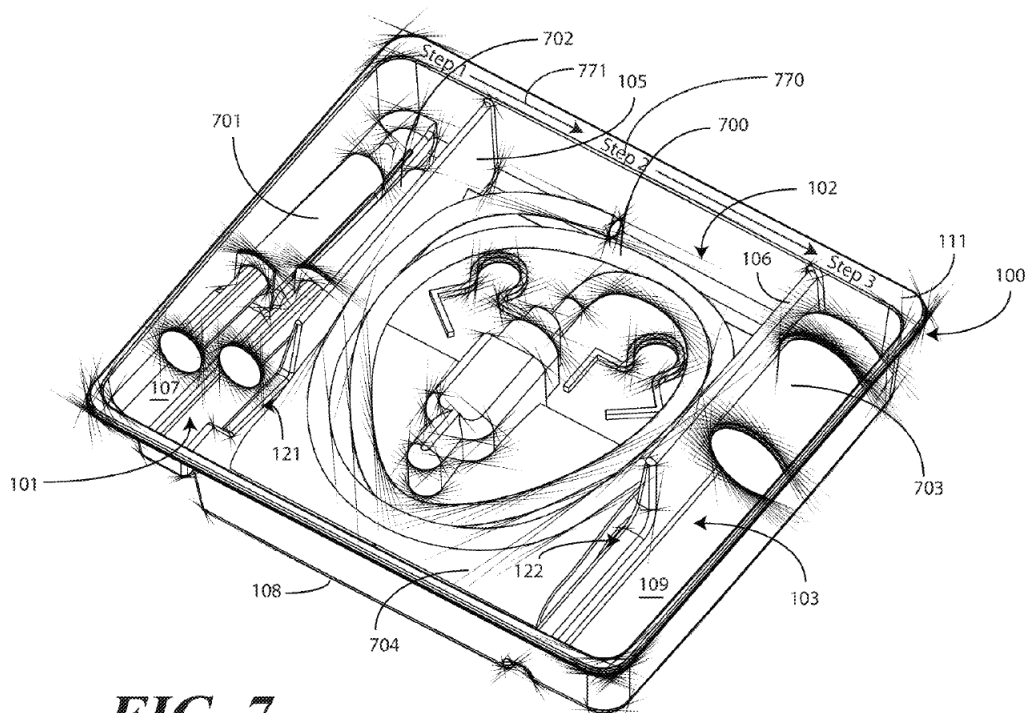
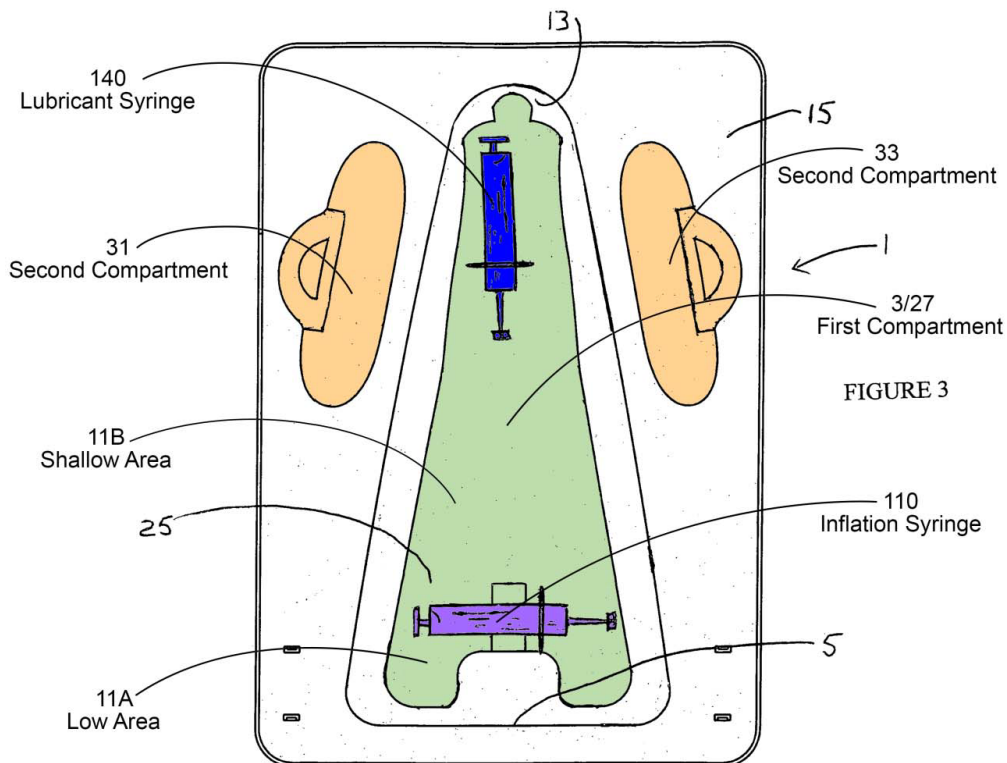


