

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C.R. BARD, INC.,
Petitioner,

v.

MEDLINE INDUSTRIES, INC.,
Patent Owner.

IPR2019-00223
Patent 9,808,596 B2

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

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. BACKGROUND

C.R. Bard, Inc. (“Petitioner”) filed a petition (Paper 2, “Pet.”) to institute an *inter partes* review of claims 7–16, 21, and 22 (the “challenged claims”) of U.S. Patent No. 9,808,596 B2 (Ex. 1001, “the ’596 patent”).

35 U.S.C. § 311. Medline Industries, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 12. On June 6, 2019, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims and all grounds advanced by Petitioner. Paper 21. The table below lists the challenges to the claims:

Claim(s) Challenged	35 U.S.C. §	References
7, 9–16, 21, 22	103	Solazzo ¹ , Serany ²
8	103	Solazzo, Serany, Boedecker ³
7, 9, 11–16, 22	103	Solazzo, Disston ⁴
8	103	Solazzo, Disston, Boedecker
10, 21	103	Solazzo, Disston, Serany

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition. Paper 32 (“PO Resp.”). Petitioner filed a Reply in support of the Petition. Paper 43 (“Reply”). Patent Owner filed a Sur-reply. Paper 49 (“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 52, 53. Patent Owner did not move to amend any claim of the ’596 patent.

We heard oral argument on March 5, 2020. A transcript of the argument has been entered in the record (Paper 57, “Tr.”).

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. 3,965,900 (Ex. 1034, “Boedecker”).

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

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 7–16, 21, and 22 of the ’596 patent 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. 93; Paper 3, 2. The parties collectively also identify as related matters petitions for *inter partes* review of claims of: U.S. Patent 9,745,088 B2 (IPR2019-00035 and IPR2019-00036); U.S. Patent 9,795,761 B2 (IPR2019-00109); and U.S. Patent 9,808,400 B2 (IPR2019-00208). Pet. 93–94; Paper 3, 2–3. Patent Owner further identifies as a related matter U.S. Patent Application No. 15/804,520, which is a continuation-in-part of the application that issued as the ’400 patent. Paper 3, 2. Patent Owner further identifies U.S. Patent Application Nos. 15/703,514; 14/265,920; 15/684,787; 15/803,383; 13/374,509; 15/640,224; and 15/051,964 as related matters because these applications “share similar disclosures and claim language” with the ’596 patent. *Id.*

C. THE ’596 PATENT

The ’596 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,

1:32–35. The Specification describes tray 100 shown in Petitioner’s annotated and colorized version of Figure 7, which we reproduce below.

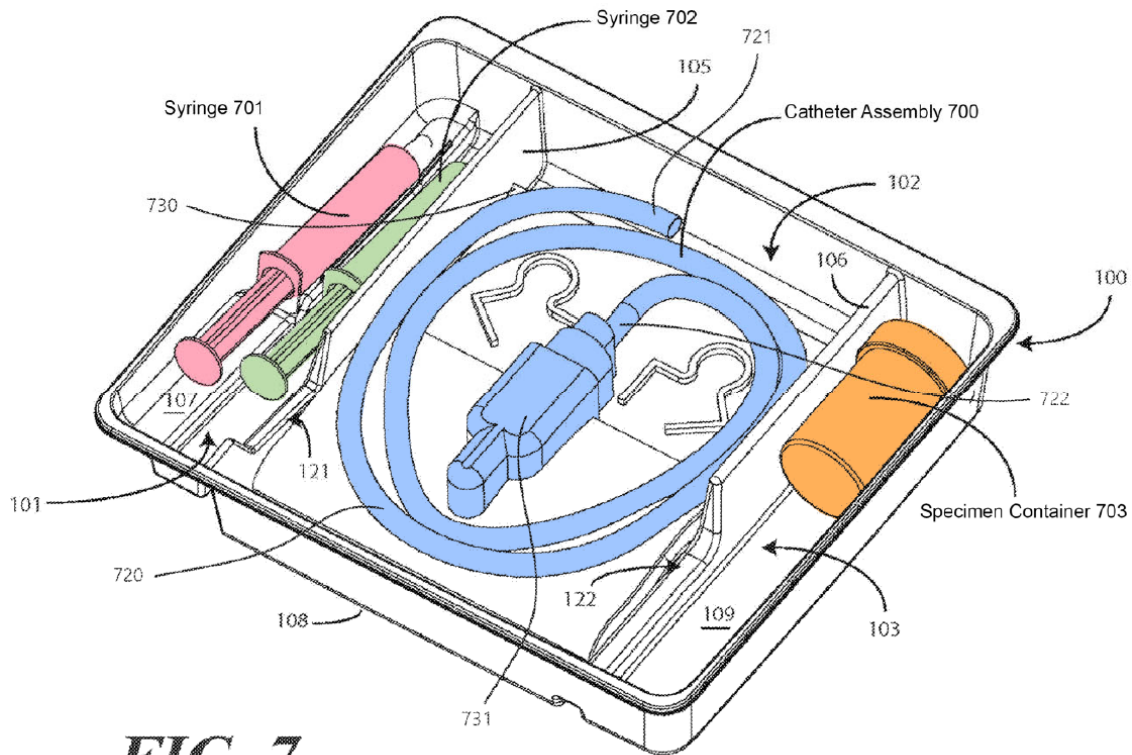


FIG. 7

Figure 7 illustrates a catheter, two syringes, and a specimen bottle located within single-level tray 100. *Id.* at 10:53–55.

Before use, tray 100 is optionally 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 11:49–59, Fig. 10. Tray 100 includes three compartments 101, 102, 103 adapted to accept various items used in a catheterization procedure. *Id.* at 8:48–54. First compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. *Id.* at 8:50–52. Second compartment 102 accommodates catheter assembly 700 (blue) comprising indwelling (or Foley) catheter coupled to fluid bag 730 by tube 720. *Id.* at 8:52–54. First end portion 721 of tube 720 is coupled to the indwelling

catheter and second end portion 722 of tube 720 is coupled to fluid bag 730 via anti-reflux device 731. *Id.* at 8:56–59. Third compartment 103 accommodates specimen container 703 for capturing samples taken from the patient via catheter 700. *Id.* at 8:59–61. Additional objects can be included with the tray, including one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, printed instructions, and so forth. *Id.* at 5:10–15.

Claims 7 and 14 are the independent claims among the challenged claims. *Id.* at 18:30–20:41. The text of each independent claim is reproduced below in Parts II.E and II.E.2 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

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).

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).

Although Petitioner separately and expressly addresses various claim terms including, “mnemonic device,” “barrier,” “lubricating jelly application chamber/compartment,” “reveal,” and “perimeter wall,” Pet. 19–20, 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 7–16, 21, and 22 on the grounds that the claims are obvious in light of various references including: Solazzo, Serany, Disston, and Boedecker. 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) (2018). “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. 18–19 (citing Ex. 1002 ¶ 14); PO Resp. 13 (citing Ex. 2040 ¶ 37). 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); PO Resp. 13 (citing Ex. 2040 ¶ 37). 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. 18–19; PO Resp. 14 (citing Ex. 2041 ¶ 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 and 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 right. 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.

