

Patent No. 9,745,088
Petition For *Inter Partes* Review

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

C. R. BARD, INC.
Petitioner,

v.

MEDLINE INDUSTRIES, INC.
Patent Owner.

Patent No. 9,745,088

Inter Partes Review No. IPR2019-00035

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.*

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Petitioner C. R. Bard, Inc. (“Petitioner” or “Bard”) respectfully petitions for *inter partes* review of claims 1, 2, 6-10, 16-19 and 25-44 of U.S. Patent No. 9,745,088 (“the ’088 patent” (Ex. 1001)) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*

I. INTRODUCTION

The ’088 patent is directed to a tray for storing medical devices such as a catheter and related medical devices. (Ex. 1001, 1:34-38.) The tray comprises multiple compartments and includes a “stair-stepped” bottom surface that holds multiple syringes at different heights and ordered for use in a catheterization procedure. (*See, e.g.*, Ex. 1001, 4:28-31; Fig. 7.) In his Notice of Allowability, the Examiner explained that the closest art (Paikoff) did not have a tray with these features.

The Examiner, however, missed Solazzo (Ex. 1005). Figure 1 (annotated) of Solazzo shows a tray with multiple compartments, such as compartments 3 and 27.

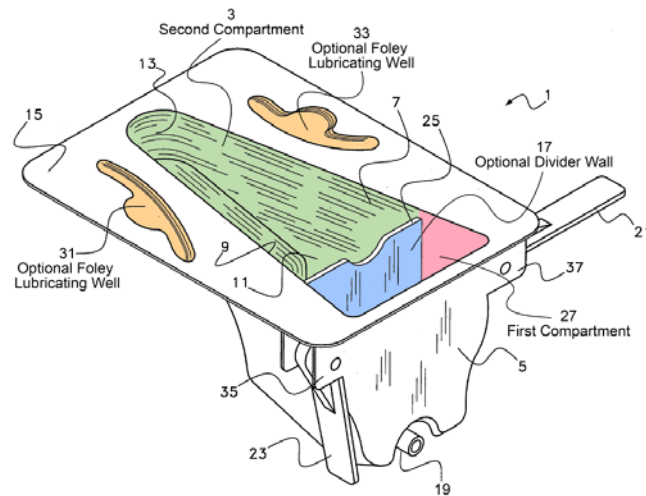
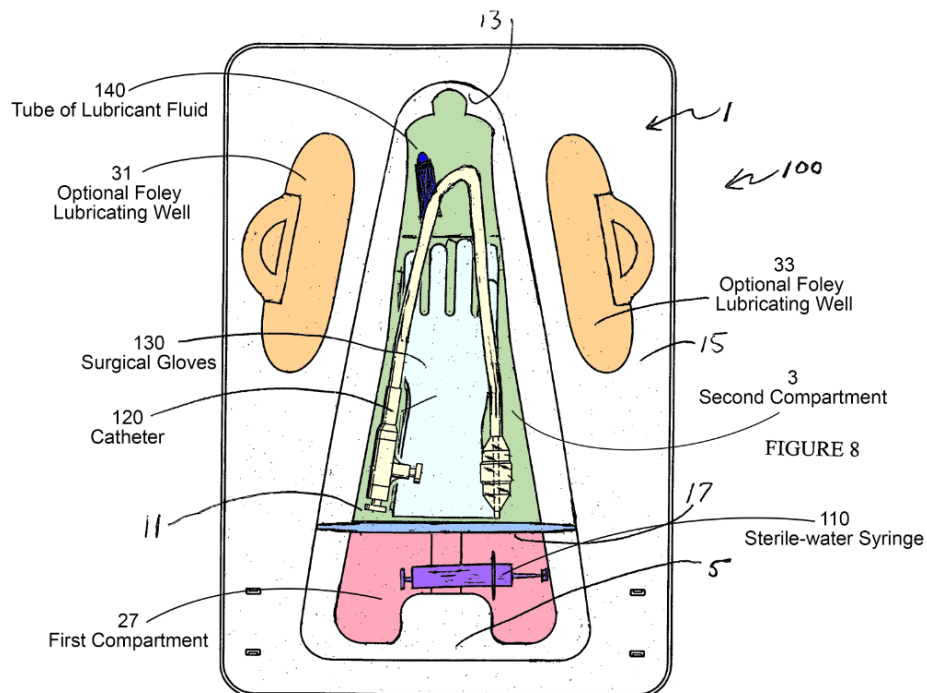


Fig. 1

Solazzo further discloses that the tray can hold multiple syringes. (Ex. 1005, 3:20-24.) Figure 8 (annotated) illustrates an example of the tray with a syringe 110 and a lubricant tube 140, which could readily be a lubricant syringe as well. Given the stair-step structure of Solazzo's tray, these two elements are at different heights and ordered for use in a catheterization procedure.



The Examiner missed Solazzo, because it was buried in an IDS with about 375 references. Moreover, it was presented *after* he had found certain claims patentable. By the end of the original examination, the Examiner had not applied or even discussed Solazzo.

Aside from the above features, the challenged claims of the '088 patent recite a number of well-known components associated with a catheterization tray. For example, independent claims 1, 25 and 37 recite that the tray is enclosed in a wrap and outer packaging. These components have been known for over 50 years. (*See, e.g.*, Ex. 1006.) Indeed, as discussed below, every element in the challenged claims was known.

Furthermore, all of the challenged claims are apparatus claims. Many of them recite functional aspects of how the tray could be used. For example, claim 7 defines a compartment as a “lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.” But if the prior art, such as Solazzo, discloses the same structure, the manner of using the chamber (e.g., for applying jelly) cannot differentiate over Solazzo.

In short, Bard respectfully submits that the challenged claims are unpatentable for this reasons set forth in this Petition. This Petition is supported by the Declarations of Mike Plishka (Ex. 1002) and Dr. Edward Yun (Ex. 1003).

II. THE STATE OF THE ART

By 2009 (the earliest purported priority date of the '088 patent), the packaging of medical devices, in particular the packaging of Foley catheters and related medical devices, was extremely well-developed. Bard first presents a summary of the state of the art as of 2009 with respect to tray structure, tray components and functional aspects of the tray. This presentation is done before addressing the '088 patent so as to place its purported inventions in context. Moreover, the state of the art is relevant to the obviousness combinations in the Petition. *See Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013).

A. Tray Structure

The practice of packaging a Foley catheter with related medical devices inside a tray dates back nearly 50 years before the earliest purported priority date of the '088 patent. (Ex. 1002, ¶ 43.) For example, U.S. Patent No. 3,166,189 to Disston (Ex. 1008) was filed on March 26, 1963 by Bard and is directed to a sealed catheterization package. The package includes an all-in-one single level tray that holds a Foley catheter pre-connected to a drainage bag (*see* annotated Figure 1 below) and its related components, such as an underpad, sterile gloves, lubricant, and a water-filled syringe for inflating the balloon of the Foley catheter. (Ex. 1008, 2:15-26; Figs. 1-2; Ex. 1002, ¶¶ 44-49.)

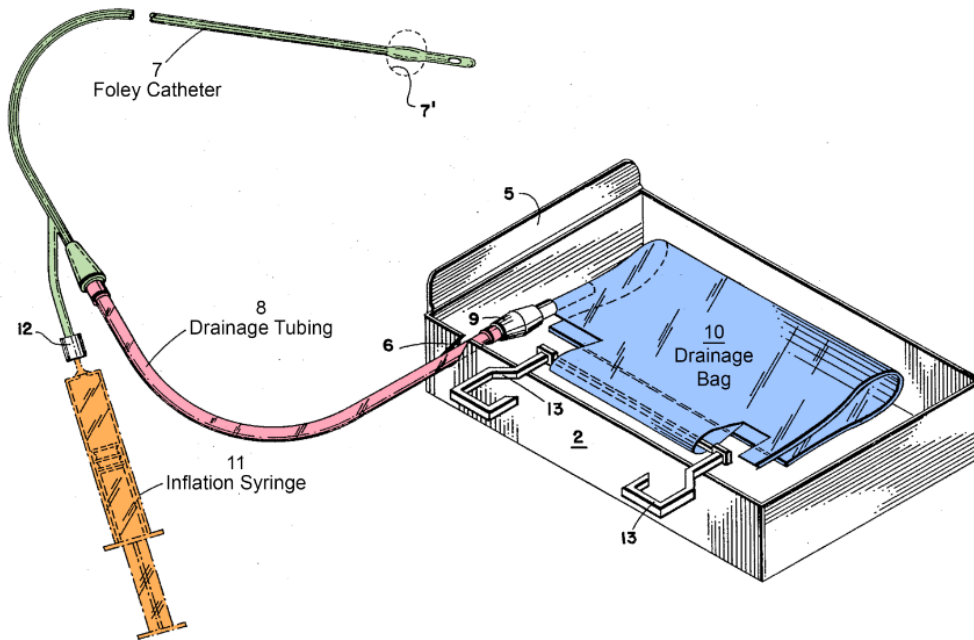
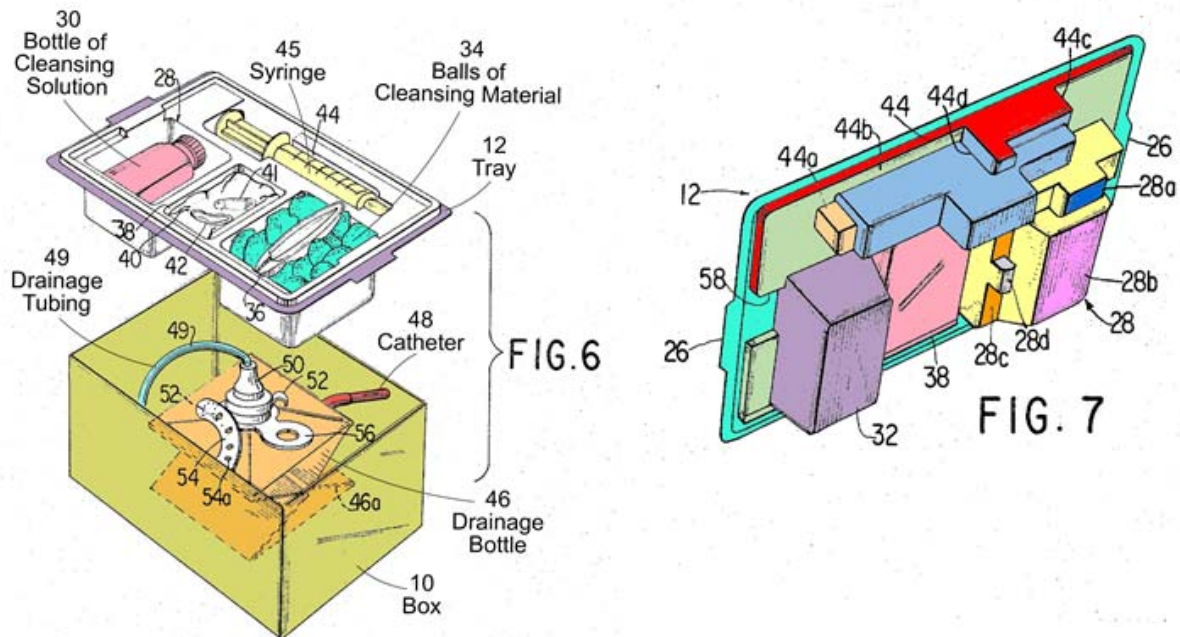


FIG.-I

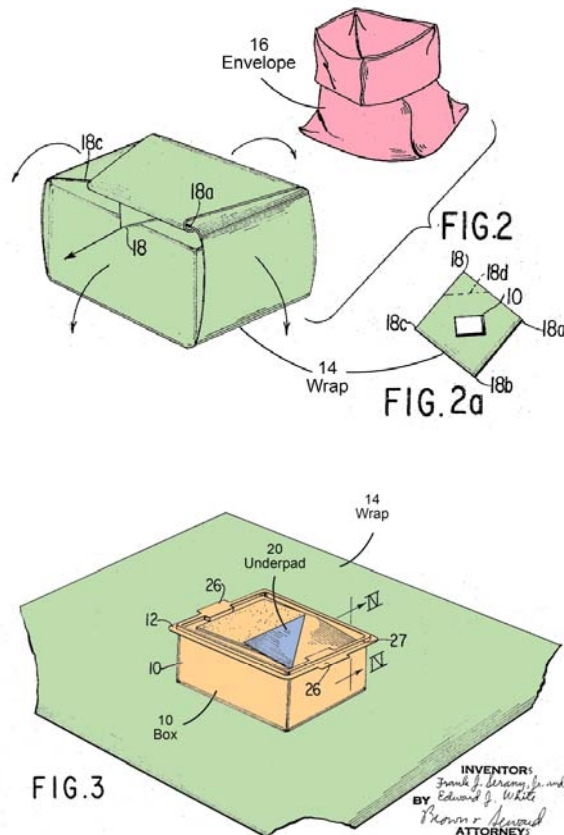
U.S. Patent No. 3,329,261 to Serany (Ex. 1006), filed on September 3, 1965 also by Bard, discloses a catheterization package including a Foley catheter preconnected to a drainage bottle via tubing, a bottom tray, and a top tray having multiple compartments contoured to fit components stored therein as shown in annotated Figs. 6 and 7 below. (Ex. 1006, 2:39-40, 3:23-26.) For example, contoured depression 44 holds a syringe and includes an upper portion 44c that is wider than the diameter of the syringe plunger handle 45a for easy grasping, and indentations 44d to accommodate a flange or finger grip 45c of the syringe. (Ex. 1006, 3:6-22; Fig. 7; Ex. 1002, ¶¶ 50-53.)



Typically, a medical device tray is wrapped in a bag or outer wrap to allow shipment while holding components inside the tray. (Ex. 1002, ¶ 54.) An inner wrap, often known as a “CSR wrap,” is often provided around the tray to maintain sterility of components within the tray. (Ex. 1002, ¶ 54.) Because Foley catheters must be sterile in order to be inserted into a patient’s body, it was common practice to wrap a Foley catheter tray in a CSR wrap and enclose the wrapped tray with an outer packaging. (Ex. 1002, ¶ 55.)

For example, as shown in the annotated figures below, Serany discloses a tray enclosed in a wrap 14 and further encased in an outer envelope 16. (Ex. 1006, 1:60-66; Figs. 1-3; Ex. 1002, ¶¶ 56-58.) Serany’s tray is “sterilized before or after

enclosure in the envelope,” whereby the “envelope 16 seals the contents to maintain the sterility of the contents.” (Ex. 1006, 1:63-66.)



B. Components Of The Tray

By 2009, it was well known to include all of the components typically used when performing a Foley catheterization procedure inside a Foley catheter tray. (Ex. 1002, ¶ 59.)

Closed system Foley catheter. “Reducing the risks associated with urinary catheters,” published in *Nursing Standard* Vol. 23 No. 29 on March 25, 2009 (referred to as “Nursing Standard article”; Exs. 1010, 1025.) describes an all-in-

one Foley tray including a “pre-connected catheter and drainage bag,” which creates a “closed system.” (Ex. 1010, 52; Ex. 1002, ¶¶ 59-61.) Using a “closed system” catheter reduces the risk of developing catheter-associated urinary tract infections (“CAUTIs”) to between 8%-15%, as opposed to a 97% risk of infection with open systems. (Ex. 1010, 51.) Disston and Serany disclose closed-system Foley catheters. (Ex. 1002, ¶¶ 62-65.)