FIG. 7

Figure 7 is a right perspective view of the claimed tray holding a catheter assembly and supporting devices including two syringes. *Id.* at 2:45–49.

Base member 107 of first compartment 101 supports syringes 701, 702, such that syringe 701 is positioned higher than syringe 702 to remind the user that syringe 701 is used before syringe 702. *Id.* at 9:57–10:3. As recited in element 1f, base member 107 “support[s] the first syringe and the second syringe” within first compartment 101. *Id.* at 27:62–63.

In its proposed combination of the teachings of Solazzo and Serany as they apply to elements 1e–1g, Petitioner relies solely upon Solazzo’s so-called “no divider wall” embodiment as reflected in Petitioner’s modified, annotated, and colorized version of Solazzo’s Figure 3,⁶ which we reproduce below. Pet. 40–49.

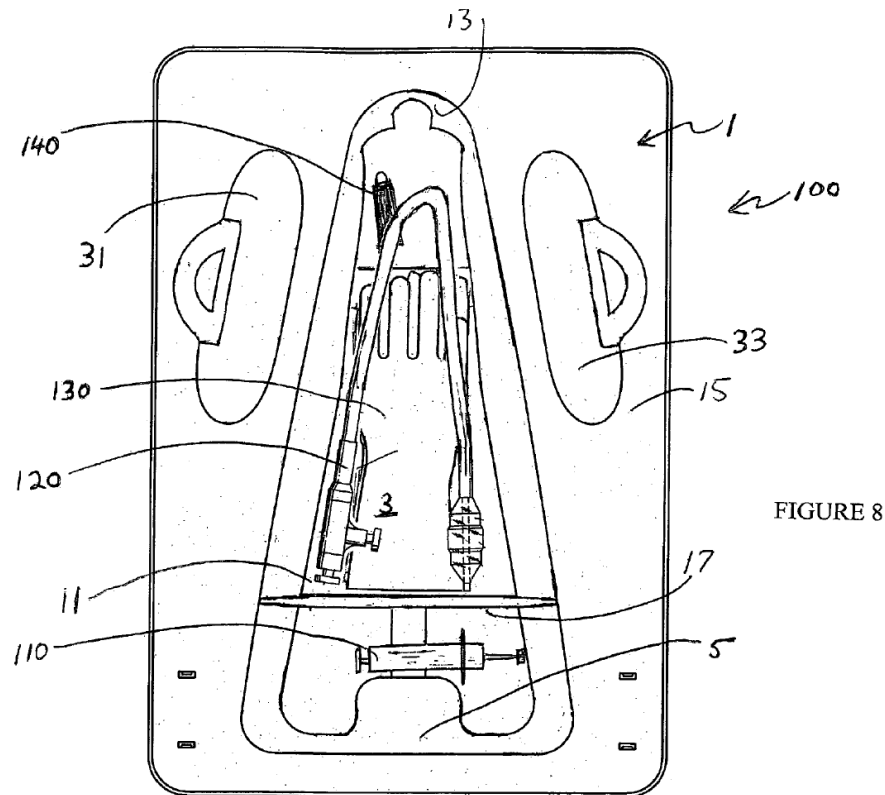


Petitioner’s modified, annotated, and colorized version of Solazzo’s Figure 3 was created by Mr. Plishka and is a plan view of Solazzo’s catheterization kit as modified by teachings from Serany. *Id.* at 41–42; Ex. 1002 ¶¶ 195–202; *see also* Ex. 1001, Fig. 3 (original version).

⁶ Petitioner contends that the figure is modified from Solazzo’s Figure 8. Pet. 41, 44–45. However, Petitioner’s figure is labeled as “FIGURE 3,” *id.*, and it appears to have been modified from Solazzo’s Figure 3, *compare id.*, with Ex. 1005, Figure 3.