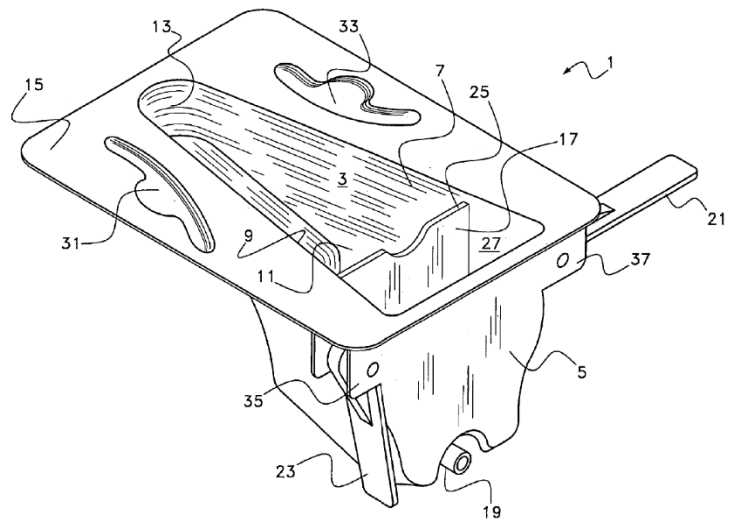


Fig. 1

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 the medical devices

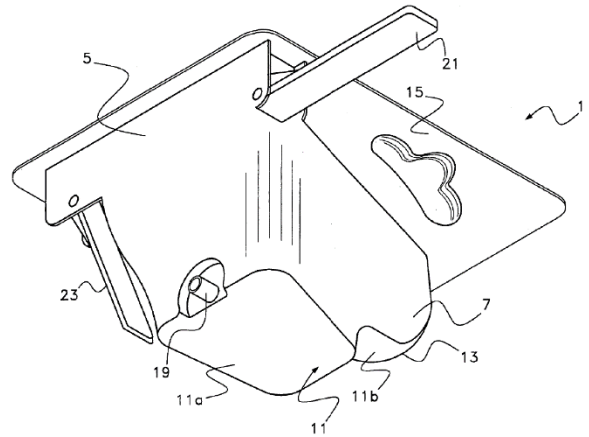


Fig. 2

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.

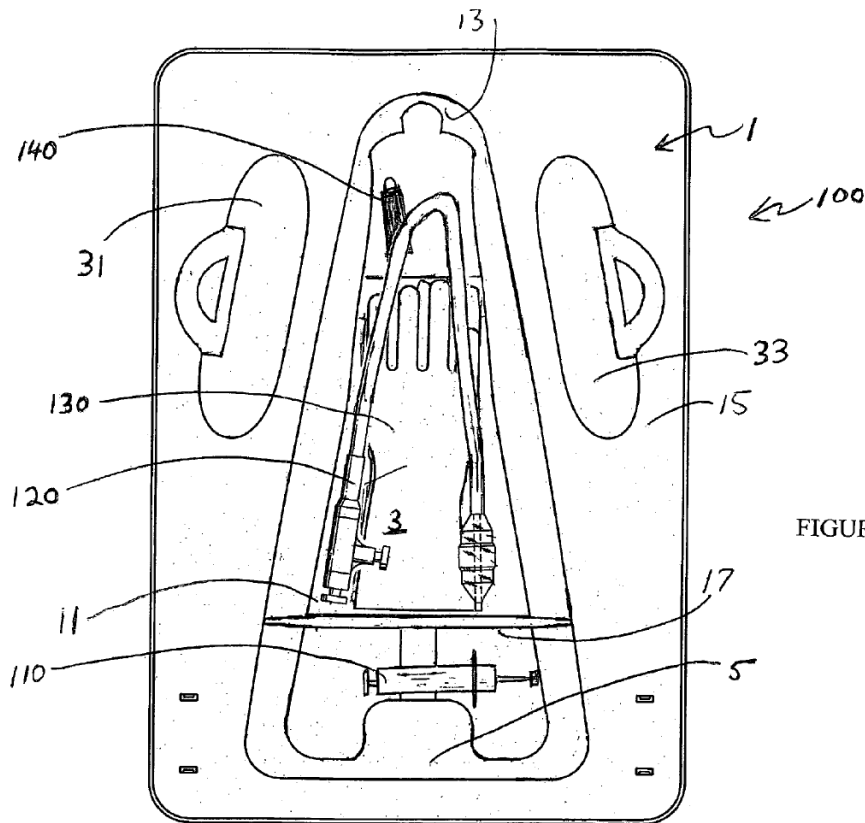


FIGURE 8

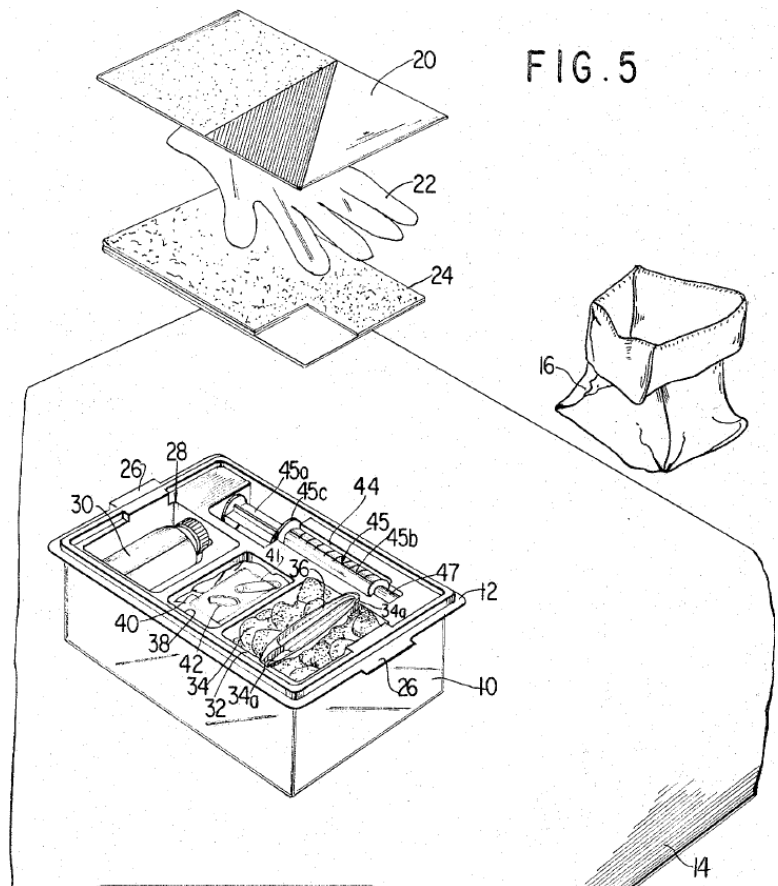
Solazzo’s Figure 8 is a top view of kit 100 illustrating various components stored in compartments of tray 1. *Id.* at 4:41–48.