Inflation Syringe. A syringe containing sterile water is used to inflate a balloon on a Foley catheter to hold the indwelling catheter in place within the patient’s bladder. For example, Disston discloses “inflation of the balloon 7 by injection of sterile water from the syringe 11.” (Ex. 1008, 2:50-51; *see also* Ex. 1006, 3:50-51; Ex. 1005, 3:20-21; Ex. 1010, 52; Ex. 1002, ¶ 66.)

Lubricant/Lubrication Syringe. A Foley catheter needs to be lubricated before insertion into a patient. For example, Disston describes that it has been “long and customary” to take certain steps in catheterization, including “removing a sterile catheter from its envelope, applying lubricant to it, inserting it in the patient, inflating its balloon (if it is a Foley type retention catheter).” (Ex. 1008, 1:13-18.) Foley catheterization packages thus include lubricant. (Ex. 1008, 1:32; Ex. 1006, 3:3-4; Ex. 1005, 3:18; Ex. 1010, 52; Ex. 1002, ¶¶ 67-68.)

Drapes/Pads. To create a sterile working area, drapes and pads are used, such as an underbuttocks drape/pad placed under the patient and a fenestrated

drape placed over the patient with an opening positioned at the insertion point of the catheter. (Ex. 1006, 2:22-31; Ex. 1010, 52; Ex. 1002, ¶¶ 69-70.)

Instructions. It was standard practice at the time of the invention to include instructions on how to perform a Foley catheterization procedure. For example, U.S. Patent No. 6,840,379 to Franks-Farah (Ex. 1007), filed on September 11, 2003, teaches a urinary catheter kit with “detailed step-by-step” instructions as shown in Fig. 2A below. (Ex. 1007, 2:33-37; Figs. 2B; Ex. 1002, ¶¶ 71-75.)

FIG. 2A

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Miscellaneous. The provision of further components for catheterization within a Foley catheter tray was commonplace by the time of the invention. For example, Foley catheter trays include hand sanitizers, gloves, a specimen

container, swab sticks and a Foley catheter securement device. (Ex. 1002, ¶¶ 74-91.)

C. Functional Aspects Of The Tray

Lubrication compartment. Compartments for lubricating catheters were well-known features of prior art trays. (Ex. 1002, ¶¶ 92-100.) For example, a prior art YouTube video, uploaded on February 7, 2008, entitled “Nursing Lab: Take Two – *Male Catheter Insertion*” (“*Male Catheter Insertion*”; Exs. 1015A-B), shows a Foley catheterization procedure performed using an all-in-one Foley catheter tray, whereby a lubricant-filled syringe is removed from the tray and lubricant is dispensed into a compartment of the tray as a healthcare provider states, “I’m going to squirt my lube into this little container where the syringe was.” (Ex. 1015A, 2:43-2:50.) Subsequently, a catheter is lubricated using the compartment. (Ex. 1015B, 0:55-1:00.)

Arranging items consistent with order of use. Ordering components within a tray according to their use during a catheterization procedure was well-known in the art. For example, Disston’s catheterization components are “arranged in such order as to be most conveniently available when the container is opened....” (Ex. 1008, 2:15-19.) In Serany’s tray, “[e]verything is available in the proper order of use...” and “in logical step-by-step order.” (Ex. 1006, 1:23-25; 1:31-35; *see also* Ex. 1002, ¶¶ 101-106.)

Arranging Items to Prompt Certain User Behavior (i.e., Affordances).

Prompting certain user behaviors through the design of things was well-known as “affordances,” a term popularized by author Donald A. Norman in his book “*The Design of Everyday Things*,” first published in 1988, which describes “affordances” as providing “clues as to the operation of things.”

Affordances provide strong clues as to the operation of things. Plates are for pushing. Knobs are for turning. Slots are for inserting things. Balls are for throwing or bouncing. When affordances are taken advantage of, the user knows what to do just by looking: no picture, label, or instruction is required.

(Ex. 1016, 9.)

Disston’s tray presents items “arranged in such order as to be most conveniently available when the container is opened” and staggered so “that it can be opened without any part of either hand of the user coming in contact with the contents.” (Ex. 1008, 2:15-23, 2:63-72; *see also* Ex. 1002, ¶¶ 107-114.)

III. THE ’088 PATENT

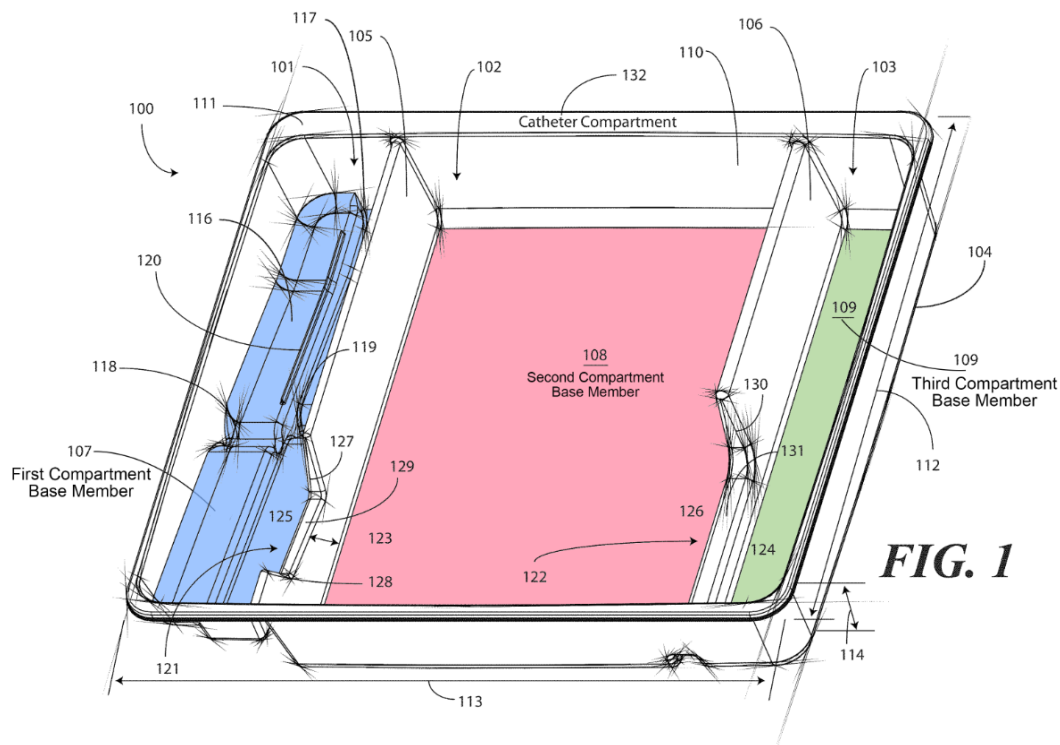
A. Summary

The ’088 patent is directed to a tray for storing medical devices such as a catheter and related medical devices. (Ex. 1001, 1:34-38.) The ’088 patent focuses on tray structure, components in the tray and functional aspects of the tray.

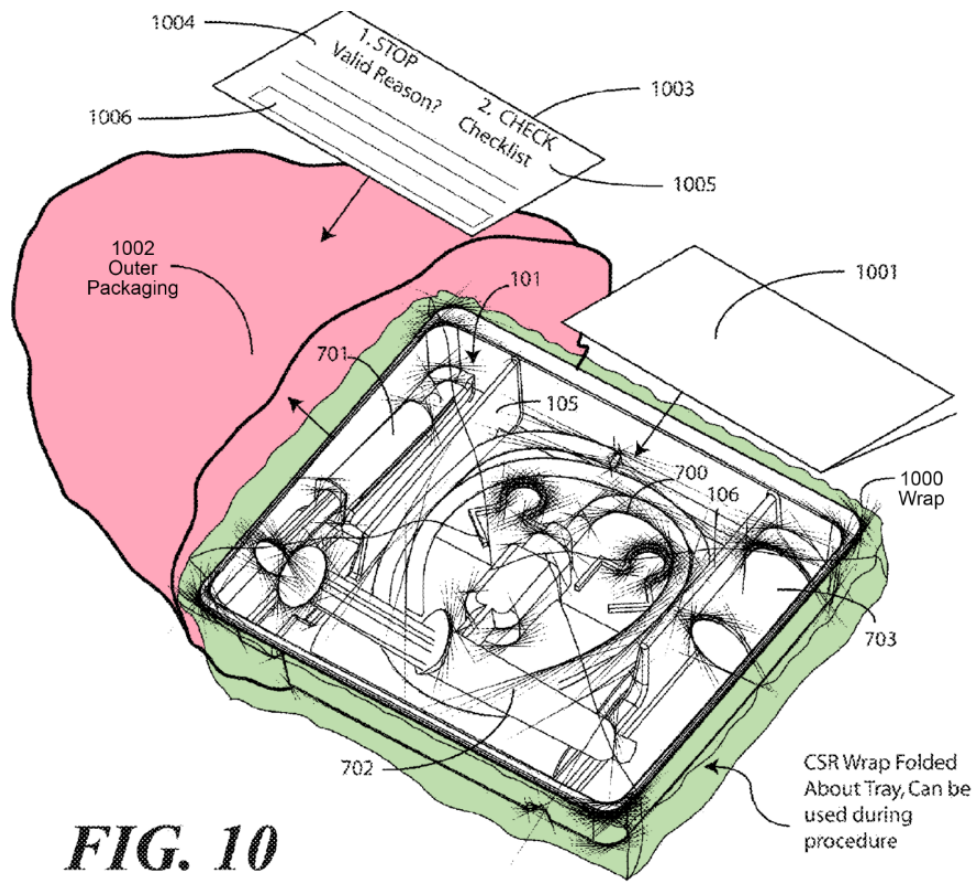
As discussed above, and in more detail below, all these aspects were well-known in the art by 2009.

1. Tray structure

As shown in annotated Fig. 1 (below), tray 100 provides multiple compartments, including a first compartment 101 (blue), a second compartment 102 (red), and a third compartment 103 (green). (Ex. 1001, 5:12-18; Fig. 1.) The multiple compartments store various medical devices (described below) in a one-level (“single layer”) tray rather than a multi-level, stacked-configuration. (Ex. 1001, 9:4-9; Fig. 7.)



As shown in annotated Fig. 10 (below), when packaged, the tray is covered in a “CSR Wrap 1000” (green) and further enclosed in a “sterile wrap 1002 such as a thermally sealed bag” (pink). (Ex. 1001, 11:45-46; 11:51-52; Fig. 10.)



2. Components of the tray

As shown in annotated Fig. 7 (below), the first compartment 101 accommodates syringes 701, 702 (red, green) containing sterile water or lubricants. (Ex. 1001, 4:18-21; 9:24-26.) The second compartment 102 accommodates a catheter assembly 700 (blue) and fluid bag. (Ex. 1001, 4:18-21.) The third

compartment 103 accommodates a specimen container 703 for capturing samples taken from the patient via the catheter (Ex. 1001, 4:22-23, 5:64-65.)

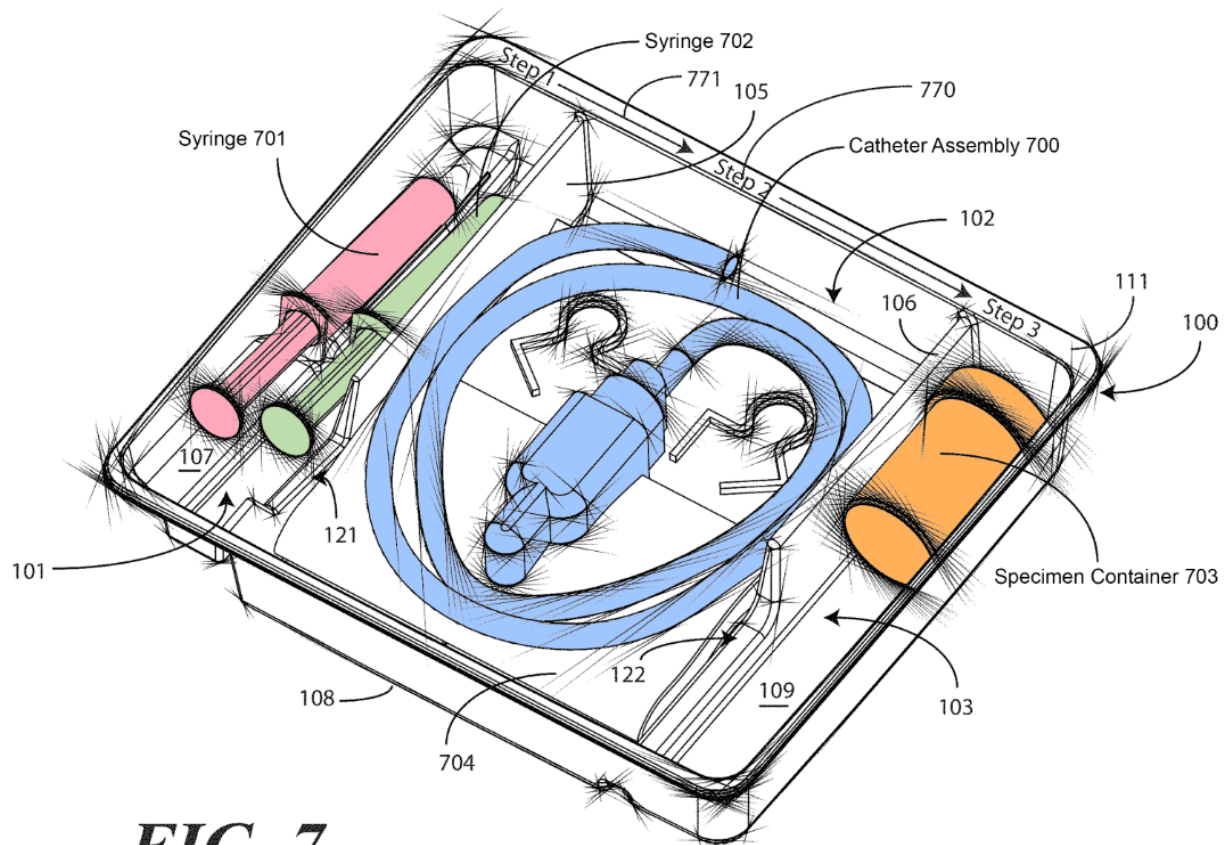


FIG. 7

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. (Ex. 1001, 5:46-51.)

3. Functional aspects of the tray

Compartments of the tray can have “multi-purpose functionality.” (Ex. 1001, 4:32-33.) For example, a compartment can both accommodate a syringe of

lubricating jelly and be used as a lubricating jelly applicator. (Ex. 1001, 4:34-37.)

For instance, the syringe of lubricating jelly is stored in the first compartment, which is configured with a stair-stepped contour that allows the compartment to serve as a lubricant applicator when lubricating jelly is dispensed along a lower step and the catheter is passed through the dispensed lubricant. (Ex. 1001, 7:38-59.)