Petitioner's modified figure includes "Lubricant syringe 140 [blue]," which is shown in the same location as tube 140 of lubricant illustrated in Solazzo's Figure 8. *Compare* Pet. 41, 44–45 (Petitioner's figure), *with* Ex. 1005, 4:44–45, Fig. 8 (showing "tube of lubricant fluid 140").

Petitioner relies upon Solazzo's Figure 8 as describing the position of lubricant in Solazzo's tray 1. Pet. 34.



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. 35 (citing Ex. 1002 ¶¶ 167–173). Mr. Plishka supports his opinion by citing objective evidence. Ex. 1002 ¶ 171 (citing Ex. 1010, 52; Ex. 1015). Mr. Plishka also

relies upon Dr. Yun’s testimony regarding the methods of applying lubricant during a catheterization procedure. Ex. 1002 ¶ 172 (citing Ex. 1003 ¶ 22).

Petitioner further argues that the positions of the “lubricant syringe” and “inflation syringe” shown in Petitioner’s modified version of Solazzo’s Figure 3 demonstrates that Solazzo describes two syringes that are “ordered . . . in accordance with their use” as recited in element 1e. Pet. 42.

Petitioner relies upon Mr. Plishka, who opines, without meaningful analysis or explanation or citation to any objective evidence, that because “of the ‘terraced arrangement’ of bottom 11 of compartment 3/27, Solazzo discloses that lubricant syringe 140 is placed higher in the tray than inflation syringe 140.” Ex. 1002 ¶ 200.

Petitioner argues that Solazzo’s bottom 11 meets element 1g for essentially the same reasons that it meets element 1e. Pet. 45–49 (citing Ex. 1002 ¶¶ 210–218). Mr. Plishka opines that “the *terraced* bottom member of Solazzo defines a mnemonic defines indicating which of the first syringe or the second syringe should be used first in the catheterization procedure” as recited in element 1g. *Id.* ¶ 216. We disagree with Petitioner’s argument and Mr. Plishka’s opinions on these two points because we determine that they are inconsistent with Solazzo’s disclosure.

On reply, Petitioner argues that an expert proffered by Patent Owner, Ms. Lori Chiappetta,⁷ “admitted that Solazzo discloses an order of use” during her cross-examination. Reply 7 (citing Ex. 1073, 180:2–18 but quoting only 180:2–14, 180:16–18). The entire cited passage reads as follows:

⁷ Ms. Chiappetta is a registered nurse with 15 years of experience. Ex. 2027 ¶¶ 8–9.

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 catheterization (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). Our review of this testimony reveals that Ms. Chiappetta made no such admission. Although Patent Owner did not specify the basis of its objection to the form of the question posed to Ms. Chiappetta, we note that the question 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 her 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 fails to persuade us that Ms. Chiappetta “admitted that Solazzo discloses an order of use.” Reply 7.

Whether Solazzo meets elements 1e and 1g 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).