Inflation syringe 110 is stored at low area 11A, 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

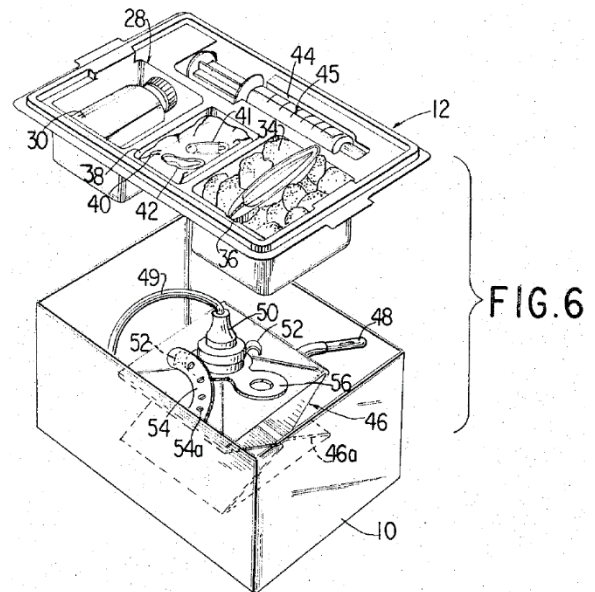
Serany is directed to a double-wrapped, sterile package providing catheterization components ready for use in the order needed. Ex. 1006, 1:8–16, 1:60–63, 3:63–4:2; Figs. 1–3, 5. Serany’s Figure 5 (reproduced at right in pertinent part) is an exploded view illustrating how various compartments are positioned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

Prefilled syringe 45 of sterile water is placed 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 2:22–33, 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 Figure 6. *Id.* at 3:33–35.



3. *Disston*

Disston is directed to a double-wrapped catheterization tray package that “provide[s] for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled.” Ex. 1008, 1:59–67, 2:60–63, Figs. 2–3. The single-level tray 2 contains catheterization devices “arranged in such order and position as to be most conveniently available when the container is opened.” *Id.* at 2:15–23. The tray is slidably received in an open-ended sleeve 1 having a flap 3 folded downwardly over an edge of the tray, and further wrapped in a plastic outer envelope. *Id.* at 1:59–67, 2:23–26, Figs. 2–3.

When opened, the tray presents contents including gloves, cleansing solution, protective pad or sheet, lubricant, sterile water packet, syringe, “and most importantly, a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately.” *Id.* at 1:26–35, 2:41–52, Fig. 1. This assembly “not only saves time and trouble but practically eliminates the danger of faulty connections and loss of sterility, inherent in the former system.” *Id.* at 1:42–46.

E. CLAIMS 7, 9–16, 21, AND 22:

OBVIOUSNESS IN VIEW OF SOLAZZO AND SERANY

1. *Independent Claim 7*

Claim 7 recites:

7. A catheterization kit comprising:

[a] a single level container defining a first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the single level container defining a second compartment bounded, at least in part, by a second

compartment base member and at least a second portion of the perimeter wall;

[b] a first syringe disposed within the first compartment of the single level container, the first syringe containing an inflation fluid;

[c][i] a second syringe disposed within the first compartment of the single level container,

[ii] the second syringe containing a lubricating jelly; and

[d][i] a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle,

[ii] the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter.

Id. at 18:30–51 (with line breaks and bracketed labels added to ease discussion).

Petitioner argues that the combined teachings of Solazzo and Serany render claim 7 unpatentable as obvious. Pet. 30–44. First, Patent Owner argues that Petitioner has failed to prove by a preponderance of evidence that the combination of Solazzo and Serany describes two syringes in one compartment and a coiled medical device including a Foley catheter coupled by a tube to a fluid receptacle in another compartment of the single level container (as collectively recited in elements 7a, 7b, 7c, and 7d.i). PO Resp. 18–29. Second, Patent Owner argues that Petitioner has failed to prove that the combination of Solazzo and Serany describes element 7d.ii. For the reasons that follow, we agree with Patent Owner on both arguments.

a) Two Syringes in One Compartment and a Medical Device in Another Compartment (Elements 7a, 7b, 7c, and 7d.i)

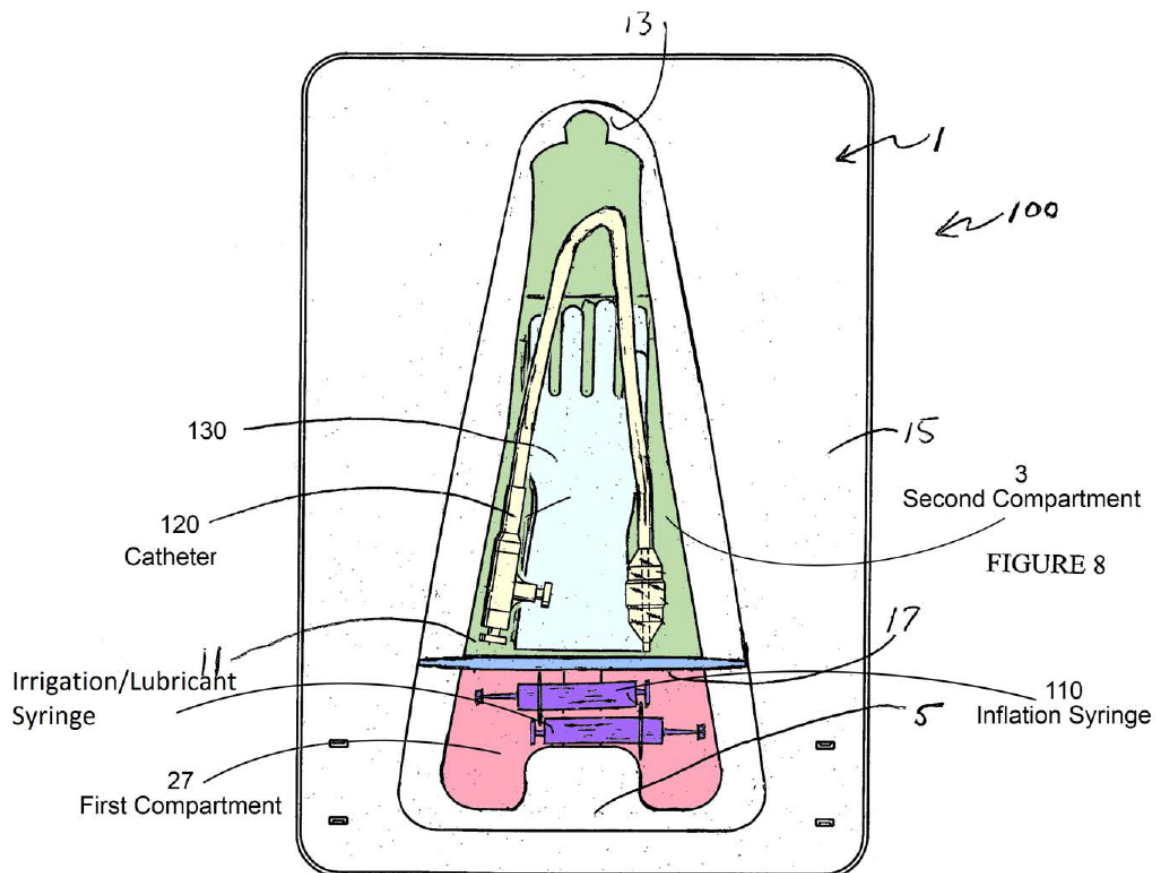
Although Solazzo states that its kit contains an inflation syringe and an irrigation syringe, Solazzo does not describe where the irrigation syringe would be placed in its kit. Ex. 1005, 3:12–24. Serany describes a single syringe, its syringe 45 in its depression 44, but Serany fails to describe a second syringe. Ex. 1006, 3:6–22, Fig. 5. Based upon our review of Solazzo and Serany, we determine that neither of them describes or suggests a tray with two syringes in one compartment and the medical assembly in a different compartment as collectively required of elements 7a, 7b, 7c, and 7d.i.