The tray orders objects “in accordance with their use during the procedure.” (Ex. 1001, 5:59-60.)

The tray provides a “medical services provider with mnemonic devices instructing them in which order to use each device.” (Ex. 1001, 4:26-27.) For example, the first compartment includes an inclined, stair-stepped base that presents the plunger of each syringe at an easy to reach angle and at different heights based upon order of use. (Ex. 1001, 4:28-31.) This arrangement serve as a mnemonic reminder, because “it may be intuitive that a syringe placed on a higher step portion may need to be used first,” the intuition enforced “when the higher step portion is disposed farther to the left in a left-to-right usage configuration.” (Ex. 1001, 6:18-22.)

B. Effective Filing Date

Application no. 12/495,148, filed on June 30, 2009 is the earliest filed application to which the '088 patent purports to claim priority. Bard assumes—for

this Petition only—that the challenged claims are entitled to a priority date of June 30, 2009. Bard reserves the right to challenge this priority date.

C. Prosecution History

The examination of the '088 patent was short and not particularly robust.

Initial filing. The '088 patent was filed on July 7, 2015 as application no. 14/793,455. Applicants presented a sole independent claim directed to a medical procedure kit comprising a tray, two syringes, a layer of wrap material and an outer packaging. (Ex. 1004, 479.)

Office Action. On May 3, 2017, the Examiner rejected independent claim 1 based on U.S. Patent No. 4,523,679 to Paikoff et al. (Ex. 1021), but found dependent claims 9, 11 and 12 to be allowable. (Ex. 1004, 390-391, 398.) These claims depended from independent claim 1 and dependent 6. (Ex. 1004, 480.) Claim 6 recited that the two syringes are ordered within the tray in accordance with their use during a catheterization procedure and that the tray comprises two compartments, with the first compartment supporting the two syringes. Claim 9 further recited a base member of the first compartment defining a mnemonic device. Claims 11 and 12 recited syringes at different heights based upon their use in a catheterization procedure.

Interview. Applicants' counsel conducted an interview with the Examiner on June 22, 2017. They discussed new claims directed to a single tray having two

syringes and a medical assembly comprising a Foley catheter, a coiled tubing and a fluid drain bag. The Examiner explained that a preliminary search did not reveal “a catheter tray with two syringes and a Foley catheter.” (Ex. 1004, 198.)

Response. Applicants’ counsel then submitted an amendment. Claim 1 was amended to include the recitations of claims 6 and 9. New claims 27 and 39 were added to recite the recitations of claim 1, 6 and 11 or 12. Moreover, Applicants’ counsel added new claims 47, 63 and 79 directed to two syringes and a Foley catheter. (Ex. 1004, 132-145.)

IDS. On the same day as the Response, and *after* Examiner had indicated allowable subject matter, Applicants’ counsel submitted a lengthy IDS spanning 21 pages and listing 375 references, including Solazzo. (Ex. 1004, 151-175.)

Allowance. On July 20, 2017, the Examiner allowed the claims with an Examiner’s Amendment. With respect to claims 1, 27 and 39, the Examiner addressed certain references—but not Solazzo—and found them lacking. According to the Examiner, the closest prior art (Paikoff) did not disclose or suggest a mnemonic device or compartments that support multiple syringes at different heights according to their order of use in a catheterization procedure or both. (Ex. 1004, 11.) The Examiner also addressed additional references that disclosed mnemonic devices but not in the context of a catheterization procedure. (Ex. 1004, 8-17.)

With respect to claims 47, 63 and 79, the Examiner found that the addressed art failed to disclose a Foley catheter, a coiled tubing, and a fluid drain bag. (Ex. 1004, 11, 14.)

Issuance. The '088 patent issued on August 29, 2017. Original claims 1, 27, 39, 47, 63 and 79 issued as claims 1, 25, 37, 45, 61 and 77, respectively. Claims 1, 25 and 37 differ with respect to limitation [g] of each claim.

D. Level Of Ordinary Skill

A person of ordinary skill in the art (“POSITA”) in the field of the '088 patent in 2009 would have at least a Bachelor of Science degree in Packaging Science or Package Engineering, chemical engineering, mechanical engineering, or industrial design. Optionally, the person of ordinary skill in the art would have had a bachelor's degree in an alternative technical field and about two years' experience in the packaging of medical devices. This person would also have had an understanding of and experience with thermoforming and the design of thermoformed packages. One of ordinary skill in the art would not need to be a practitioner that would use the claimed methods or products (*i.e.*, catheterization trays), but would have learned about the procedures from those skilled in the procedures for which the claimed products and methods would be used (*e.g.*, a nurse). (Ex. 1002, ¶¶ 14-16.)

E. Litigation And Other Matters

Patent Owner has asserted the '088 patent against Bard in a co-pending litigation: *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:17-cv-07216 (N.D. Ill.). This co-pending litigation will be referred herein as *Medline III*, because Patent Owner has asserted other patents against Bard in two other pending litigation matters: (1) *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:14-cv-03618 (N.D. Ill.) ("*Medline I*") and (2) *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:16-cv-03529 (N.D. Ill.) ("*Medline II*").

In *Medline I*, Bard requested *inter partes* review of U.S. Patent Nos. 8,448,786 (IPR2015-00509); 8,678,190 (IPR2015-00514); and 8,631,935 (IPR2015-00511 and -00513). The Board instituted review of certain claims in the 513 and 514 IPR proceedings. Patent Owner subsequently cancelled those claims, thereby terminating the proceedings. The Board denied institution in the two other IPR proceedings. Importantly, none of these IPR proceedings was based on Solazzo—the primary reference in this Petition.

IV. CLAIM CONSTRUCTION

A claim of an unexpired patent is given the “broadest reasonable construction” in light of the specification during *inter partes* review. 37 C.F.R. § 42.100(b). For the purposes of this Petition, Bard submits that the terms of the challenged claims of the '088 patent should be accorded their ordinary and

customary meanings as understood by one of ordinary skill in the art and consistent with the '088 patent's disclosure. Accordingly, no term or phrase requires specific construction to find that the challenged claims are invalid.

Nevertheless, Bard notes that Patent Owner has proposed constructions in district court litigation. The first two Patent Owner constructions below are from *Medline III*, where the '088 patent is at issue, while the third Patent Owner construction is from *Medline II*. (Ex. 1022; Ex. 1023, 13.)

Claim Term Or Phrase	Patent Owner Construction
mnemonic device	feature intended to assist the memory, such as ordering items left to right or top to bottom.
catheter assembly	a medical device that includes a Foley catheter connected via coiled tubing to a drainage receptacle
Lubricating jelly application chamber/ compartment	a compartment or channel where lubrication is applied

The application of the art in this Petition would meet the above claim language under Patent Owner's constructions. Indeed, the application of art in this Petition would also meet Bard's constructions of these terms in *Medline II* and *III*. (Ex. 1023; Ex. 1024.)

V. THE MANNER OF USING THE CLAIMED KIT DOES NOT DIFFERENTIATE THE KIT OVER THE PRIOR ART

Before addressing the individual Grounds, it is important to note the claimed kits have a number of limitations directed to the manner in which the kit is used.

For example:

- “a *mnemonic* device indicating which of the first syringe or the second syringe should be used first in the catheterization procedure” (claim 1); and
- “a *lubricating jelly application chamber* to lubricate at least a portion of a catheter assembly” (claim 17)

The italicized limitations cannot differentiate over the grounds in this Petition if the prior art of those grounds discloses the same structure. Apparatus claims, like a “medical procedure kit” of the challenged claims, cover what a device is, not what a device does. *See* MPEP § 2114 (citing *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990)). More specifically, “a claim containing a ‘recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus’ if the prior art apparatus teaches all the structural limitations of the claim.” *Id.* (quoting *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)).

Here, the '088 patent describes a mnemonic device being “an inclined, stair-stepped bottom member” of a compartment. (Ex. 1001, 4:25-31; 6:16-25.) If a prior art reference—like Solazzo—discloses a stair-stepped bottom member, then the term “mnemonic” does not differentiate claim 1 from Solazzo. It is simply irrelevant whether or not Solazzo discloses what kind of reminder or cue the user receives, because that arises from how the kit is used.

Similarly, if the prior art discloses all the recited chambers or compartments, as does Solazzo, a “lubricating jelly application chamber” does not differentiate claim 7 from Solazzo. What is applied to the chamber is directed to how the chamber is used.

VI. “PRINTED INSTRUCTIONS” DESERVE NO PATENTABLE WEIGHT

A number of the challenged claims are directed to “printed instructions.” For example, claim 18 recites that the medical procedure kit further comprises “printed instructions for using the tray.” Claim 19, which depends from claim 18, further recites that the printed instructions are “to instruct application of lubricating jelly to the catheter assembly using the lubricating jelly application chamber.” Such claims deserve no patentable weight. If the claimed kit is known—which Bard will show below—then the addition of printed instructions does not render the kit patentable. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (“[Ngai] is

not, however, entitled to patent a known product by simply attaching a set of instructions to that product.”).

Even if the limitations are given weight, Bard herein presents grounds with the reference Franks-Farah (Ex. 1007) that discloses the recited printed instructions.

VII. PRECISE REASONS FOR RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.104(b), Bard respectfully requests cancellation of claims 1, 2, 6-10, 16-19 and 25-44 of the '088 patent based on the following references:

Prior Art Reference	Abbreviation
U.S. Patent No. 7,278,987 to Solazzo	“Solazzo” (Ex. 1005)
U.S. Patent No. 3,329,261 to Serany, Jr. et al.	“Serany” (Ex. 1006)
U.S. Patent No. 6,840,379 to Franks-Farah et al.	“Franks-Farah” (Ex. 1007)
U.S. Patent No. 3,166,189 to Disston	“Disston” (Ex. 1008)

The statutory grounds for the challenge of each claim are set forth below.

All of the statutory citations are pre-AIA.

Ground	35 U.S.C. §	Claim	Prior Art Reference(s)
1	103(a)	1-2, 6-10, 16-17	Solazzo, Serany
2	103(a)	18-19	Solazzo, Serany, Franks-Farah

3	103(a)	25-32, 36-41	Solazzo, Serany
4	103(a)	33-34, 42	Solazzo, Serany, Disston
5	103(a)	35	Solazzo, Serany, Franks-Farah
6	103(a)	43-44	Solazzo, Serany, Disston, Franks-Farah

Below, Bard discusses why the challenged claims are unpatentable under the statutory grounds raised, including by specifying how and where the prior art satisfies each limitation of each challenged claim, as required by 37 C.F.R. § 42.104(b)(4). Bard's showing establishes a reasonable likelihood that it will prevail on each ground of invalidity as to each challenged claim. Bard also provides the Declarations of Michael Plishka (Ex. 1002) and Dr. Edward Yun (Ex. 1003) to support its showing.

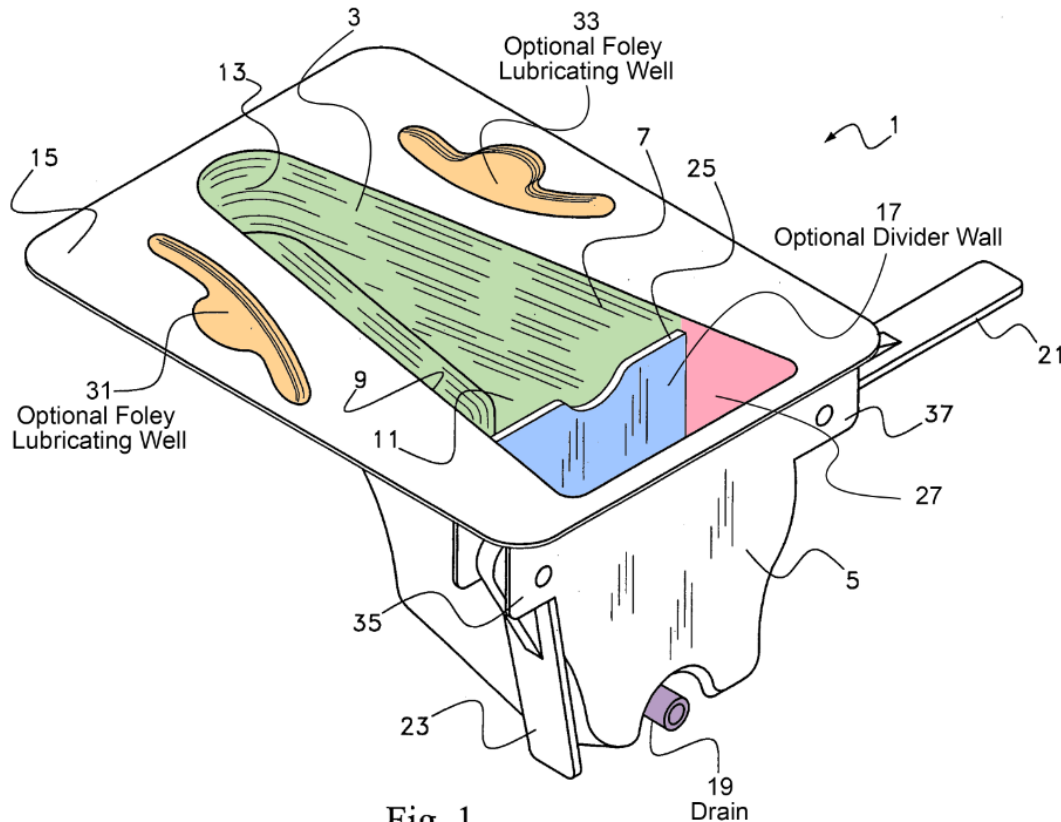
A. Ground 1 – Obvious Based On Solazzo And Serany

1. Summary of Solazzo

Solazzo was filed on July 9, 2004, and issued on October 9, 2007. Solazzo is therefore prior art to the '088 patent pursuant to at least 35 U.S.C. § 102(b).

Solazzo is directed to an ergonomic, single layer catheterization/irrigation tray having multiple compartments, including recessed area 3, compartment 27 and

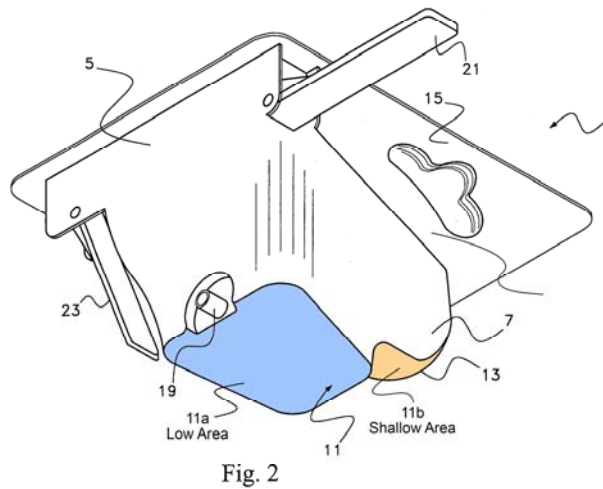
wells 31, 33 as shown in annotated Figure 1 below.¹ (Ex. 1005, 4:15-25; Fig.1; Ex. 1002, ¶¶ 118-136.)