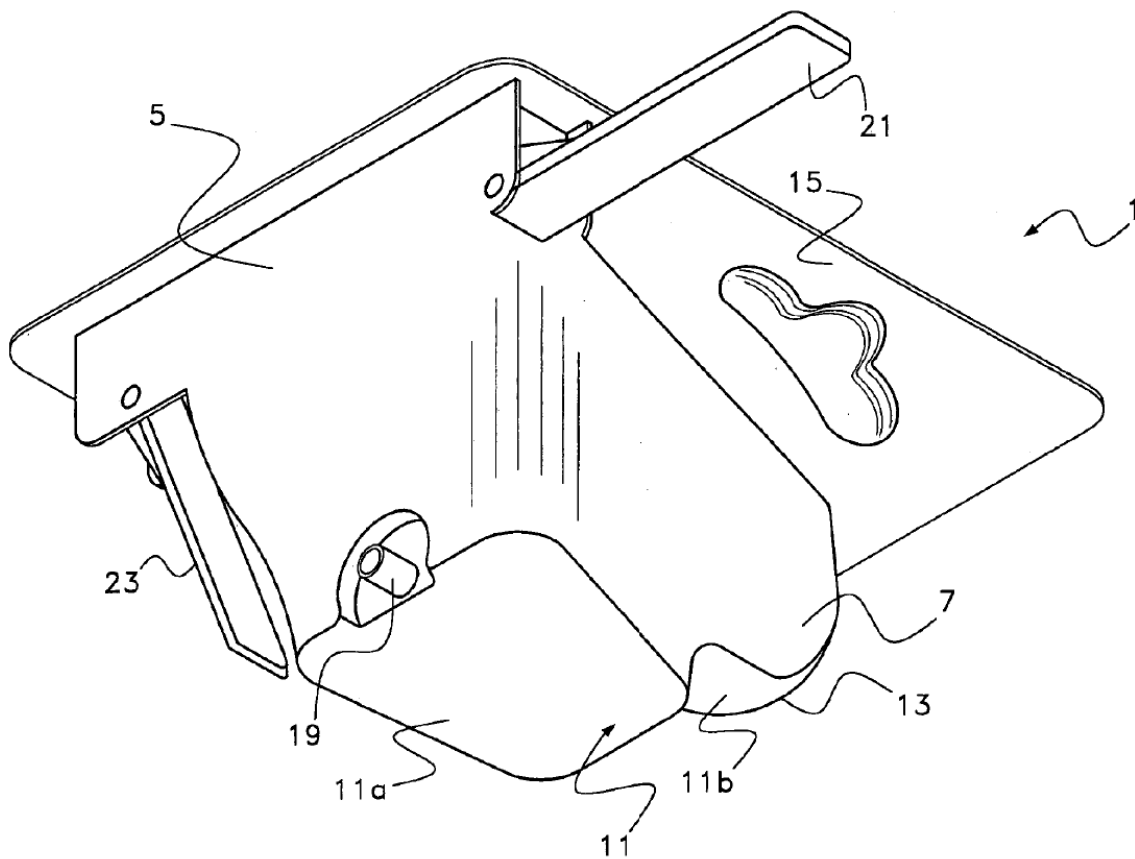
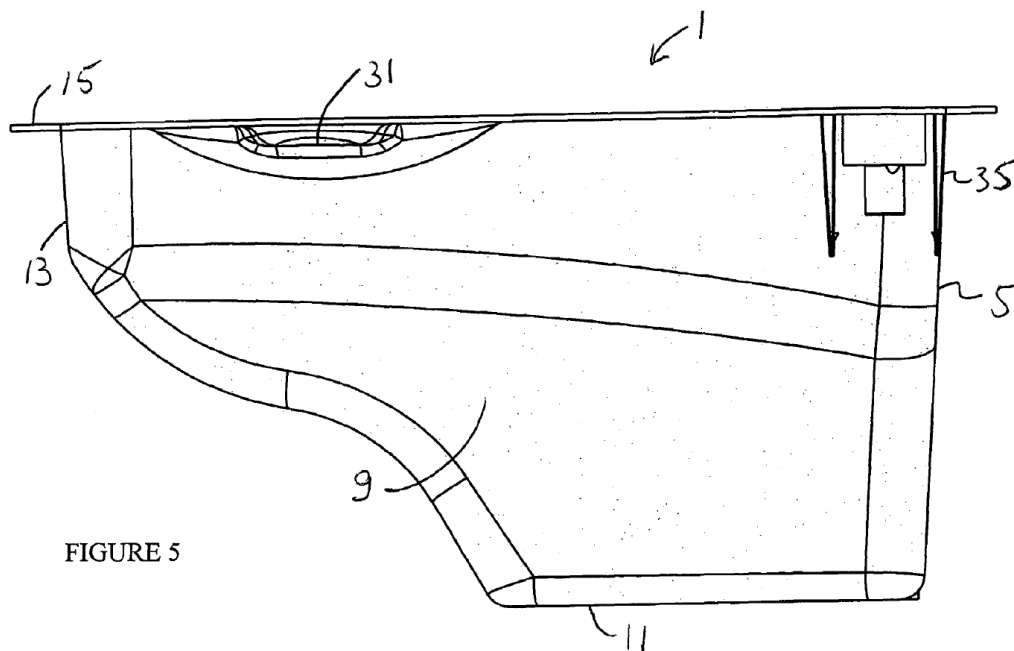


Fig. 2

Solazzo's Figure 2 is a bottom perspective view of its tray 1. Ex. 1005, 3:34–35.

Solazzo’s recess 3 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.