First, Petitioner contends that Solazzo expressly describes that its tray includes two syringes, inflation syringe 110 and an irrigation syringe. Pet. 26 (citing Ex. 1005, 3:14–24). Elements 7a and 7b require two syringes, one filled with inflation liquid and the other filled with lubricating jelly. Ex. 1001, 18:37–42. Petitioner argues that replacing Solazzo’s lubrication tube 140 with a syringe containing lubricant would have been an obvious “simple substitution of one container . . . for another known type of container . . . to produce predictable results.” Pet. 37 (citing Ex. 1002 ¶¶ 172–174).

Even accepting Petitioner’s argument, Solazzo and Serany fail to describe an inflation syringe and a lubrication syringe placed in one compartment that is different from the compartment containing the medical device. Although Solazzo does not expressly describe where its second syringe is located within recessed area 3, Petitioner contends that compartment 27 is the “natural place to store the lubricant syringe because it already holds the inflation syringe.” *Id.* at 34 (citing Ex. 1002 ¶¶ 372–376).

We are not persuaded by Petitioner’s speculation about the location of a lubricant syringe in the same compartment with the inflation syringe, especially given that Solazzo describes placing lubricant tube 140 in one compartment (recess 3) and placing inflation syringe 110 in the other compartment (overflow compartment 27) of Solazzo’s “divider wall” embodiment. Ex. 1005, Fig. 8.

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. 35. 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 ¶ 377.

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. 35 (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 ¶ 165. 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 Serany's 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 as Solazzo expressly describes.

Petitioner alternatively argues that "compartment 27 could hold all three syringes (which could be inflation, irrigation, and lubricant syringes)" and cites another prior art reference as demonstrating this possibility, Imai.⁶ Pet. 36 (citing Ex. 1012, Fig. 1; Ex. 1002 ¶¶ 166–167). Although Imai depicts three syringes in one compartment of its epidural anesthesia kit, Ex. 1012 ¶ 13, Imai merely establishes the possibility of placing three syringes in one compartment without explaining why an ordinarily skilled artisan would have done so in Solazzo's tray. We find that none of the references suggests placing the recited inflation and lubrication syringes

⁶ Japanese Patent No. 2007-229520 to Imai et al. (Exhibit 1011 with translation at Exhibit 1012 (collectively, "Imai")).

together in one compartment and the medical device in a different compartment.

Accordingly, we determine that Solazzo and Serany fail to describe the requirement of claim 7 that the first compartment contains an inflation syringe and a lubrication syringe and another compartment contains the medical device (Foley catheter, tubing, and fluid receptacle). 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 7a, 7b, 7c, and 7d.i. Accordingly, Petitioner's challenge to independent claim 7 fails.

- b) A "fluid receptacle . . . between the second compartment base member and the Foley catheter" (Element 7d.ii)

Element 7d.ii refers to the following portion of claim 7: "the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter." Ex. 1001, 18:48–51.

Petitioner correctly notes that Solazzo describes placing its catheter 120 in recessed area 3 (i.e., the second compartment). Pet. 42 (citing Ex. 1005, Figure 8). Petitioner relies upon Serany's arrangement, shown in Figure 6, in which "catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." *Id.* at 43 (quoting Ex. 1006, 3:33–35). When stored in this manner, Serany's bottle 46 is folded flat between the bottom of box 10 and tube 49. *Id.* (citing Ex. 1006, 3:26–32). Petitioner argues that Serany suggests arranging the closed-system Foley catheter with the drainage receptacle under the Foley catheter and attached tubing and on the bottom of the tray by indicating that

components should be arranged in their “proper order of use.” *Id.* at 43–44 (citing Ex. 1006, 1:9–12, 1:23–25; Ex. 1002 ¶¶ 192–194).

Patent Owner argues that Serany fails to meet element 7d.ii because Serany’s catheter is not disposed “such that the fluid receptacle is between the second compartment base member and the Foley catheter” as recited in claim 7. PO Resp. 30–31. Patent Owner relies upon Serany’s Figure 6 and testimony from Dr. Singh to support its position. *Id.* at 35 (citing Ex. 1006, Fig. 6; Ex. 2040 ¶¶ 80–82). Based on his review of Figure 6 and Serany’s description of the catheter, Dr. Singh opines that “the catheter 48 is shown extending from below the top edge of the bottle near the top side of the box 10 behind the bottle 46.” He concludes, therefore, that Serany’s catheter is “coiled in the box about the bottle, rather than on top of the bottle.” *See, e.g.,* Ex. 2040 ¶ 80. We agree.

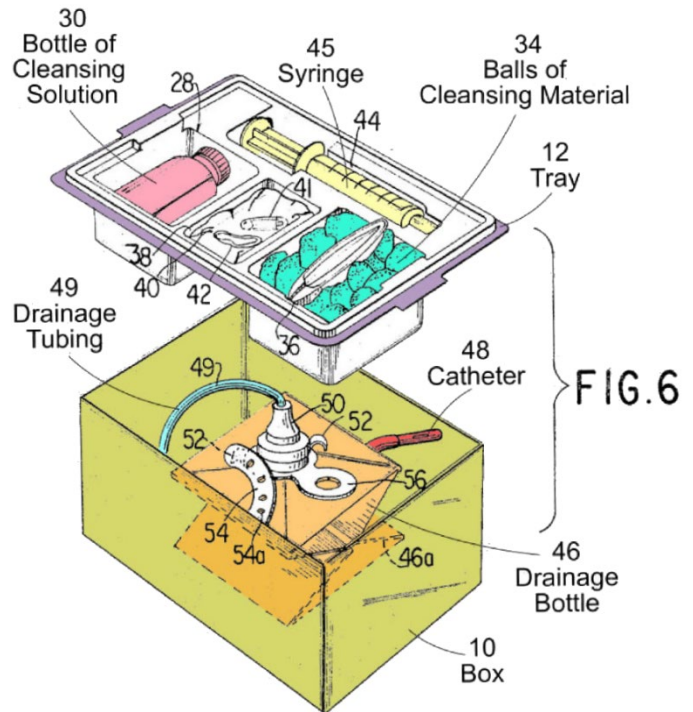
Element 7d.i recites that the medical device comprises three distinct components, “a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle.” Ex. 1001, 18:46–48. Element 7d.ii requires that: “the fluid receptacle is between the second compartment base member and the Foley catheter.” Ex. 1001, 18:48–51.

We have reproduced
Petitioner's annotated and colorized
version of Serany's Figure 6 at right,
which is a partially exploded view
of Serany's kit illustrating the
contents of tray 12 and box 10.

Serany's Figure 6 illustrates every
visible part of catheter 48 (red) as
being positioned below the top of
bottle 46 (orange). None of
Serany's figures illustrates the fully
collapsed configuration of bottle 46

(orange) to show how catheter 48 is positioned relative to bottle 46 when it
is collapsed. Without such an express description, we agree with Dr. Singh
that Serany illustrates at least a portion of the fluid receptacle being located
above the catheter, not between the catheter and the bottom of the container
as recited in element 7d.ii.