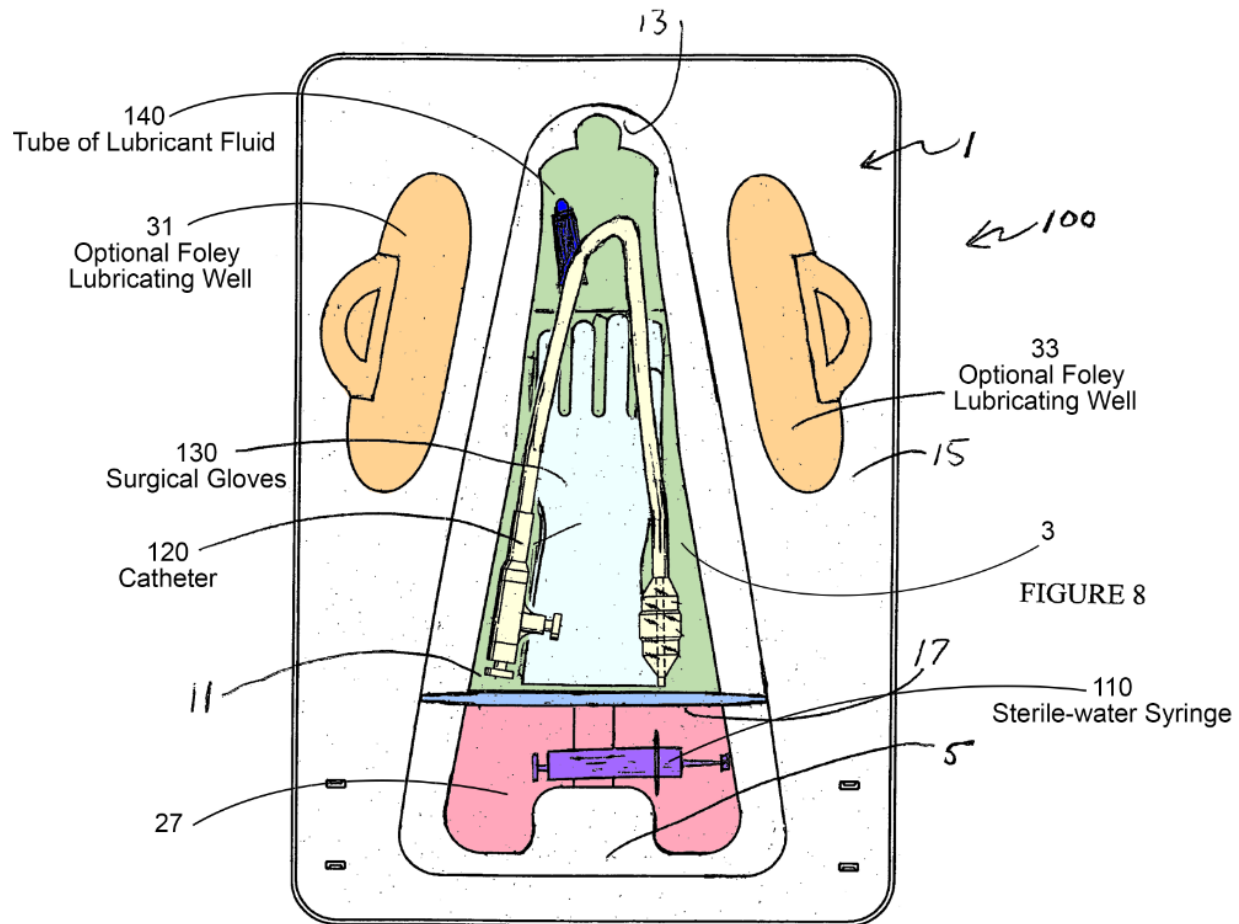
The recessed area 3 / compartment 27 is trapezoidal-shaped with a “non constant depth” provided by a terraced bottom 11 having low area 11A and shallow area 11B as shown in annotated Figure 2 below. (Ex. 1005, 3:61-66; Fig.

¹ It should be noted Solazzo uses the terms “compartment” and “well” interchangeably. For example, he refers to compartments 3 and 27 as “irrigation well” and “drainage well.” (Ex. 1005, 5:12-15; Ex. 1018, [0044].)

5.) Drain 19 may connect to drain hole(s) in the terraced bottom 11 and to tubing for other receptacles. (Ex. 1005, 4:12-15; Figs. 1-2.)



Solazzo further discloses his invention in the context of kit as shown in annotated Fig. 8 below. The recessed area 3 and compartment 27 store medical devices included in tray kit 100, including a Foley catheter, urinary tract lubricant, surgical gloves, inflation syringe, irrigation syringe, evacuation tubing, and antiseptic solutions. (Ex. 1005, 3:14-24, 4:1-8; Fig. 8.) In the tray kit 100, inflation syringe 110 is stored at low area 11A, while lubricant fluid 140 is stored at shallow area 11B. (Ex. 1005, 4:41-45; Fig. 8.)



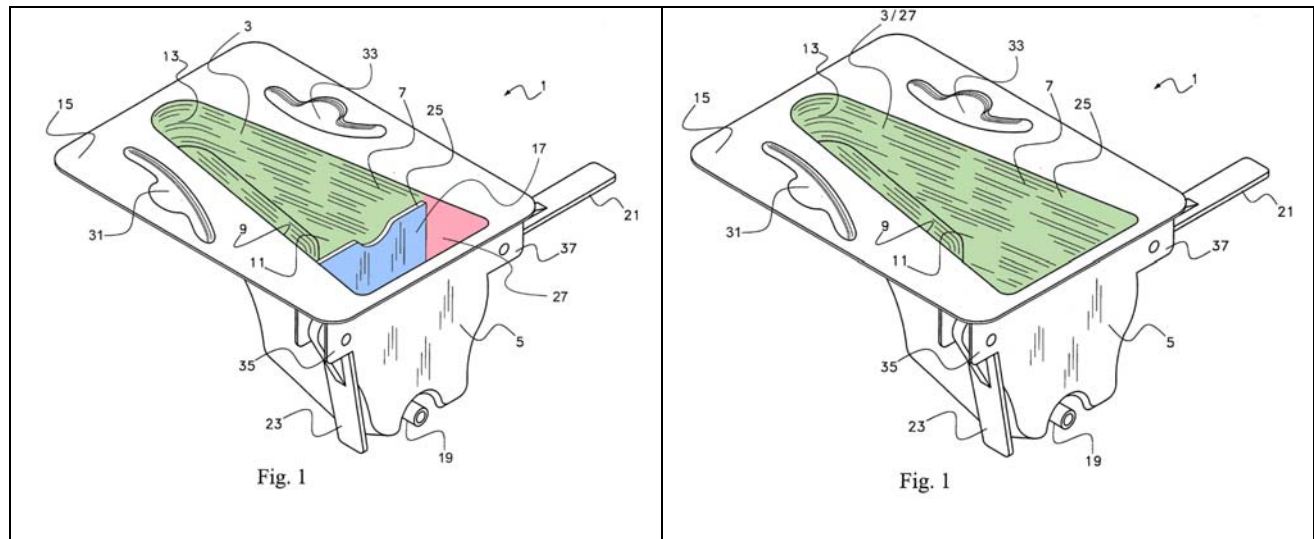
In use, the recessed area 3 and compartment 27 fit between the legs of “[a] patient requiring an urological procedure” while flange 15 and wing supports 21, 23 rest atop the legs when the patient is seated. (Ex. 1005, 1:8-12, 3:66-4:10, 4:26, 4:32-33; Fig.1.) A surgeon proceeds to “evacuate the bladder of its contents, urine and/or clots” using kit 100, e.g., by wearing the gloves, lubricating and inserting the catheter, and inflating with inflation syringe. (Ex. 1005, 4:32-33, 46-48.)

Two Embodiments: “Divider Wall” and “No Divider Wall”

As shown below on the left, Solazzo discloses an embodiment where a divider wall 17 divides recessed area 3 and compartment 27 into two compartments. This will be referred herein as the “divider wall” embodiment.

Solazzo, however, notes that the divider wall is “optional.” (Ex. 1005, 4:15-16.)

As shown below on the right, Figure 1 has been modified to remove the divider wall to illustrate a single compartment labeled 3/27. This will be referred herein as the “no divider wall” embodiment.



2. Summary of Serany

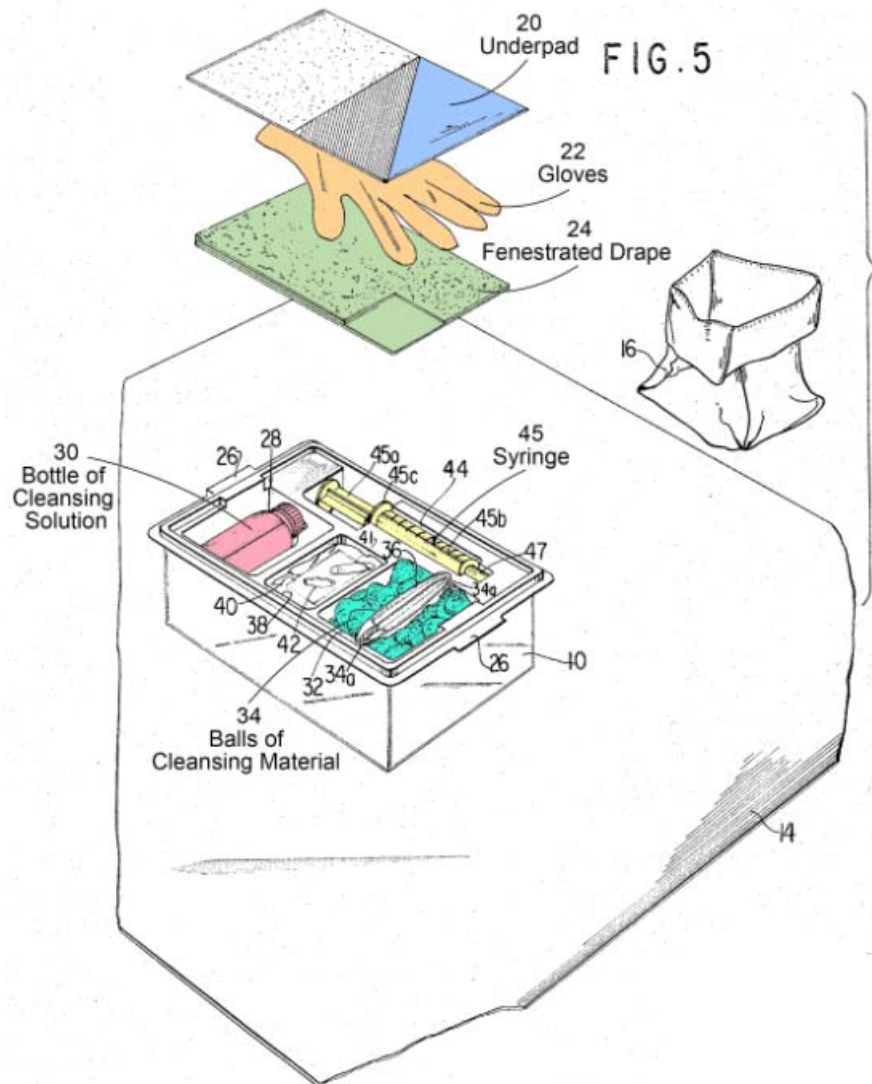
Serany issued on July 4, 1967. Serany is therefore prior art to the '088 patent pursuant to at least 35 U.S.C. § 102(b).

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; Ex. 1002, ¶¶ 137-142.) The package includes a

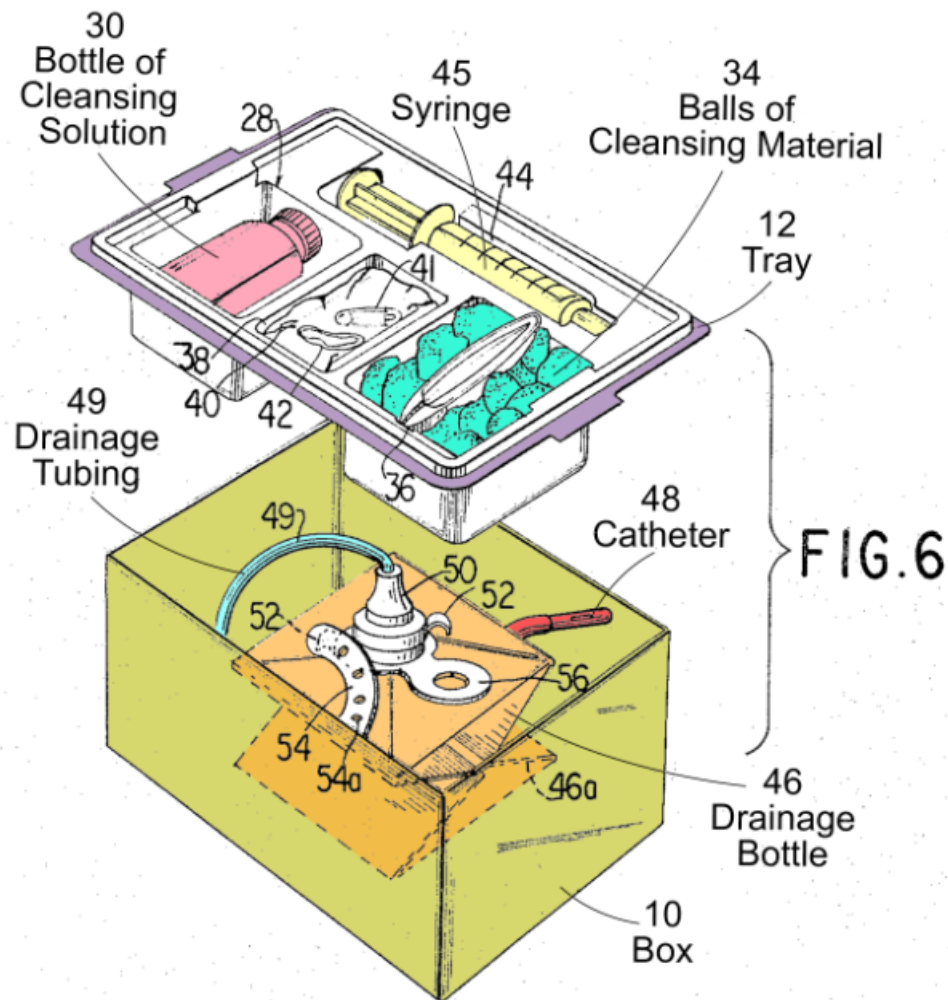
multi-compartment single-layer tray 12 mounted on a box 10 and enclosed with a sealed outer envelope 16 and an inner wrap 14 that unfolds to provide a sterile field work area (as shown in the figures in Section II of this Petition). (Ex. 1006, 1:60-72, 2:17-20; Figs. 1-5.)

Serany's compartments and depressions suitably accommodate components received therein, *e.g.*, a prefilled syringe 45 of sterile water is stored in depression 44, which includes indentations 44d along the sides to accommodate the syringe's flange. (Ex. 1006, 2:40-41, 3:6-22; Figs. 6-7.)