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 in an arrangement within recess 3 that reminds the user of 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 alone. Accordingly, we determine that Solazzo's bottom 11 fails to meet the requirements of claim 1 that the first compartment: (1) "support[s] the first

syringe and second syringe” such that the syringes “are ordered within the tray in accordance with their use,” and (2) comprises “a base member that defines a mnemonic device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure.” Based upon our review of the parties’ arguments and the evidence of record, Petitioner fails to persuade us by a preponderance of evidence that the combined teachings of Solazzo and Serany describe elements 1e and 1g. Accordingly, Petitioner’s challenge to independent claim 1 fails.

F. INDEPENDENT CLAIM 25

Independent claim 25 recites:

25. A medical procedure kit, comprising:

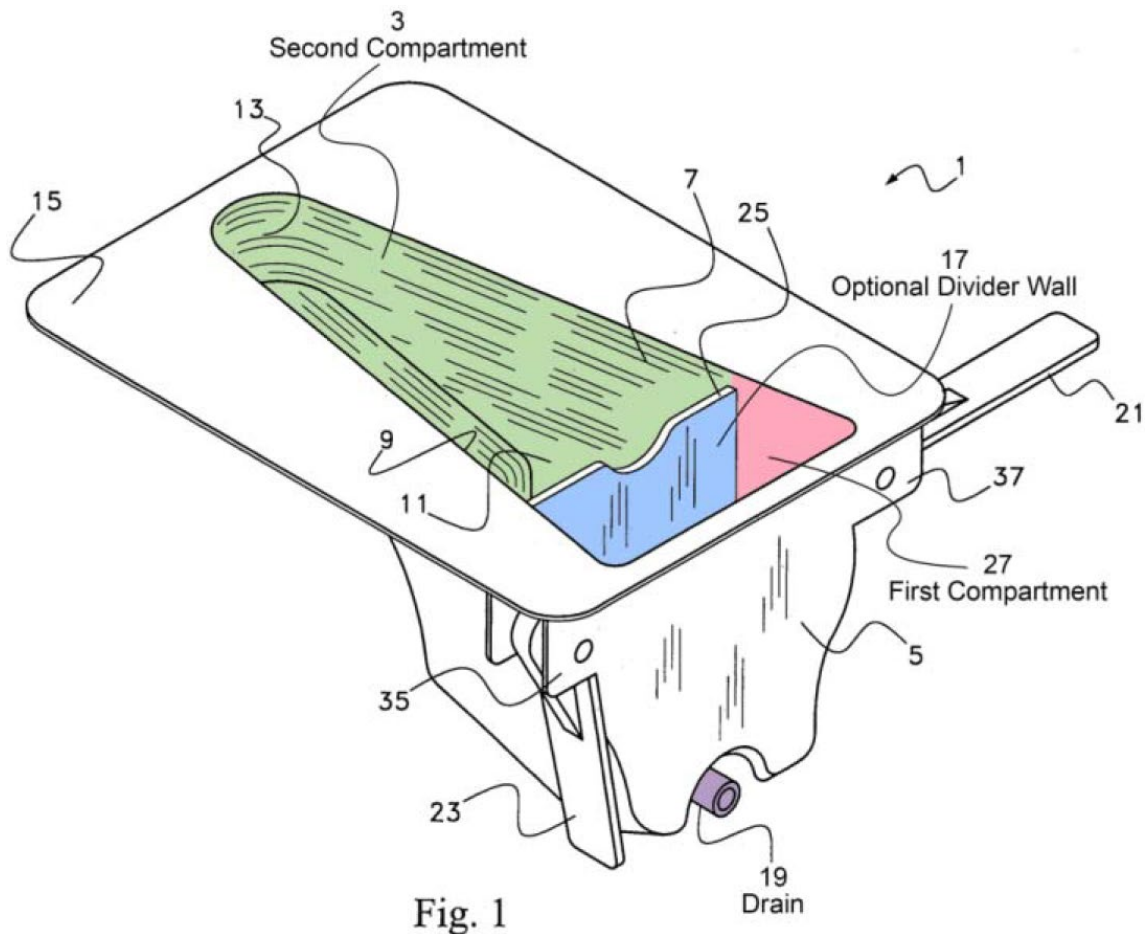
- [a] a tray having a compartment for receiving a medical assembly;
- [b] a first syringe and a second syringe disposed within the tray;
- [c] at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
- [d] an outer packaging disposed about both the tray and the at least one layer of wrap material,
- [e] wherein: the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and
- [f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe;
- [g] the first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure.