Petitioner contends that Patent Owner's argument "tries to rewrite
7[d][ii] to require that the *entire* catheter be above the *entire* receptacle."
Reply 8. We read element 7d.ii slightly more broadly to require that the
entire fluid receptacle is between the base member of the second
compartment and the catheter. As shown in its Figure 6, Serany fails to
illustrate any portion of catheter 49 as being located above its bottle 46 in
the partially extended position. Moreover, neither Serany's Figure 6 nor the
text of Serany ever describes fluid receptacle 46 being wholly positioned
between catheter 49 and the bottom of box 10. Serany describes bottle 46 in



its collapsed condition with “catheter 48 and drainage tubing 49 . . . coiled in the box about the bottle.” Ex. 1006, 3:31–34. Serany simply fails to expressly describe or illustrate a fluid receptacle that is wholly located between the bottom of the container and the catheter. We therefore determine that Petitioner has failed to prove by a preponderance of evidence that Serany describes element 7d.ii.

c) Conclusion

For the reasons expressed above, we conclude that Petitioner has failed to prove by a preponderance of evidence that the combined teachings of Solazzo and Serany render independent claim 7, or its dependent claims 9–13 unpatentable as obvious. We address additional reasons that Petitioner’s challenges to dependent claims 9 and 11 fail immediately below.

2. Dependent Claim 9

Claim 9 depends directly from claim 7 and further recites:

“[i] wherein the first compartment is configured to receive the lubricating jelly from the second syringe [ii] to lubricate a tip of the Foley catheter when the tip is placed into the first compartment.” Ex. 1001, 18:54–57 (with bracketed labels to aid discussion). Collectively, elements 9.i and 9.ii require that the first compartment not only hold syringes, but also be configured to receive lubricating jelly so that a tip of the catheter may be lubricated with that jelly.

Petitioner argues that Solazzo describes elements 9.i and 9.ii. Pet. 45–50. Petitioner maps the claimed first compartment to Solazzo’s compartment 27, which is defined within Solazzo’s recess 3 by divider wall 17. *Id.* at 45. Patent Owner argues that Solazzo fails to describe the claimed configuration of the first compartment because Solazzo’s

compartment 27 is not suitably configured for lubricating the tip of the catheter. PO Resp. 32–35. For the reasons that follow, we agree with Patent Owner.

As seen in Solazzo's Figures 1 and 5 (reproduced below), divider wall 17 defines two compartments within recess 3, one of which is compartment 27.

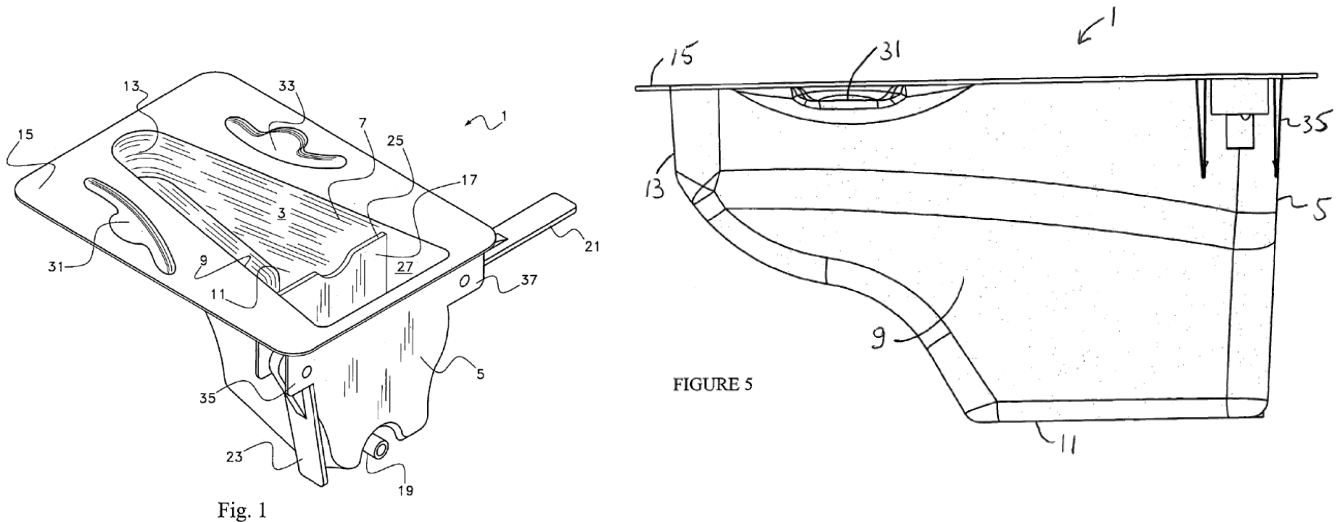


Fig. 1
Figures 1 and 5 above left and right respectively depict a top perspective view and a side elevation view of a catheterization and irrigation tray. Ex. 1005, 3:31–33.

Solazzo does not describe 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 serve as an overflow receptacle, compartment 27 is structured to be notably deeper than much of the portion of recess 3 on the other side of divider wall 17; compartment 27 also and includes a portion of 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 so that a user can lubricate a Foley catheter by “filling the well with lubricant and sliding” it through that lubricant. Petitioner’s proposed use of deep compartment 27, an overflow compartment to receive urine, to apply lubrication is incongruous with Solazzo’s express teaching to use wells 31, 33 to lubricate the tip of a catheter.

The ’596 patent also provides insight into the type of structure the inventors associated with a lubricating jelly application chamber. Figure 1 of the ’596 patent is reproduced below.

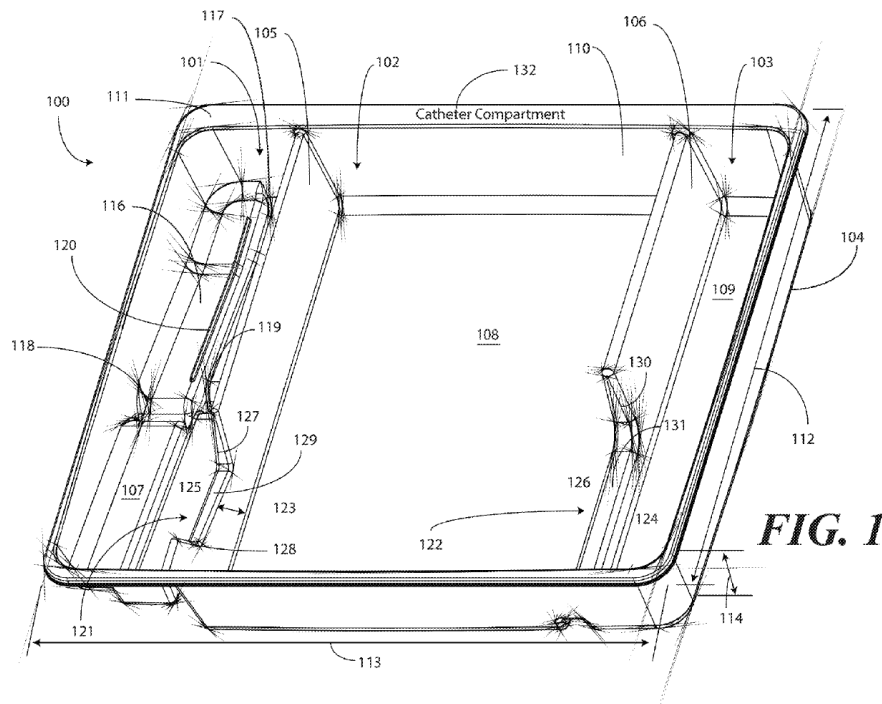


Figure 1 above illustrates an “embodiment of a tray for a catheter or similar assembly.” Ex. 1001, 2:26–27.