Serany's package further includes a waterproof underpad 20, gloves 22, fenestrated drape 24, cleansing solution bottle 30, rayon balls 34, forceps 36, lubricating jelly pouch 40, safety pin 41 and rubber band 42, and a "ready for use" Foley catheter 48 preconnected to a collapsible drainage bottle 46 via tube 49 as shown in annotated Figure 5 below. (Ex. 1006, 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.” (Ex. 1006, 3:26-31; Fig. 6.) The catheter and tubing are coiled in the box about the bottle as shown in annotated Figure 6 below. (Ex. 1006, 3:33-35.)



3. The Combination

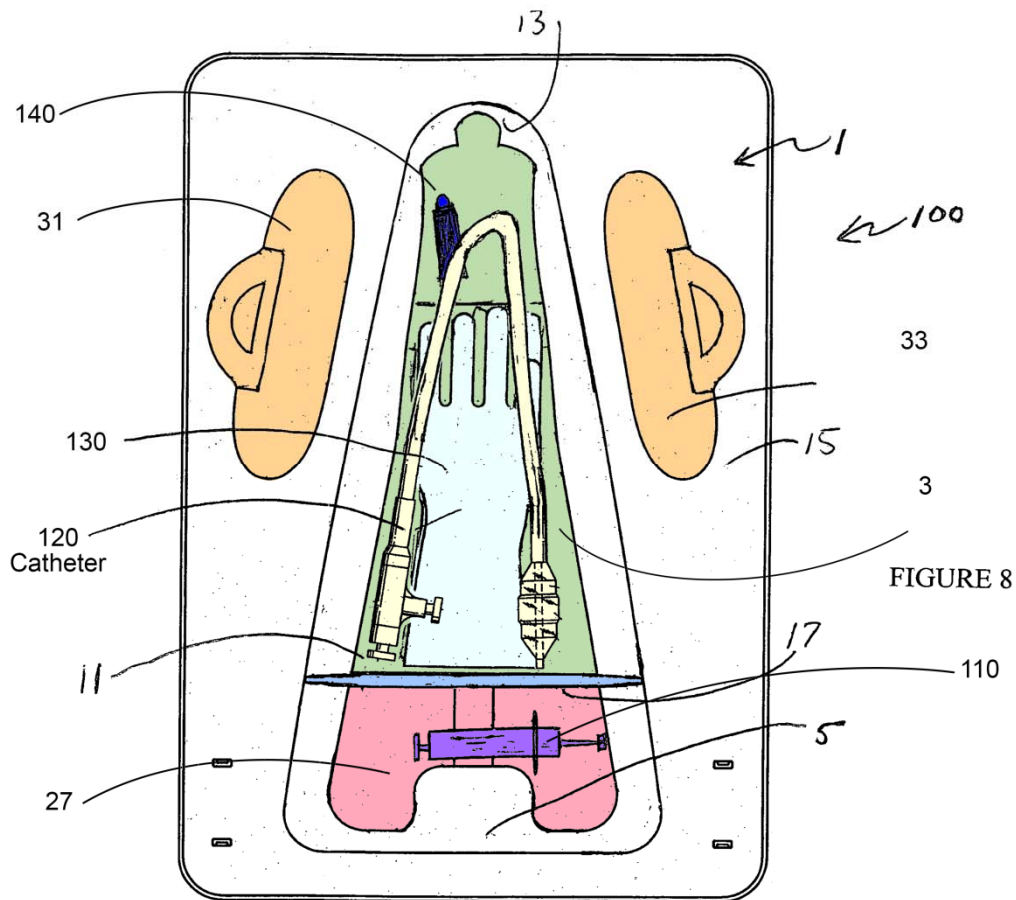
As set forth below, Solazzo in view of Serany discloses all the elements in the claims in this ground and renders those claims as obvious.

1) Claim 1

(a) Preamble and 1[a]: “A medical procedure kit ...”

Solazzo discloses “[a] medical procedure kit, comprising: a tray having a compartment for receiving a medical assembly.”

Solazzo discloses a single-level tray having multiple compartments, including a compartment (“recessed area 3”) for receiving a medical assembly. (Ex. 1005, 2:48-51; 3:52-57; Figs 1 & 8.) Figure 8 provides “a top view of the present invention kit 100” that “includes tray 1 described above with identical components identically numbered.” (Ex. 1005, 4:41-46.). The components include a medical assembly: Foley “catheter 120.” (Ex. 1005, 3:17; 4:41-46.)



As shown in annotated Figure 8 above, a Foley catheter is a medical assembly. The assembly includes a catheter and a Y-connector where the balloon

of the catheter is inflated via an inflation syringe. Accordingly, Solazzo discloses this claim element. (Ex. 1002, ¶¶ 157-161.)

To the extent Patent Owner may argue that Solazzo does not disclose a medical assembly, it would have been obvious to utilize a closed-system Foley catheter in view of Serany. Serany discloses a closed-system Foley catheter that is “ready for use” including a Foley catheter 48 that is pre-connected to a collapsible drainage bottle 46 via drainage tubing 49. (Ex. 1006, 3:23-26; Fig. 6.) Serany further describes a “catheterization package which reduces the rate of infection.” (Ex. 1005, 1:31-32; 3:23-36). Closed-system Foley catheters have been shown to dramatically reduce the rate of CAUTIs. (Ex. 1010, 52.)

In view of Serany, a POSITA would have been motivated to include a closed-system Foley catheter, including a fluid/drainage bag, in the tray of Solazzo to provide a device that is “ready for use” without further manipulation (no parts need connection) and to reduce the rate of infection. (Ex. 1002, ¶¶ 162-166; Ex. 1003, ¶ 15.)

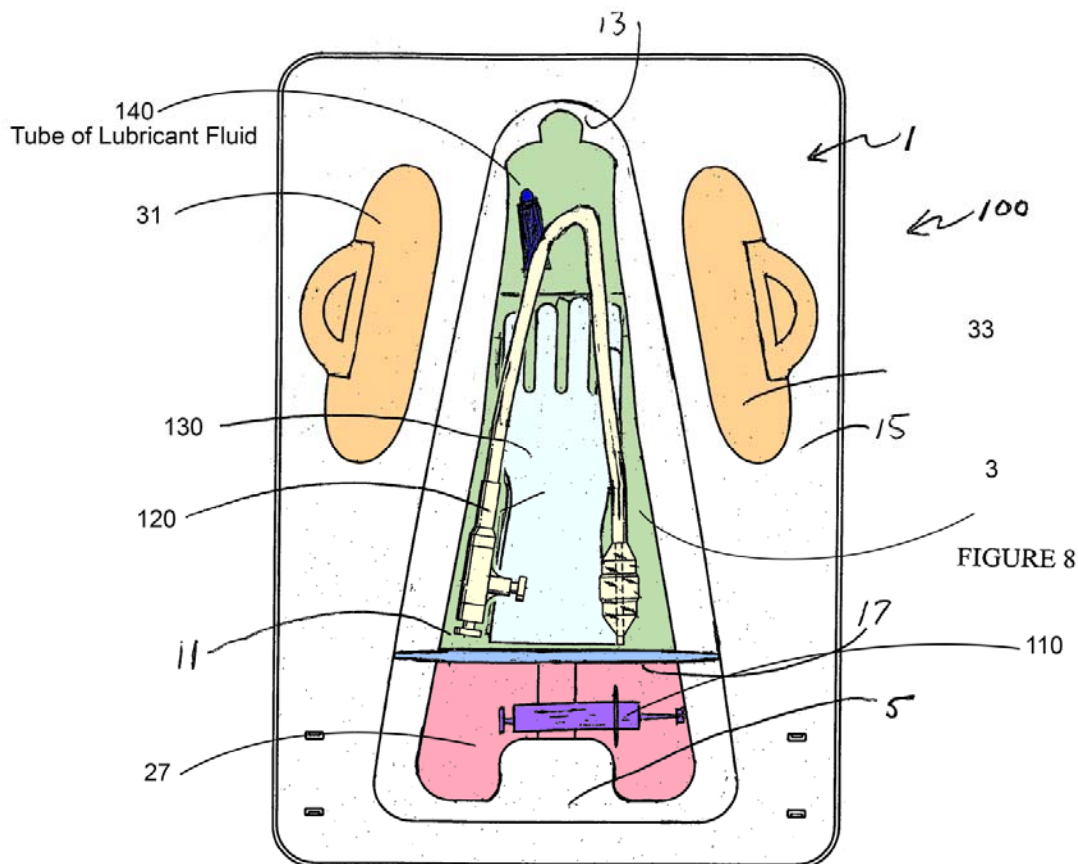
It should be noted that the addition of closed-system Foley catheter does not eliminate either Solazzo’s catheterization feature or its irrigation feature. The tray would still be used during catheterization. As discussed in Dr. Yun’s declaration (Ex. 1003), the tray may also be used for irrigation if a clot develops during the catheterization. (Ex. 1003, ¶¶ 38-40.)

(b) 1[b]: “a first syringe and a second syringe ...”

Solazzo discloses “a first syringe and a second syringe disposed within the tray.”

Solazzo discloses a kit with two syringes: “[t]he kit includes: ... (e.) an inflation syringe for inflation of a catheter with fluid; (f.) irrigation syringe.” (Ex. 1005, 3:15-24.)

Solazzo’s kit also includes “a tube of lubricant fluid 140” (Ex. 1005, 4:41-46) disposed in the tray” as show in annotated Figure 8:



Although Solazzo expressly discloses this claim element because it describes a kit that includes two syringes, it would have further been obvious to a POSITA at the time of the invention to provide a *syringe* of lubricant fluid in place of the *tube* of lubricant fluid. Doing so would merely involve a simple substitution of one container (a tube as taught by Solazzo) for another known type of container (a syringe as also taught by Solazzo) to produce predictable results. (Ex. 1002, ¶¶ 167-173.) Indeed, the Board has found such a substitution to be obvious. (*See* IPR2015-00513, 13 (“On the current record, we agree with Petitioner that “[s]ubstituting one container for another type of container (*e.g.*, substituting a lubricant in a ‘packet’ with a lubricant in a syringe) would have been an obvious substitution of components known to be suitable to yield predictable results.”).)

Further, a lubricant syringe (unlike a tube) has a tapered tip that allows for injection of lubricant directly into a male patient’s urethra (a favored approach of urologists to avoid wasting lubricant). (Ex. 1003, ¶ 22.) Thus, a known technique (injecting lubricant directly into a patient’s urethra using a lubricant syringe) is applied to improve a known device (a Foley catheter tray) to yield predictable results.

Accordingly, Solazzo discloses this claim element.

(c) ***1[c]: “at least one layer of wrap material ...”***

Claim 1[c] requires “*at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material.*”

Solazzo discloses an “ergonomic urological catheterization/irrigation tray kit,” but does not recite how the tray is packaged.

Serany discloses a Foley catheter tray with “*at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material.*” Specifically, Serany discloses a Foley catheter tray that is “enclosed within a wrap 14.” (Ex. 1006, 1:60-63.) Annotated Figure 2 shows the tray enclosed within one or more folds of the wrap material 14 in green:

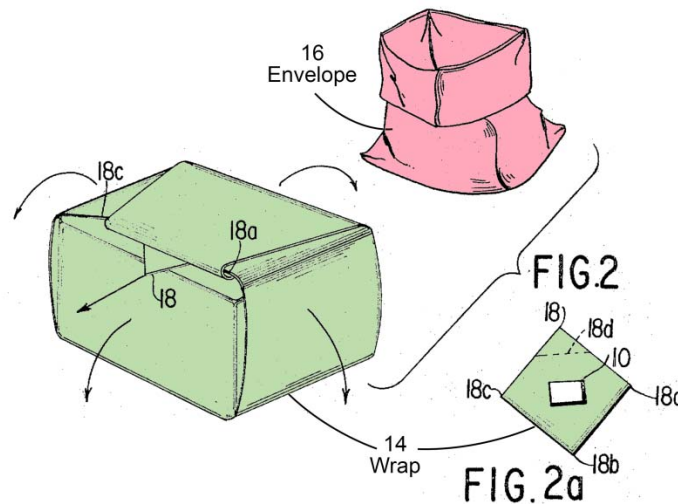
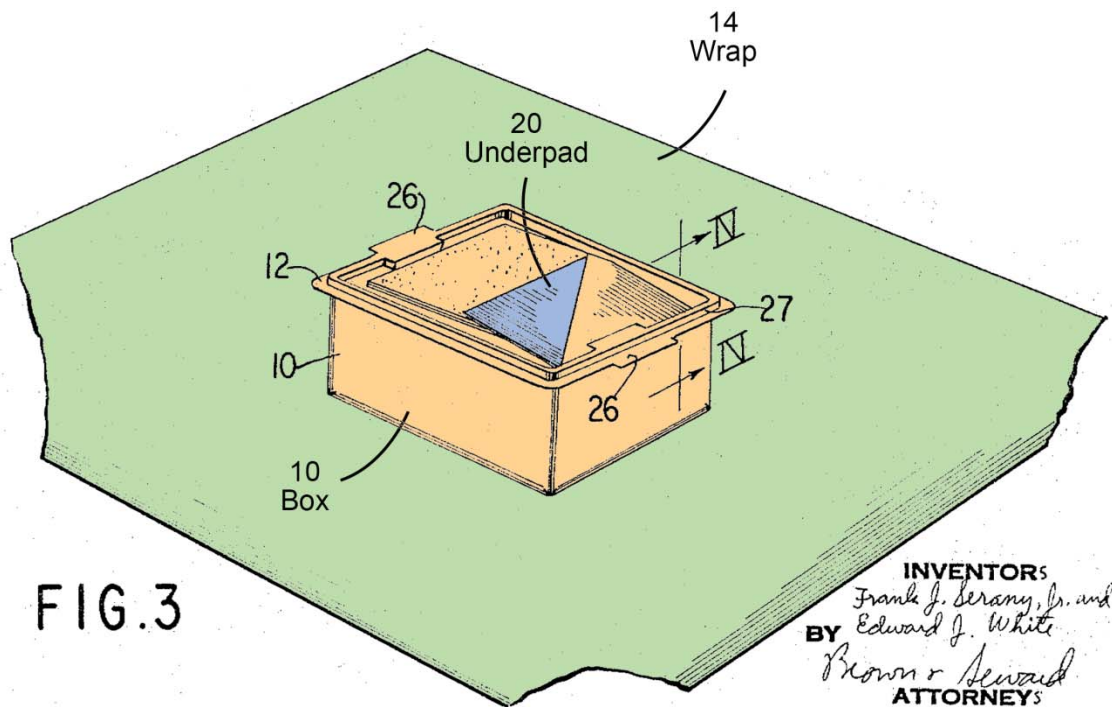


Figure 3 (annotated) of Serany shows the wrap 14 when unfolded:



The wrap of Serany ensures that “components are maintained sterile until the package is opened.” (Ex. 1006, 1:13-16.) Additionally, when the wrap 14 is unfolded about the tray, a “sterile field may be maintained as the components are removed from the package and used.” (Ex. 1006, 1:13-16; 2:1-20.)