Ex. 1001, 29:29–48 (with added letter designations a–g to ease discussion).

Petitioner argues that claim 25 is unpatentable as obvious in view of the combined teachings of Solazzo and Serany. Pet. 59–69. Patent Owner argues that the combination of Solazzo and Serany fails to render independent claim 25 unpatentable as obvious because neither Solazzo nor Serany describe element 25g. PO Resp. 38–40. For the reasons that follow, we agree with Patent Owner. We determine that Petitioner has failed to prove by a preponderance of evidence that the combination of Solazzo and Serany describes element 25g and thus fails to establish that claim 25 is obvious. *Id.*

Element 25g recites limitations that parallel those of elements 1e and 1g above by requiring “the first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure.” Ex. 1001, 29:46–48. Petitioner argues that bottom 11 of Solazzo’s “no divider wall” embodiment meets the requirements of element 25g. Pet. 65–66. Patent Owner reiterates its arguments relating to elements 1e and 1g of claim 1 when arguing that Solazzo’s “no divider wall” embodiment fails to describe element 25g. PO Resp. 38. We agree, for the reasons expressed in Part II.E above.

Petitioner also argues that portion 11a of bottom 11 in Solazzo’s “divider wall” embodiment meets the requirements of element 25g in two ways, neither of which is persuasively supported by objective evidence. Pet. 66–69. Petitioner provides an annotated and colorized version of Solazzo’s Figure 1, reproduced below, to explain its argument.

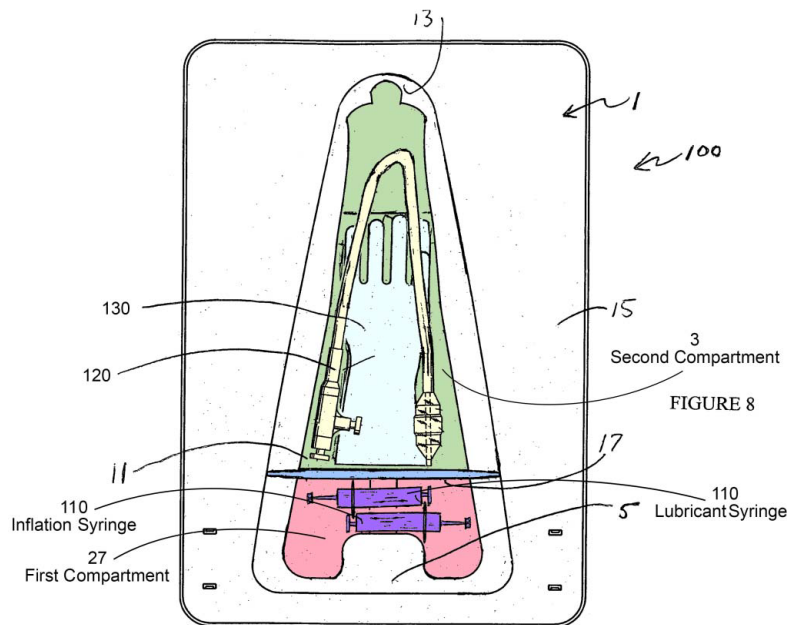


Petitioner's annotated and colorized version of Solazzo's Figure 1 is a top perspective view of Solazzo's tray with the optional divider wall 17. Pet. 66; Ex. 1005, Fig. 1.

First, Petitioner contends that Solazzo's portion 11a within compartment 27 is "inclined to facilitate drainage through drain 19." Pet. 66. Petitioner cites no evidence to support this contention. *Id.* Petitioner recognizes as much when, in the next sentence, it hedges by offering an argument that such an incline would be obvious if we were to see that "Solazzo does not explicitly disclose that [portion 11a] is inclined." *Id.* Petitioner argues that the labeling of compartment 27 as a "drainage well" in Solazzo's claim 3 suggests that portion 11a is inclined. *Id.* (citing Ex. 1005, claim 3 (5:12–15)). Petitioner's argument is unpersuasive.