Tray 100 includes first compartment 101 separated from second compartment 102 by barrier 105. *Id.* at 4:44–48. Compartment 101 accommodates syringes and includes a stair-stepped contour 115 (not numbered in Figure 1) with first step portion 116 and second step portion 117, with the step portions arranged at different heights. *Id.* at 5:25–46. The '596 patent further explains the following:

[T]he medical services provider may dispense the lubricating jelly along the second step portion 117. As the second step portion 117 is lower in the tray 100 than the first step portion 116, the second step portion 117 serves as a channel in which the lubricating jelly may spread. A medical services provider may then pass the catheter through the first opening 121, through the channel formed by the second step portion 117, i.e., along the second step portion 117 through the dispensed lubricating jelly, and out the top of the tray 100 to the patient.

Id. at 7:8–17.

Thus, the '596 patent describes a type of lubricating jelly application chamber (step portion 117) 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 easily applying lubrication to a catheter.

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. 45.

Dr. Yun’s testimony, however, is general in nature, and he does not testify that an ordinarily skilled artisan 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, applying lubricating jelly to the tip of 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. 45 (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 is configured for receiving lubricating jelly so that it may be applied to the tip of a catheter.

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 chamber of a catheterization tray regardless of its size and shape as being configured for receiving lubricating jelly and facilitating the lubrication of the tip of a catheter. Patent Owner points to testimony of its declarant, Ms. Chiappetta, (PO Resp. 32–33), who testifies that an ordinarily skilled artisan would not have regarded Solazzo's compartment 27 as being suitable for lubricating a catheter because of its structural dissimilarity to Solazzo's expressly disclosed lubrication wells 31, 33 and because compartment 27 is "deep for collection of urine" and "too deep." Ex. 2041 ¶ 174. Patent Owner also relies on Ms. Chiappetta's testimony (PO Resp. 37) that compartment 27 would not have been viewed as a configured for applying lubricating jelly 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. 2041 ¶ 176. The testimony of Dr. Singh, on which Patent Owner also relies (PO Resp. 35), is in accord with that of Ms. Chiappetta. To that end, Dr. Singh agrees the use of divider wall 17 to form Solazzo's compartment 27 and its purpose to accommodate urine overflow renders it unsuitable for applying lubricating jelly to a catheter. Ex. 2040 ¶ 115. 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 is configured to receive the lubricating jelly . . . to lubricate a tip of the Foley catheter” as required by claim 9.

3. Dependent Claim 11

Claim 11 depends directly from claim 7 and further recites that: “the first syringe and the second syringe are positioned at different elevations within the first compartment, the different elevations being associated with an order of use of the first syringe and the second syringe during a catheterization procedure.” Ex. 1001, 18:65–19:3.

Petitioner argues that an ordinarily skilled artisan would have been motivated to arrange the inflation and lubrication syringes within Solazzo's compartment 27 “by height” on the “inclined, bottom surface of compartment 27.” Pet. 55. Petitioner relies on Mr. Plishka's testimony that the bottom of compartment 27 is inclined “to facilitate [] drainage.” Ex. 1002 ¶¶ 233–234. Mr. Plishka cites no persuasive objective evidence to support his conclusion that the bottom of compartment 27 is inclined. *Id.*

More importantly, his testimony is inconsistent with Solazzo's Figure 5, which illustrates the bottom 11 of tray 1 within compartment 27 as being flat. Ex. 1006, Fig. 5.

Additionally, 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.

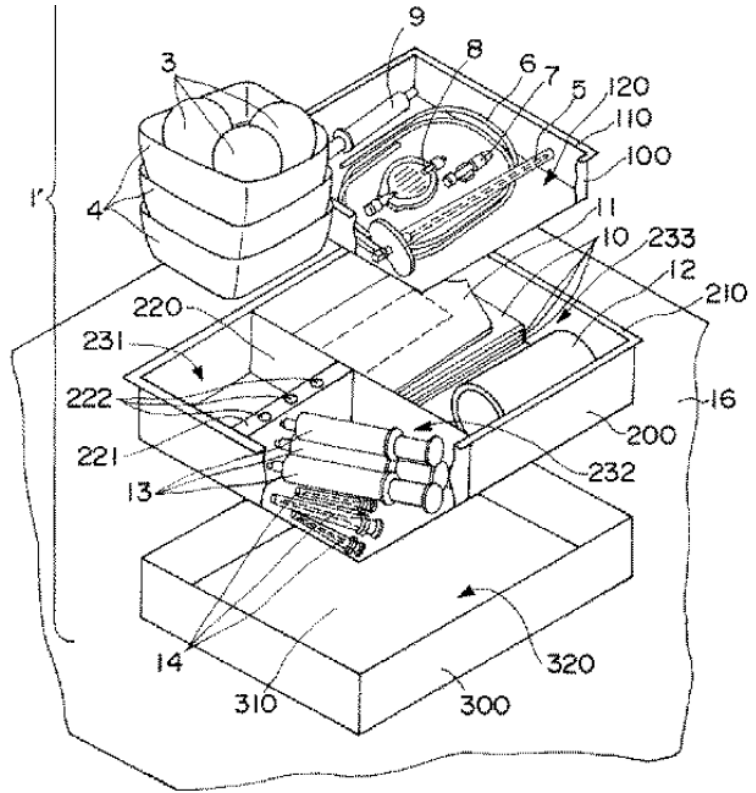
Based on our review of Petitioner's argument and cited evidence, we determine that Petitioner fails to prove that compartment 27 has an "inclined" bottom as a mechanism for meeting the limitations introduced in claim 11.

Petitioner alternatively argues that "the syringes could [also] be stacked on top of each other, which would also present them at different

heights within

compartment 27.” Pet. 56.

Petitioner cites Imai’s Figure 1, reproduced at right in pertinent part, as evidence to support its argument. *Id.* 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 according to their order of use as required of claim 11. Accordingly, we determine that Petitioner fails prove by a preponderance of evidence that Imai suggests arranging Solazzo’s syringes as recited by the limitations introduced in claim 11.

For the reasons expressed above, Petitioner fails to demonstrate by a preponderance of evidence that Solazzo and Serany describe or suggest arranging an inflation syringe and a lubrication syringe at different heights according to their order of use. Accordingly, we conclude that Petitioner has

failed to demonstrate that Solazzo and Serany render claim 11 unpatentable as obvious.