A POSITA would understand that Solazzo’s tray needs to be packaged for shipping to maintain the components within the tray in their respective compartments *and* to preserve the sterility of the components provided inside the tray. For example, Solazzo teaches sterile components such as “a Foley catheter” and “surgical gloves.” (Ex. 1005, 3:15-24.)

It would have been obvious to a POSITA at the time of the invention to combine the wrap taught by Serany with the catheterization tray of Solazzo. Serany and Solazzo are analogous art because they both disclose trays for holding a Foley catheter and related medical devices. The wrap of Serany and the tray of Solazzo are both well-known elements and could be combined with each other with each performing the same function as it does separately. The resulting combination would be utterly predictable. (Ex. 1002, ¶¶ 174-183.)

Accordingly, the combination of Solazzo in view of Serany discloses this claim element.

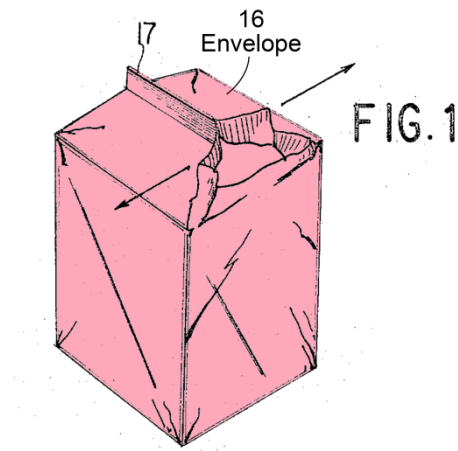
(d) *1[d]: “an outer packaging ...”*

Claim 1[d] requires “*an outer packaging disposed about both the tray and the at least one layer of wrap material.*”

Solazzo discloses an “ergonomic urological catheterization/irrigation tray kit,” but does not recite how the tray is packaged.

Serany disclose “*an outer packaging disposed about both the tray and the at least one layer of wrap material.*” Specifically, Serany discloses a Foley catheter tray that is “encased within an envelope 16.” (Ex. 1006, 1:60-63.)

Figure 1 (annotated) shows the tray encased in an outer packaging 16:



Serany teaches a packaging solution wherein “components are maintained sterile until the package is opened.” (Ex. 1006, 1:13-16.) The outer packaging (envelope 16) of Serany serves this function: “The envelope 16 seals the contents to maintain the sterility of the contents, the latter, of course, having been sterilized before or after enclosure in the envelope.” (Ex. 1006, 1:63-72.)

It would have been obvious to a POSITA at the time of the invention to combine the outer packaging taught by Serany with the catheterization tray of Solazzo. Serany and Solazzo are analogous art because they both disclose trays for holding a Foley catheter and related medical devices. The outer packaging of Serany and the tray of Solazzo are both well-known elements and could be combined with each other with each performing the same function as it does separately. The resulting combination would be utterly predictable. (Ex. 1002, ¶¶ 184-194.)

Accordingly, the combination of Solazzo in view of Serany discloses this claim element.

(e) 1[e]: “the first syringe and the second syringe are ordered ...”

Solazzo discloses “the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure.”

For the reasons set forth in claim 1[b], it would have been obvious to substitute the *tube* of lubricant 140 with a *syringe* of lubricant. Furthermore, Solazzo discloses that “bottom 11 has *terraced* arrangement with low area 11A and shallow area 11B (FIG. 2).” (Ex. 1005, 3:63-66.) Figure 2 shows the *terraced* bottom of the tray:

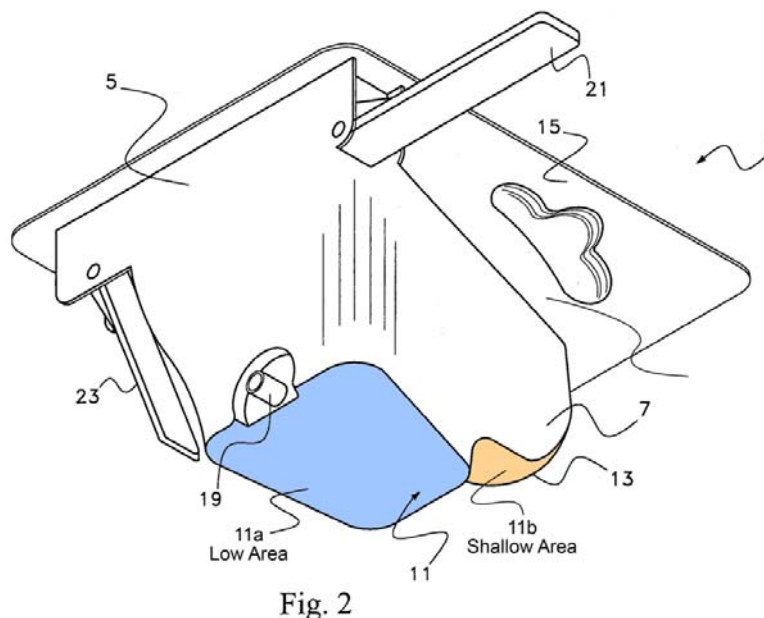
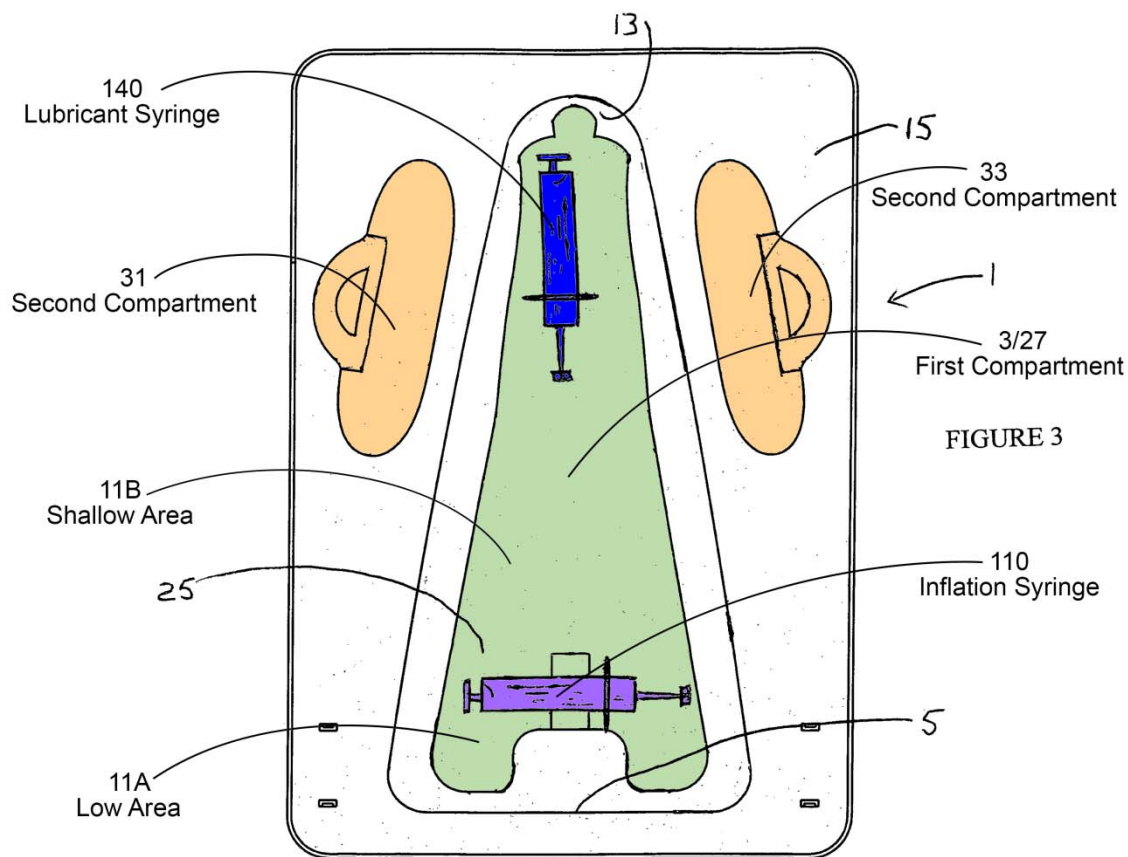


Figure 8 discloses the placement of lubrication fluid 140 and the inflation syringe 110 within the tray, with the lubrication fluid in the shallow area and the inflation syringe in the low area. As discussed above, Solazzo discloses a “no divider wall” embodiment. If Figure 8 is modified to reflect that embodiment and to substitute lubrication fluid 140 for a syringe, then the first syringe (lubricant fluid 140) is placed on the “*shallow*” portion of the terraced bottom member and the second syringe (inflation syringe 110) is placed on the “*low*” portion of the terraced bottom member as shown below.



As a result 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. Consequently, Solazzo discloses “*wherein the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure.*” The placement of the syringes within the tray further corresponds to an order of use of a catheterization procedure within Solazzo’s tray. The lubricant fluid 140 is placed nearer the “Foley catheter lubricating wells 31 and 33.” (Ex. 1005, Figs. 1 & 8.) The inflation syringe 110 is placed nearer the inflation port of the Y-connector of the Foley catheter. (Ex. 1002, ¶¶ 195-200.)

Furthermore, in view of Serany, a POSITA would have been motivated to arrange the components of Solazzo, including the lubrication and inflation syringes, in their order of use. Serany provides motivation for arranging components in their order of use by teaching components that are “arranged in logical step-by-step order to facilitate the nurse’s or physician’s task.” (Ex. 1006, 1:34-35.) Such an arrangement would facilitate the practitioner’s task in performing catheterization with Solazzo’s tray. (Ex. 1002, ¶¶ 201-202.)

Accordingly, Solazzo discloses this claim element. To the extent one might argue that Solazzo does not disclose this claim element, the combination of Solazzo in view of Serany discloses this claim element.

(f) 1[[f]]: “a first compartment to support the first syringe and the second syringe ...”

Solazzo discloses “*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.*”

In the “no divider wall” embodiment, recessed area 3 and compartment 27 form a single compartment (referred to as “compartment 3/27”) as shown in modified Figure 1 below:

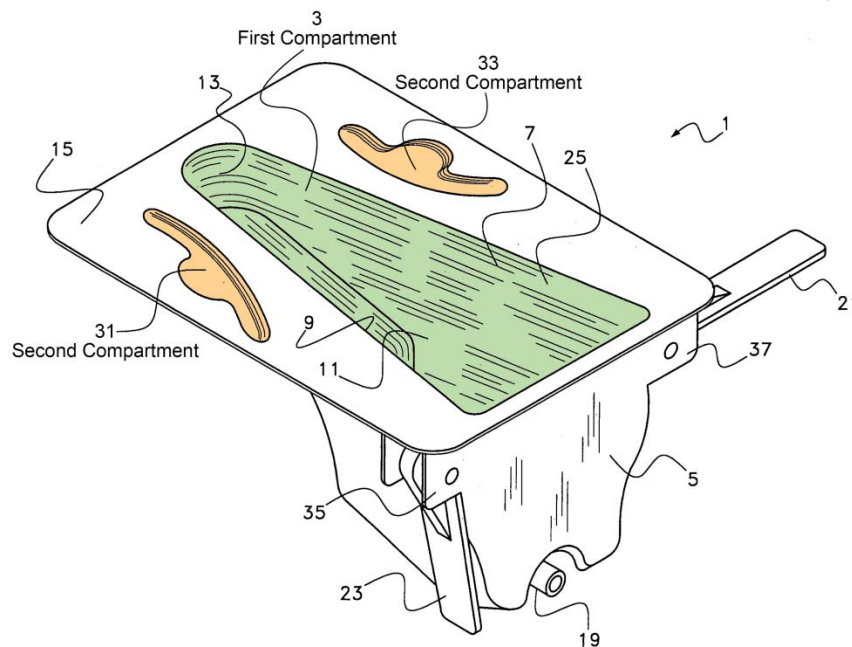
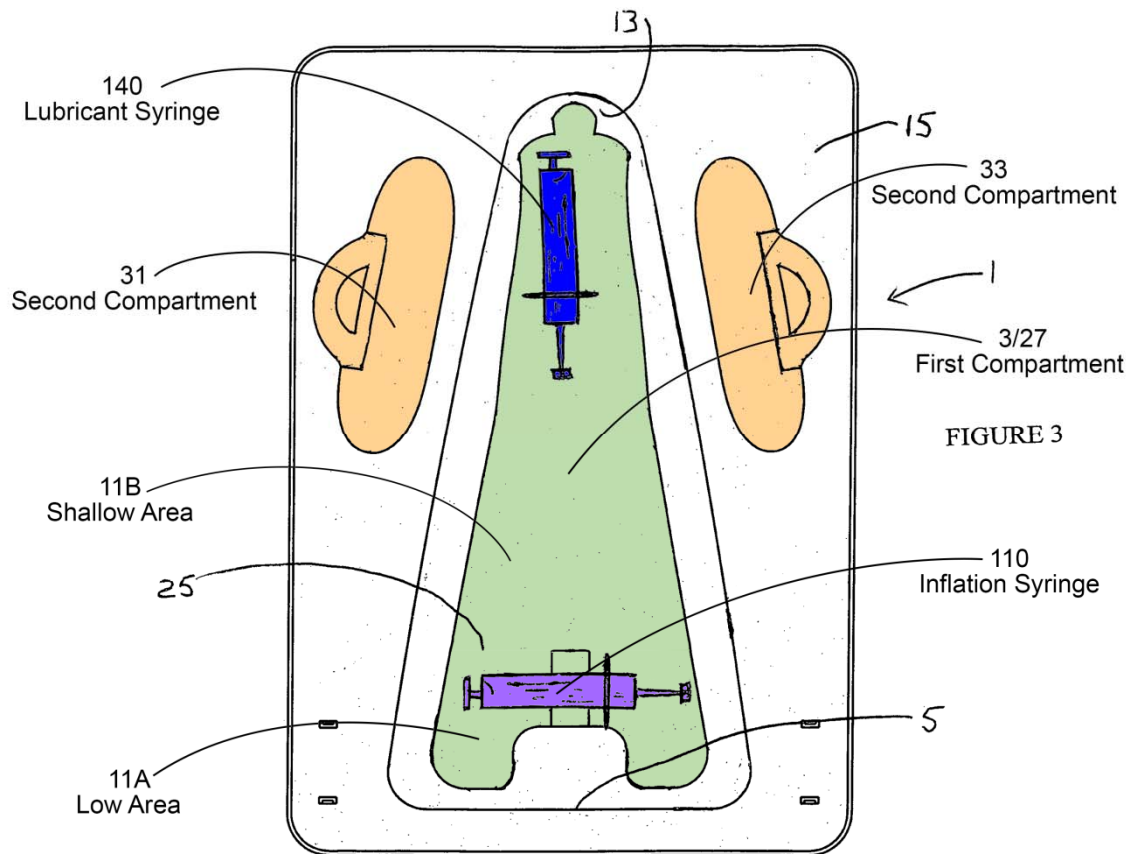


Fig. 1

Thus, in this embodiment, Solazzo discloses “*the tray comprises a surface defining at least two compartments*” because compartment 3/27 is a *first* compartment and one or more of the “lubricating wells 31 and 33” is a *second*

compartment. (Ex. 1005, 4:21-25; Figs. 1; Ex. 1002, ¶¶ 204-207.) Note that Solazzo uses the terms “compartment” and “well” interchangeably. For example, it refers to compartments 3 and 27 as “irrigation well” and “drainage well,” respectively. (Ex. 1005, claim 3.)