Solazzo’s claim 3 states that the tray “includes a divider wall creating two separate compartments to create an irrigation well and drainage well.” Ex. 1005, 5:13–15. The claim does not identify which compartment is the drainage well, and Solazzo’s specification is ambiguous about whether compartment 27 is used for “drainage.” Solazzo also states that “[d]rain 19 is located near bottom 11 for liquid drainage and may be directly connected to one or two drain holes in bottom 11.” *Id.* at 4:10–12. This passage provides no explicit guidance on the position of the holes in bottom 11 through which fluids enter drain 19 or from which compartment that fluid originates in tray 1. The passage also provides no insight into whether portion 11a is inclined as Petitioner argues.

Second, 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 that is modified rather extensively from Solazzo's Figure 8. Pet. 67. We reproduce Petitioner's modified figure below.



Petitioner's modified version of Solazzo's Figure 8 illustrates two syringes within compartment 27. Pet. 67; Ex. 1002 ¶ 283.

Petitioner's argument is unpersuasive. Solazzo never expressly describes placing two syringes or even tube 140 within compartment 27. Petitioner attempts to account for this shortcoming by citing Serany's disclosure of placing multiple balls of cleaning material in one compartment and Serany's generalized statement that components in its kit are "arranged in logical step-by-step order." Pet. 63 (citing Ex. 1006, 2:57–61, 1:31–35).

Mr. Plishka cites the same portions of Serany as evidence for the same conclusion. Ex. 1002 ¶¶282–285. However, Serany never describes two syringes, much less how to arrange two syringes in an irrigation kit. *See* Ex. 1006, 3:6–7, Fig. 6 (describing and illustrating one syringe).

Accordingly, we do not discern why the grouping of cleansing materials or general statements about arranging components in "logical" order demonstrates the obviousness of arranging two syringes in one compartment rather than two different compartments as Solazzo expressly describes.

Even if Solazzo and Serany collectively were to suggest grouping two syringes in Solazzo's compartment 27, we are not persuaded by Petitioner's argument that the asserted prior art describes or suggests arranging those syringes at different heights within compartment 27. On this point, Petitioner argues that "the syringes could also be stacked on top of each other in compartment 27" and cites another prior art reference as demonstrating this possibility, Imai.⁸ Pet. 67–68.

⁸ Japanese Patent No. 2007-229520 to Imai et al. (Exhibit 1011 with translation at Exhibit 1012 (collectively, "Imai")).

Petitioner cites Imai's Figure 1, reproduced at right in pertinent part, as evidence to support its argument.

Pet. 67–68. The Figure is an exploded perspective view of Imai's epidural anesthesia kit. Ex. 1012 ¶ 13. The Figure depicts three syringes 13 and three injection needles 14 within storage cell 232. *Id.*

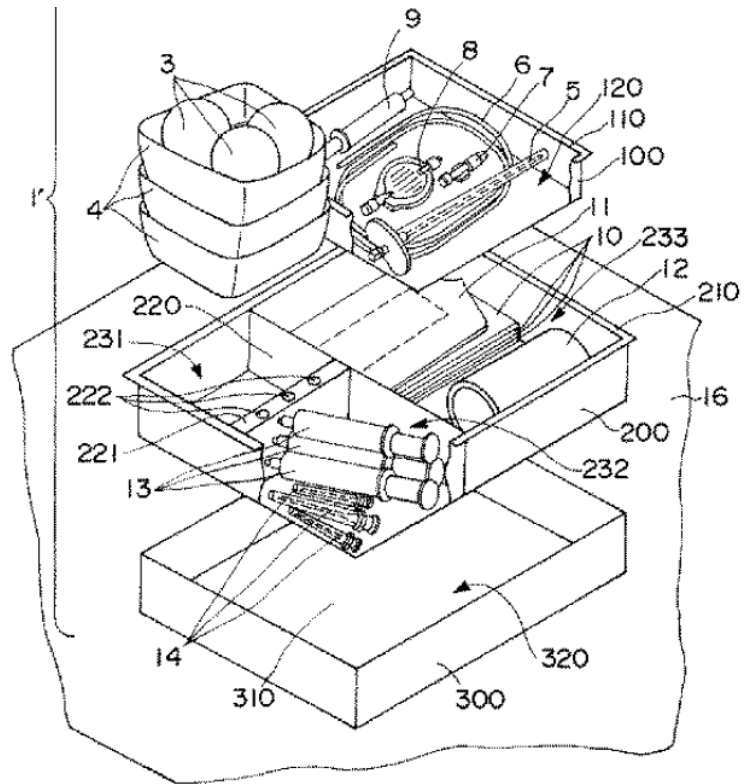
¶ 28. Petitioner identifies no mechanism, and we discern none, for supporting syringes 13 in any particular arrangement by height. Rather, Imai's storage cell 232 is illustrated as flat-bottomed, rectangular compartment. We view Imai's illustration as schematic in nature and failing to suggest a compartment that supports syringes at different heights as required of element 25g.