4. Independent Claim 14:

Obviousness in View of Solazzo and Serany

Independent claim 14 recites:

14. A catheterization kit, comprising:

- [a] a single level tray defining a first compartment and a second compartment, the first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall, the single level tray including a barrier separating the first compartment from the second compartment;
- [b] a first syringe disposed in the first compartment of the single level tray at a first elevation, the first syringe containing an inflation fluid;
- [c] a second syringe disposed within the first compartment of the single level tray at a second elevation, the second elevation below the first elevation relative to a top of the single level tray, the second syringe containing a lubricating jelly, the first compartment configured to receive the lubricating jelly from the syringe; and
- [d] a coiled medical device disposed within the second compartment of the single level tray, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle, a tip of the Foley catheter configured to be placed within first compartment to lubricate a tip of the Foley catheter when the lubricating jelly has been dispensed from the second syringe into the first compartment.

Ex. 1001, 19:10–37 (with bracketed labels added to ease discussion).

Petitioner argues that claim 14 is unpatentable as obvious in view of the combined teachings of Solazzo and Serany and largely cross-references its arguments and evidence for elements 7a, 7b, 7c of claim 7, and claims 9, and 11, and 12. Pet. 59–61 (cross-referencing 30–37 (elements 7a, 7b, 7c), 45–48 (claim 9), 54–57 (claims 11, 12)). Patent Owner argues that for all the reasons expressed in connection with claims 7, 9, and 11, Petitioner’s challenge to claim 14 as obvious over Solazzo and Serany fails. PO Resp. 42 (cross-referencing arguments for claims 7, 9, and 11). We agree with Patent Owner on all points.

a) Two Syringes in One Compartment and a Medical Device in Another Compartment (Aspects of Elements 14a, 14b, 14c, 14d)

We determine that claim 14 recites materially similar limitations as are recited in elements 7a, 7b, 7c, and 7d.i. Claim 14, like claim 7, requires (1) a single level tray with two compartments (element 14a akin to element 7a); (2) an inflation syringe and a lubrication syringe disposed within the first compartment (elements 14b, 14c akin to elements 7b, 7c); and (3) a coiled medical device disposed in the second compartment (element 14d akin to element 7d.i). For the reasons expressed in Part II.E.1.a) above in connection with our analysis of claim 7, we conclude that Petitioner has failed to establish by a preponderance of evidence that the teachings of Solazzo and Serany describe an inflation syringe and a lubrication syringe in one compartment and a medical device in a different compartment as required of claim 14.

b) Arrangement of Two Syringes by Height in One Compartment
(Elements 14b and 14c)

Portions of elements 14b and 14c in claim 14 further require that the inflation syringe and lubrication syringe are arranged at different heights within the first compartment. Ex. 1001, 19:20–26. Dependent claim 9 introduces materially identical requirements. *Id.* at 18:54–57. As explained in Part II.E.2 above, we have determined that Petitioner fails to prove by a preponderance of evidence that Solazzo and Serany describe or suggest arranging the inflation and lubrication syringes at different heights within the same compartment as introduced in claim 9. For the same reasons, we also determine that Petitioner has failed to demonstrate by a preponderance of evidence that Solazzo and Serany describe two syringes arranged at different heights in one compartment of the tray as required in claim 14.

c) First Compartment Configured to Receive and Apply
Lubrication to the Tip of the Catheter (Elements 14c, 14d)

Portions of elements 14c and 14d in claim 14 further require that the first compartment is configured to receive lubrication and apply that lubrication to the tip of the catheter. Ex. 1001, 19:26–37. Dependent claim 11 introduces materially identical requirements. *Id.* at 18:65–19:3. As explained in Part II.E.3 above, we have determined that Petitioner fails to prove by a preponderance of evidence that Solazzo and Serany describe or suggest the configuration of the first compartment for lubricating the tip of the catheter as introduced in claim 11. For the same reasons, we also determine that Petitioner has failed to demonstrate by a preponderance of evidence that Solazzo and Serany describe the configuration of the first compartment to receive and apply lubrication to the tip of the catheter as required in claim 14.

d) Conclusion

For all the reasons expressed above, we conclude that Petitioner fails to prove that the combined teachings of Solazzo and Serany render independent claim 14 or its dependent claims 15, 16,⁷ 21, and 22 unpatentable as obvious.

F. CLAIMS 7, 9, 11–16, AND 22:

OBVIOUSNESS IN VIEW OF SOLAZZO AND DISSTON

1. Claims 7, 9, and 11–13

Petitioner’s challenge to independent claim 7 based on Solazzo and Disston relies upon the same portions of Solazzo as the challenge analyzed in Part II.E.1 above (“Ground 1”). Pet. 70–82 (cross-referencing arguments for “Ground 1.”) Petitioner substitutes Disston for Serany as describing the closed system Foley catheter (element 7d.i) and the physical arrangement between the catheter and the fluid receptacle (element 7d.ii). *Id.* at 77–79 (element 7d.i), 79–82 (element 7d.ii).

a) Two Syringes in One Compartment and a Medical Device in Another Compartment (Elements 7a, 7b, 7c, 7d.i)

Disston, like Serany, describes only one syringe in its catheterization kit. Ex. 1008, 2:41–52, Fig. 1. Therefore, we determine that Disston fails to cure the defects in Petitioner’s challenge to claim 7 based on Solazzo and Serany that we analyze in Part II.E.1.a) above. For the same reasons expressed in that Part, we also conclude that Petitioner has failed to prove by a preponderance of evidence that the teachings of Solazzo and Disston

⁷ Because we have expressed multiple reasons why Petitioner’s challenge to independent claim 14 fails, we do not reach Patent Owner’s distinct arguments that dependent claims 15 and 16 remain patentable. *See* PO Resp. 42–47.

describe elements 7a, 7b, 7c, and 7d.i. Accordingly, Petitioner's challenge to independent claim 7 fails.

b) Fluid Receptacle Between Catheter and Base Member (Element 7d.ii)

For the reasons that follow, we conclude that Petitioner has failed to prove by a preponderance of evidence that the combined teachings of Solazzo and Disston describe element 7d.ii.

Disston relates to a single-level, wrapped catheterization tray package that "provide[s] for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled." Ex.1008, 1:59–67, 2:60–63; Fig. 2. Single-level tray 2 contains catheterization devices "arranged in such order and position as to be most conveniently available when the container is opened." *Id.* at 2:15–23. Disston's package includes "a pre-assembled catheter-drainage tube-drip chamber-drainage bag," *id.* at 1:33–34, including a Foley catheter 7, drainage tube 8, drip chamber 9, drainage bag 10, with "suitable adapters being interposed, if necessary, between the catheter and tube and/or between the drip chamber and bag," *id.* at 2:15–23, Fig. 1.

Based on our review of Disston, we determine that Petitioner fails to prove by a preponderance of evidence that Disston describes element 7d.ii. Essentially, Disston fails to describe a "fluid receptacle . . . between the second compartment base member and the Foley catheter." Petitioner relies upon Disston's Figure 1, reproduced below, as illustrating the claimed arrangement for element 7d.ii.