Solazzo’s embodiment with “no divider wall,” i.e., compartment 3/27, also discloses “*the at least two compartments comprising a first compartment to support the first syringe and the second syringe*” because bottom 11 of compartment 3/27 supports the first and second syringe. (Ex. 1005, Figs. 1, 2, 8.) The tube of lubricant 140 (replaceable with a syringe) and syringe 110 are supported in a first compartment when the “*optional divider wall 17*” is omitted as shown in modified Figure 8 below. (Ex. 1002, ¶¶ 208-209.)



Accordingly, Solazzo discloses this claim element.

(g) 1[g]: “... a mnemonic device ...”

Solazzo discloses “*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.*”

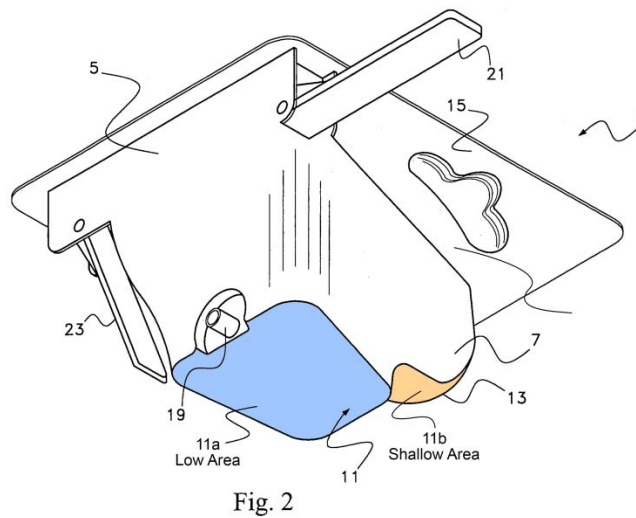
For the reasons set forth in claim 1[b], it would have been obvious to substitute the *tube* of lubricant 140 with a *syringe* of lubricant.

The '088 patent describes a tray with an “inclined, *stair-stepped* bottom member” that forms a *mnemonic device* by providing syringes “at different heights based upon order of use.”

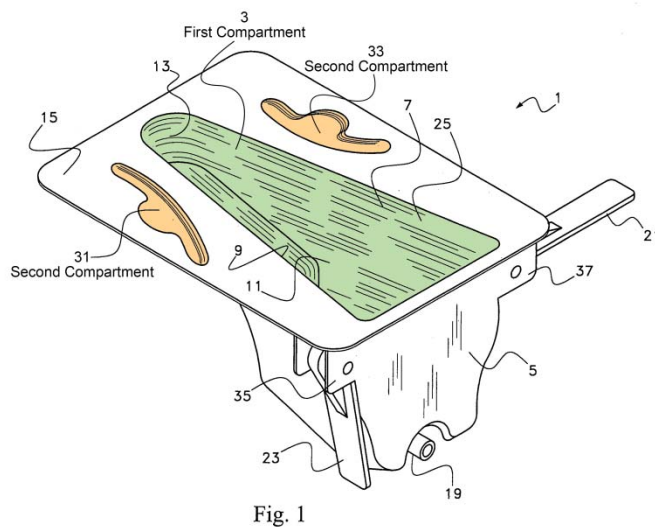
[I]n one embodiment the tray is configured to provide the medical services provider with mnemonic devices instructing them in which order to use each device. For example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle and at different heights based upon order of use.

(Ex. 1001, 4:24-31.)

Solazzo discloses a tray with an inclined, *terraced* bottom member (11) that provides lubricant fluid 140 (replaceable with a syringe) and inflation syringe 110 at different heights based upon order of use. Specifically, the “bottom [11] has a non-flat topography.” (Ex. 1005, 3:12-13.) Further, the bottom is *terraced*: “In this embodiment bottom 11 has terraced arrangement with low area 11A and shallow area 11B (FIG. 2).” (Ex. 1005, 3:63-66.) Figure 2 (annotated) shows the *terraced* bottom of the tray:



The bottom 11 of the tray is also inclined, as shown modified Figure 5, below, the “no divider wall” embodiment, i.e., compartment 3/27:



The *terraced* bottom member of Solazzo supports lubricant 140 and inflation syringe 110 at different heights based upon order of use because the lubricant 140 and inflation syringe 110 are supported by different portions of the bottom

member. Specifically, the *first* syringe (lubricant fluid 140) is placed on the “shallow area 11B” of the terraced bottom member and the *second* syringe (inflation syringe 110) is placed on the “lower area 11A.” (Ex. 1005, 3:63-66; Figs. 1 and 8.) The syringes are therefore supported at different heights within the tray.

As described in claim element 1[e], a lubricant syringe is used first in a catheterization procedure before an inflation syringe. Thus, 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. (Ex. 1002, ¶¶ 210-216.) As discussed in Section V of this Petition, given the structural identity of the tray structures of Solazzo and the '088 patent, the “mnemonic” claim limitation is met. It is simply irrelevant whether or not Solazzo discloses what kind of reminder or cue the user receives, because that arises from how the kit is used.

Furthermore, it was well-known in the art of device design (including the design of medical trays) to include affordances to aid a user in performing operations in the correct order. (Ex. 1016; Ex. 1002, ¶¶ 217-218.) For example, Serany discloses a Foley catheter tray that provides “components in their preferred order of use” and “proper order of use.” (Ex. 1006, 1:9-12; 1:23-25.) In view of Serany, a POSITA would have been motivated to arrange the syringes in their

order of use on the base member of Solazzo's tray, which would include placing a *first* syringe at higher height than a *second* syringe, as a design affordance.

Accordingly, Solazzo discloses this claim element. To the extent Patent Owner might argue that Solazzo does not disclose this claim element, the combination of Solazzo in view of Serany discloses this claim element.

Solazzo in view of Serany therefore renders claim 1 obvious.

2) Claim 2

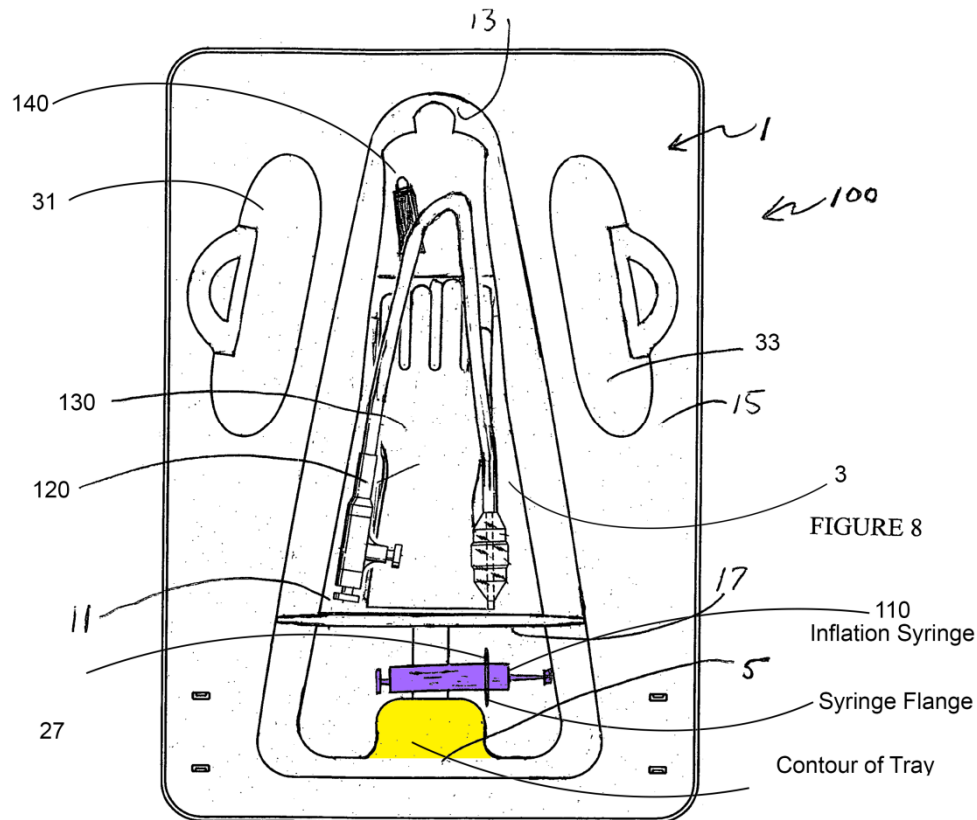
Solazzo discloses “*the first syringe and the second syringe ordered within the tray in accordance with their use during the catheterization procedure.*”

Claim 2 recites a claim element that is present in claim 1. (See claim 1[e].) Solazzo in view of Serany therefore renders claim 2 obvious.

3) Claim 6

Claim 6 requires “*the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.*”

As shown in Figure 8 (annotated) below, Solazzo discloses a contour in the first compartment of the tray. That contour accommodates the flanges of syringe 110. (Ex. 1002, ¶¶ 222-223.)



Accordingly, Solazzo discloses this element. To the extent Patent Owner might argue that Solazzo does not disclose this claim element, the combination of Solazzo in view of Serany discloses this claim element. (Ex. 1002, ¶¶ 224-225.) Solazzo in view of Serany therefore renders claim 6 obvious.

4) Claim 7

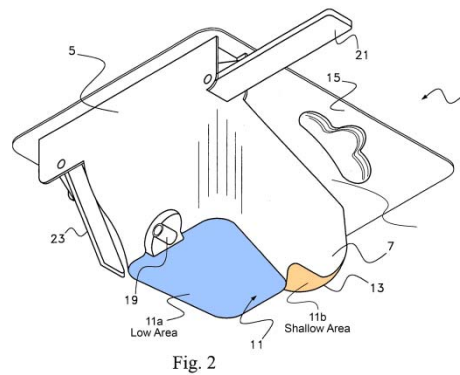
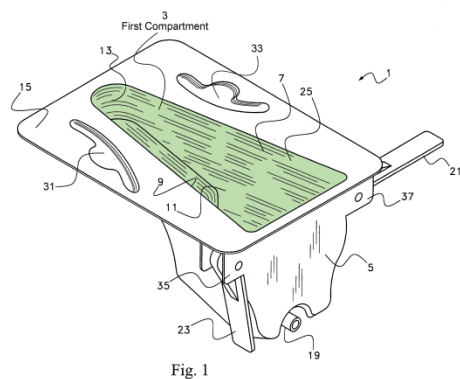
Solazzo discloses “*the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.*”

Solazzo discloses a “*lubricating jelly application chamber to lubricate at least a portion of a catheter assembly,*” namely, “*optional Foley catheter*

lubricating wells 31 and 33.” (Ex. 1005, 4:21-25 (emphasis added).) A POSITA would further have recognized that other compartments of Solazzo’s tray, including compartment 3/27 would also have functioned as a “*lubricating jelly application chamber*.” As Dr. Yun explains, practitioners place lubricant in many different locations on a tray depending on user preference (e.g., where the lubricant is found or directly on the catheter). (Ex. 1003, ¶¶ 20-21; Ex. 1002, ¶ 227.)

The ’088 patent describes the “first compartment” as being “a lubricant applicator for the catheter” when the first compartment is *stair-stepped*. (Ex. 1001, 7:38-59.) Specifically, lubricating jelly may be “spread” along the “second step portion 117,” which is lower in the tray than the “first step portion 116.” (Ex. 1001, 7:38-59.) The ’088 Patent states that the *lower* second-step portion of the bottom member forms a “channel.” (Ex. 1001, 7:38-59.)

Solazzo discloses the same essential structure as the ’088 Patent. In the “no divider wall” embodiment, i.e., compartment 3/27 (shown below on left), the bottom 11 of Solazzo’s tray has a second step portion (“low area 11A”) that is *lower* in the tray than a first step portion (“shallow area 11B”). (Ex. 1005, 3:63-66; Figs. 1, 2.)



The “terraced arrangement” of the bottom member of Solazzo would necessarily function as a “*lubricating jelly application chamber*” to lubricate the catheter for the same reason a “stair-stepped” base member functions as a lubricating jelly application chamber. (See Section V of this Petition.) Specifically, the “low area 11A” would function as a channel where lubricant may be spread to lubricate the catheter. Alternatively, the catheter could be lubricated in the “shallow area 11B” where the catheter and lubricant tube are supported. (Ex. 1002, ¶¶ 228-236.)

Accordingly, Solazzo discloses this claim element. Solazzo in view of Serany therefore renders claim 7 obvious.

To the extent Patent Owner might argue that Solazzo does not disclose a catheter assembly, it would further been obvious to utilize a closed-system Foley catheter in view of Serany for the reasons as claim 1[a].

5) Claims 8-10

Solazzo discloses “*the first compartment to support the first syringe at a shallower depth within the tray than the second syringe*” (claim 8); “*the first compartment to support the first syringe and the second syringe at different heights based upon use during the catheterization procedure*” (claim 9); and “*wherein a higher of the first syringe or the second syringe is for use in the catheterization procedure before a lower of the first syringe or the second syringe*” (claim 10.)

For the reasons set forth in claim 1[b], it would have been obvious to substitute the *tube* of lubricant 140 with a *syringe* of lubricant.

For the reasons set forth in claim 1[e] and 1[g], Solazzo discloses providing a first syringe and a second syringe at different heights because of the terraced arrangement of the bottom of the tray and use during the catheterization procedure.

Solazzo discloses a “tube of lubricant 140” (replaceable with a syringe) that is supported at a shallower depth within the tray than an inflation syringe 110 because the bottom 11 is terraced to include a “shallow area 11B” and a “low area 11A.” (Ex. 1005, 3:63-66; Figs. 1, 2, 8; Ex. 1002, ¶¶ 237-251.) The higher syringe (lubricant 140) is used first in catheterization procedure because lubricant is applied before insertion and inflation of the catheter. (See claim 1[e].)

Accordingly, Solazzo discloses these claim elements. To the extent Patent Owner might argue that Solazzo does not disclose these claim elements, the

combination of Solazzo in view of Serany discloses these claim elements as discussed in claims 1[e] and 1[g]. Solazzo in view of Serany therefore renders claim 8 obvious.

6) Claim 16

Solazzo discloses “*the tray comprising a surface defining at least two compartments, the at least two compartments comprising the first compartment to support the first syringe.*”

Claim 16 recites a claim element that is present in claim 1. (See claim 1[f].) Solazzo in view of Serany therefore renders claim 16 obvious.

7) Claim 17

For the reasons set forth in claim 7, Solazzo discloses “*the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.*”

Solazzo in view of Serany therefore renders claim 17 obvious.