For the reasons expressed above, Petitioner fails to demonstrate by a preponderance of evidence that Solazzo and Serany describe or suggest element 25g. Accordingly, we conclude that Petitioner has failed to demonstrate that Solazzo and Serany render claim 25 unpatentable as obvious.

G. INDEPENDENT CLAIM 37

Independent claim 37 recites:

37. A medical procedure kit, comprising:



- [a] a tray having a compartment for receiving a medical assembly;
- [b] a first syringe and a second syringe disposed within the tray;
- [c] at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material; and
- [d] an outer packaging disposed about both the tray and the at least one layer of wrap material,
- [e] wherein: the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure; and
- [f] the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe;
- [g] wherein steps of the catheterization procedure use a higher of the first syringe or the second syringe before a lower of the first syringe or the second syringe.

Ex. 1001, 30:16–36 (with added letter designations a–g to ease discussion).

Petitioner argues that claim 37 is unpatentable as obvious in view of the combined teachings of Solazzo and Serany for reasons argued in connection with claims 1 and 25. *See* Pet. 76–77 (cross-referencing arguments for various elements of claims 1 and 25). Patent Owner argues that the combination of Solazzo and Serany fails to render independent claim 37 unpatentable as obvious because neither Solazzo nor Serany describes a compartment that supports two syringes at different heights according to their order of use, as recited in elements 37e and 37g. *See* PO Resp. 50 (cross-referencing arguments regarding element 1e (ordered syringes) and element 25g (using different height to indicate order of use)). For the reasons expressed above in Parts II.E and II.F, we agree with Patent

Owner. Accordingly, we determine that Petitioner has failed to prove by a preponderance of evidence that the combination of Solazzo and Serany describes elements 37e and 37g and thus fails to establish that claim 37 is obvious.

H. DEPENDENT CLAIMS 2, 6–10, 16–19, 26–36, AND 38–44

Petitioner argues that dependent claims 2, 6–10, 16–19, 26–36, and 38–44 are obvious in view of Solazzo and Serany and in further view of one or both of Disston and Franks-Farah. Pet. 49–59 (claims 2, 6–10, 16–19), 70–75 (claims 26–36, 39, 40), 77–78 (claims 38, 41), 86–87 (claims 43, 44).

Claims 2, 6–10, and 16–19 depend ultimately from independent claim 1; claims 26–36 depend ultimately from independent claim 25, and claims 38–44 depend ultimately from independent claim 37. Because we have concluded that Petitioner has failed to demonstrate obviousness by a preponderance of evidence for any of independent claims 1, 25, and 37, we reach the same conclusion with respect to dependent claims 2, 6–10, 16–19, 26–36, and 38–44. *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)).

I. OBJECTIVE INDICIA OF NONOBVIOUSNESS

Because 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, we need not determine whether Patent Owner’s evidence of objective indicia of nonobviousness weighs further against a conclusion of obviousness.

The Federal Circuit has found it unnecessary to consider arguments relating to objective indicia of nonobviousness 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 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, we do not reach the merits of Patent Owner’s objective indicia of nonobviousness.

J. SUMMARY

Petitioner has not demonstrated by a preponderance of the evidence that any challenged claim is unpatentable as obvious.

III. CONCLUSION

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 6–10, 16, 17, 25–32, 36–41	103	Solazzo, Serany		1, 2, 6–10, 16, 17, 25–32, 36–41

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
18, 19, 35	103	Solazzo, Serany, Franks-Farah		18, 19, 35
33, 34, 42	103	Solazzo, Serany, Disston		33, 34, 42
43, 44	103	Solazzo, Serany, Disston, Franks- Farah		43, 44
Overall Outcome				1, 2, 6–10, 16–19, 25–44

IV. ORDER

For the reasons given, it is:

ORDERED, Petitioner has failed to establish based on a preponderance of evidence that claims 1, 2, 6–10, 16–19, and 25–44 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.

IPR2019-00035
Patent 9,745,088 B2

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