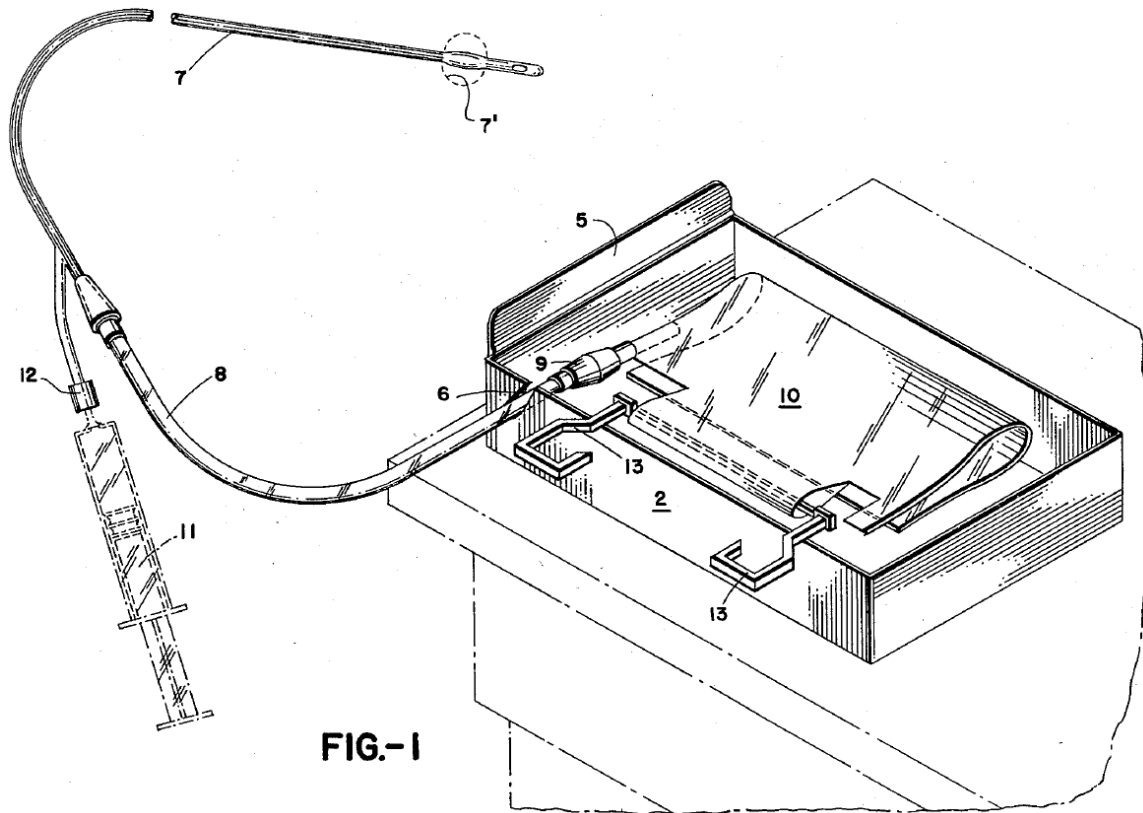


FIG.-1

Disston's Figure 1 is "a perspective view of the catheter-to bag assembly, extended in condition for use with the bag temporarily left in the tray portion of the container from which the sleeve portion has been removed." Ex. 1008, 1:49-52.

Figure 1 illustrates Disston's catheter assembly "extended in condition for use" but not as arranged before the package is opened. *Id.*;
Tr. 59:23-60:9. None of Disston's other Figures illustrates the contents of Disston's container before opening. *See id.* Figures 2-4 (failing to illustrate any contents of Disston's container). In the "condition for use" shown in Figure 1, we are unsure of how catheter 7, drainage tube 8, and drainage bag 10 are arranged inside the compartment of tray 2. Petitioner cites Disston's statement that items are "arranged in such order and position as to be most conveniently available when the container is opened" as proving that bag 10 is "between the second compartment base member and the Foley

catheter” as recited in element 7d.ii. Pet. 81–82 (citing Ex. 1008, 2:15–19, Fig. 1). This portion of Disston fails, however, to prove by a preponderance of evidence that Disston’s catheter and fluid receptacle are arranged as recited in element 7d.ii. Rather, Disston merely generally states that the items are arranged “to be most conveniently available when the container is opened.” Petitioner’s citation to Mr. Plishka’s testimony is also unavailing because Mr. Plishka relies on the same portion of Disston to opine that “the drainage bag of Disston is designed to fit in the bottom of a catheter tray, and the Foley catheter *can be* placed on top of and/or wrapped around the drainage receptacle.” *Id.* at 81–82 (citing Ex. 1002 ¶ 323 (emphasis added)). Mr. Plishka opines about how items “can be” placed in Disston’s tray, but he cites no persuasive evidence that Disston did arrange tubing and a fluid receptacle as required in element 7d.ii. Based on our careful review of Disston, it is simply too ambiguous on this point to prove by a preponderance of evidence that it describes element 7d.ii.

Without persuasive evidence that the combined teachings of Solazzo and Disston described element 7d.ii, Petitioner’s argument that independent claim 7 is unpatentable as obvious fails.

c) Conclusion

For the reasons expressed above, we conclude that Petitioner has failed to prove by a preponderance of evidence that the combined teachings of Solazzo and Disston render independent claim 7, or its dependent claims 9 and 11–13 unpatentable as obvious.

2. Claims 14, 15, 16, and 22

Petitioner’s challenge that independent claim 14 is obvious in view of Solazzo and Disston materially tracks the argument and evidence proffered

by Petitioner in its challenge based on Solazzo and Serany, except that Petitioner relies upon Disston rather than Serany for the same purposes. Pet. 84–86 (cross-referencing challenges based on Solazzo and Serany for claim 14 or Solazzo and Disston for claim 7). Based on our review of the record, Petitioner’s substitution of Disston for Serany fails to address persuasively any of the multiple deficiencies in Petitioner’s challenge to claim 14 based on Solazzo and Serany that we set out in Parts II.E.4 and II.F.1.a) above. Accordingly, for the reasons expressed in those Parts, we conclude that Petitioner has failed to prove by a preponderance of evidence that the combined teachings of Solazzo and Disston render independent claim 14, or its dependent claims 15, 16, and 22 unpatentable as obvious.

III. CONCLUSION

In summary,

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
7, 9–16, 21, 22	103	Solazzo, Serany		7, 9–16, 21, 22
8	103	Solazzo, Serany, Boedecker		8
7, 9, 11–16, 22	103	Solazzo, Disston		7, 9, 11–16, 22
8	103	Solazzo, Disston, Boedecker		8
10, 21	103	Solazzo, Serany, Disston		10, 21
Overall Outcome				7–16, 21, 22

IV. ORDER

For the reasons given, it is:

ORDERED, Petitioner has failed to establish based on a preponderance of evidence that claims 7–16, 21, and 22 of U.S. Patent 9,808,596 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.

IPR2019-00223
Patent 9,808,596 B2

For PETITIONER:

Mehran Arjomand
Cong Luo
MORRISON & FOERSTER LLP
marjomand@mofo.com
cluo@mofo.com

For PATENT OWNER:

Nicholas T. Peters
Paul B. Henkelmann
Allen E. Hoover
Jon Birmingham
FITCH, EVEN, TABIN & FLANNERY LLP
NtPete@fitcheven.com
PHenkelmann@fitcheven.com
AHoover@fitcheven.com
Jbirmi@fitcheven.com

Jeffrey P. Kushan
SIDLEY AUSTIN LLP
jkushan@sidley.com