B. Ground 2 – Obvious Based On Solazzo, Serany, and Franks-Farah

1. Summary of Franks-Farah

Franks-Farah was filed on September 11, 2003, and issued on January 11, 2005. Franks-Farah is therefore prior art to the '088 patent pursuant to at least 35 U.S.C. § 102(b).

Franks-Farah is directed to a urinary catheterization kit tray that contains various devices for performing catheterization, such as a catheter, antibacterial soap, lubricant, and step-by-step instructions. (Ex. 1007, 2:5-14; Figs. 1-1A.) The tray “includes extremely detailed and specific step-by-step instructions 34 as illustrated in FIGS. 2A and 2B that the user uses with the intermittent catheterization system 1.” (Ex. 1007, 4:13-17; Figs. 2A-2B; Ex. 1002, ¶¶ 146-150.)

2. The Combination

As set forth below, Solazzo in view of Serany and Franks-Farah discloses all the elements of the claims in this ground and renders those claims as obvious.

1) Claim 18

Claim 18 requires “*further comprising printed instructions for using the tray.*”

Adding printed matter (such as “*printed instructions for using the tray*”) to a known kit is not a patentable distinction over the prior art because claim elements directed to printed matter generally do not have patentable weight. (*See* Section VI of this Petition.) Because claim 18 does not add anything to claim 17 besides the recitation of printed instructions, claim 18 is invalid for the same reason as claim 17.

To the extent this claim is found to have patentable weight, claim 18 would have been obvious. Solazzo discloses a catheterization/irrigation kit including components that are used to perform a catheterization procedure, but does not expressly recite a tray that includes printed instructions. Franks-Farah teaches a urinary catheter kit that includes common devices for performing a catheterization procedure, including printed instructions. In particular, the kit “includes extremely detailed and specific step-by-step instructions 34 as illustrated in FIGS. 2A and 2B that the user uses with the intermittent catheterization system 1.” (Ex. 1007, 4:12-16.) Figure 2(A) is provided below:

FIG. 2A

34



In view of Franks-Farah, a POSITA would have been motivated to include printed instructions in the tray of Solazzo. Franks-Farah provides motivation because it provides “extremely detailed and specific step-by-step instructions” to help ensure that physicians perform a catheterization or irrigation procedure using the proper technique. (Ex. 1002, ¶¶ 258-263.)

Accordingly, the combination of Solazzo in view of Franks-Farah discloses this claim element. Solazzo in view of Serany and Franks-Farah therefore renders claim 18 obvious.

2) Claim 19

Claim 19 requires “*the printed instructions to instruct application of lubricating jelly to the catheter assembly using the lubricating jelly application chamber.*”

Again, adding printed matter (such as “*printed instructions to instruct application of lubricating jelly to the catheter assembly using the lubricating jelly application chamber*”) to a known kit is not a patentable distinction over the prior art because claim elements directed to printed matter generally do not have patentable weight. Because claim 19 does not add anything to claim 17 besides the recitation of printed instructions, claim 19 is invalid for the same reason as claim 17.

To the extent this claim is found to have patentable weight, claim 19 would have been obvious. For the reasons set forth in claim 7, Solazzo discloses “*the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.*”

For the reasons set forth in claim 18, Solazzo in combination with Serany and Franks-Farah discloses “*printed instructions for using the tray.*”

Step 3 of Figure 2(a) of Franks-Farah includes a step that teaches lubricating the catheter:

The Catheter

3 Take the Catheter out of the package and lay it on the paper towel. Flip open the cap of the Lubricating Jelly. Squeeze 3 inches of Jelly onto the Catheter, starting at the tip. Be careful not to touch the Catheter with the tube.



In view of Franks-Farah, a POSITA would have been motivated to include printed instructions in the tray of Solazzo that includes instructions regarding how to lubricate the catheter using Solazzo's tray. A POSITA would have specifically been motivated to “*instruct application of lubricating jelly to the catheter assembly using the lubricating jelly application chamber*” because compartments of the tray, including the first compartment 3/27 in the “no divider wall” embodiment

described in claim 1[f], function as a lubricating jelly application chamber. (Ex. 1002, ¶¶ 264-271.)

Accordingly, the combination of Solazzo in view of Serany and Franks-Farah discloses this claim element. Solazzo in view of Serany and Franks-Farah therefore renders claim 19 obvious.

C. Ground 3 – Obvious Based On Solazzo and Serany

1. Separate Ground

Bard is separately presenting the combination of Solazzo and Serany in this ground from Ground 1, because Solazzo is applied based on both its disclosure of compartment 3/27 (“no divider wall” embodiment) and recessed area 3 and compartment 27 (“divider wall” embodiment).

2. The Combination

As set forth below, Solazzo in view of Serany discloses all the elements in these claims in this ground and renders those claims as obvious.

1) Claim 25

(a) Preamble and 25[a]: “A medical procedure kit ...”

For the reasons set forth in claim 1[a], Solazzo discloses “[a] *medical procedure kit, comprising: a tray having a compartment for receiving a medical assembly.*”

(b) 25[b]: “a first syringe and a second syringe ...”

For the reasons set forth in claim 1[b], Solazzo discloses “*a first syringe and a second syringe disposed within the tray.*”

(c) 25[c]: “at least one layer of wrap material...”

For the reasons set forth in claim 1[c], the combination of Solazzo in view of Serany discloses “*at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material.*”

(d) 25[d]: “an outer packaging...”

For the reasons set forth in claim 1[d], the combination of Solazzo in view of Serany discloses “*an outer packaging disposed about both the tray and the at least one layer of wrap material.*”

(e) 25[e]: “the first syringe and the second syringe are ordered ...”

For the reasons set forth in claim 1[e], Solazzo discloses “*the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure.*”

(f) 25[f]: “...a first compartment to support the first syringe and the second syringe”

Solazzo discloses “*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.*”

Claim element 25[f] is met under the “no divider wall” embodiment and the “divider wall” embodiment. Both embodiments are analyzed separately below.

“No Divider Wall” Embodiment

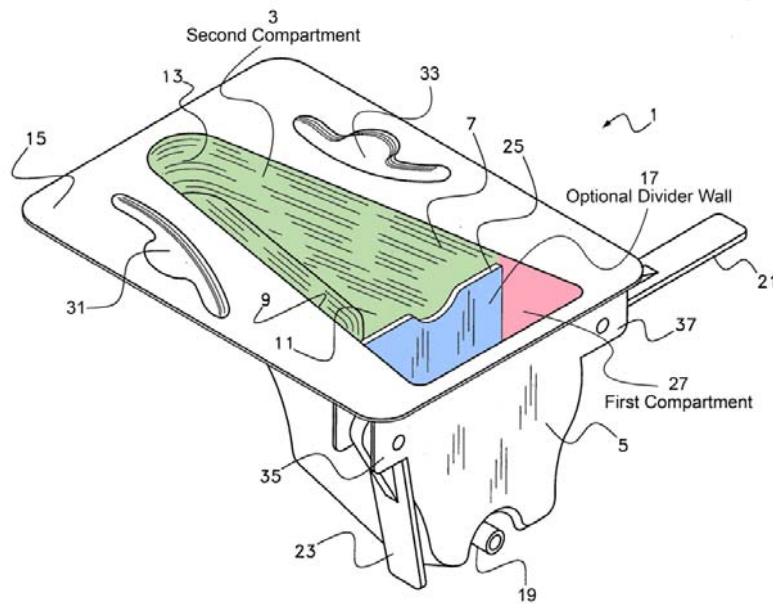
For the reasons set forth in claim 1[f], Solazzo discloses “*the tray comprises a surface defining at least two compartments, the at least two compartments comprising a first compartment to support the first syringe and the second syringe.*”

To summarize, the removal of the dividing wall creates a *first* compartment (“compartment 3/27”) that supports via bottom 11 both the tube of lubricant 140 (replaceable with a syringe) and syringe 110. (Ex. 1005, 2:61-63; Figs. 1, 2, 8; *see also* claim 1[f]). One or more of the “lubricating wells 31 and 33” is a second compartment. (Ex. 1005, 4:21-25; Figs. 1 & 8; Ex. 1002, ¶ 278.)

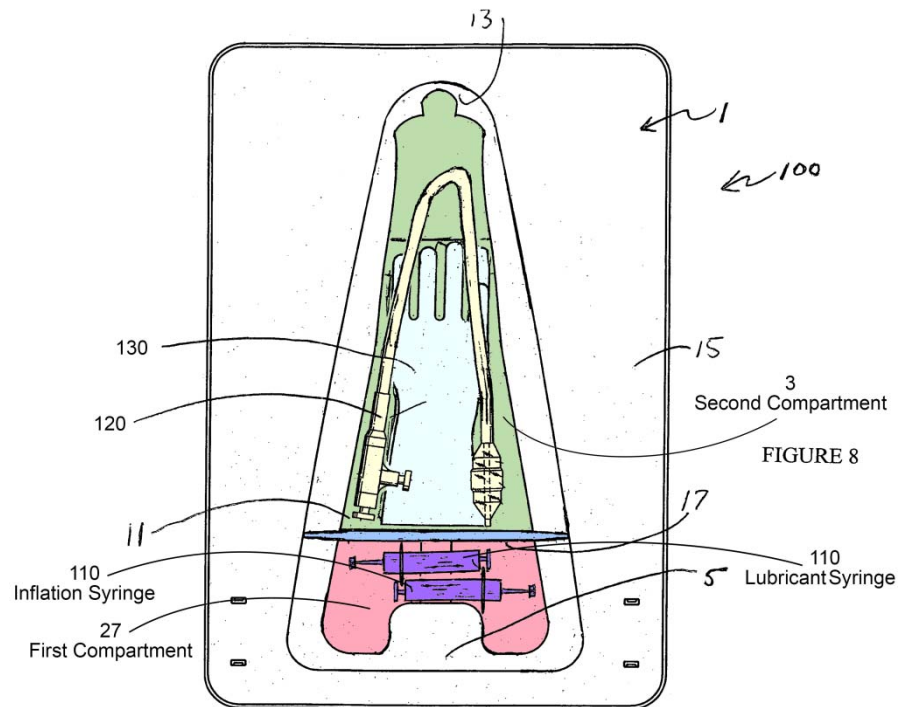
Accordingly, Solazzo discloses this claim element.

“Divider Wall” Embodiment

Annotated Figure 1 below shows an embodiment of the tray with a first and a second compartment formed by the divider wall 17 to create a first compartment 3 and second compartment 27. (Ex. 1005, 2:61-63.)

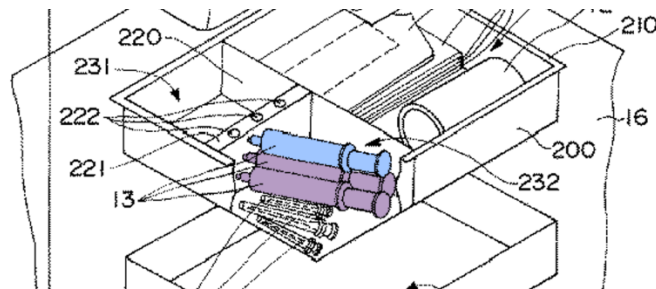


Providing the syringes (lubricant syringe and inflation syringe) in the same compartment would have been obvious to a POSITA. In particular, both syringes could be supported in *first* compartment 27. Figure 8 below has been modified to depict one obvious arrangement of the syringes in the first compartment 27 (along with the removal of the “optional” lubricating wells).



It was well-known in the art to group like items in the same compartment of a tray. For example, Serany disclose grouping multiple balls of cleansing material in the same compartment: “The tray also has a depression 32 for balls 34 of cleansing material, e.g. rayon, which are used to prepare the patient for catheterization.” (Ex. 1006, 2:57-61.) Serany further describes an object of the invention as making it easier for physicians to perform a catheterization procedure because “all the components [are] arranged in logical step-by-step order to facilitate the nurses or physicians task.” (Ex. 1006, 1:31-35; (Ex. 1002, ¶¶ 282-285.)

Additionally, Imai (Exs. 1011 and 1012), directed to a package that organizes treatment tools with high usability, discloses grouping syringes in the same compartment of a catheter tray, as shown in Figure 1 below:



In view of Serany, a POSITA would have been motivated to group the syringes in the first compartment of Solazzo to arrange them in a “logical step-by-step order to facilitate the nurses or physicians task.” A POSITA would have further been motivated to group the syringes together in the first compartment because it removes the lubricant syringe from compartment 3, which contains the Foley catheter. This would ensure the lubricant syringe does not damage the Foley catheter during shipment of the tray. (Ex. 1002, ¶¶ 286-288.)

Accordingly, Solazzo discloses this claim element. Furthermore, the combination of Solazzo in view of Serany discloses this claim element.

(g) 25[g]: “...to support the first syringe and the second syringe at different heights ...”

Solazzo discloses “*the first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure.*”

As with claim element 25[f], claim element 25[g] is met by both the “no divider wall” embodiment and the “divider wall” embodiment of Solazzo.

“No Divider Wall” Embodiment

For the reasons set forth in claim 1[g] and 9, Solazzo discloses “*the first compartment to support the first syringe and the second syringe at different heights according to predetermined steps of the catheterization procedure.*”

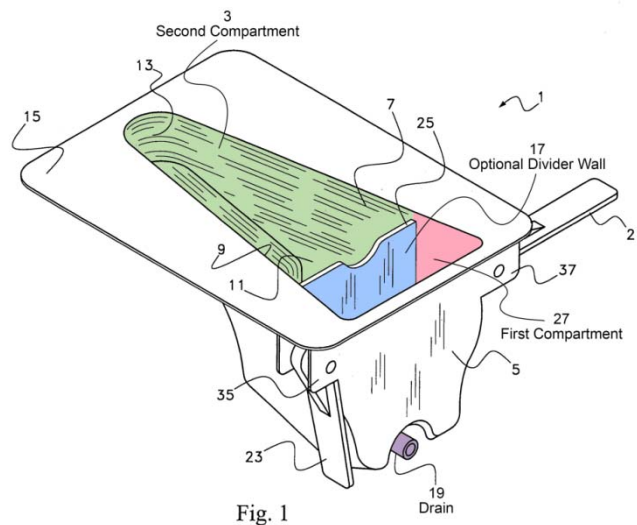
The removal of the dividing wall creates a *first* compartment (“compartment 3/27”) that supports via bottom 11 both lubricant 140 (replaceable with a syringe) and syringe 110. (Ex. 1005, 2:61-63; Figs. 1, 2, 8). Lubricant 140 is supported at a different height within the tray of Solazzo than inflation syringe 110 because the bottom 11 is terraced to include a “shallow area 11B” and a “low area 11A.” (Ex. 1005, 3:63-66; Figs. 2 and 8.) The different heights are based upon predetermined steps of the catheterization procedure. Such predetermined steps include the use of lubricant to lubricate a catheter before the catheter is inflated with the inflation syringe. (Ex. 1003, ¶¶ 28-29; Ex. 1002, ¶¶ 292-293.) This order of procedure as to the syringes is also taught by Solazzo: “The gloves being worn by the surgeon, the

catheter being lubricated, inserted and then inflated with fluid using the syringe.”
(Ex. 1005, 4:46-48.)

Accordingly, Solazzo discloses this claim element.

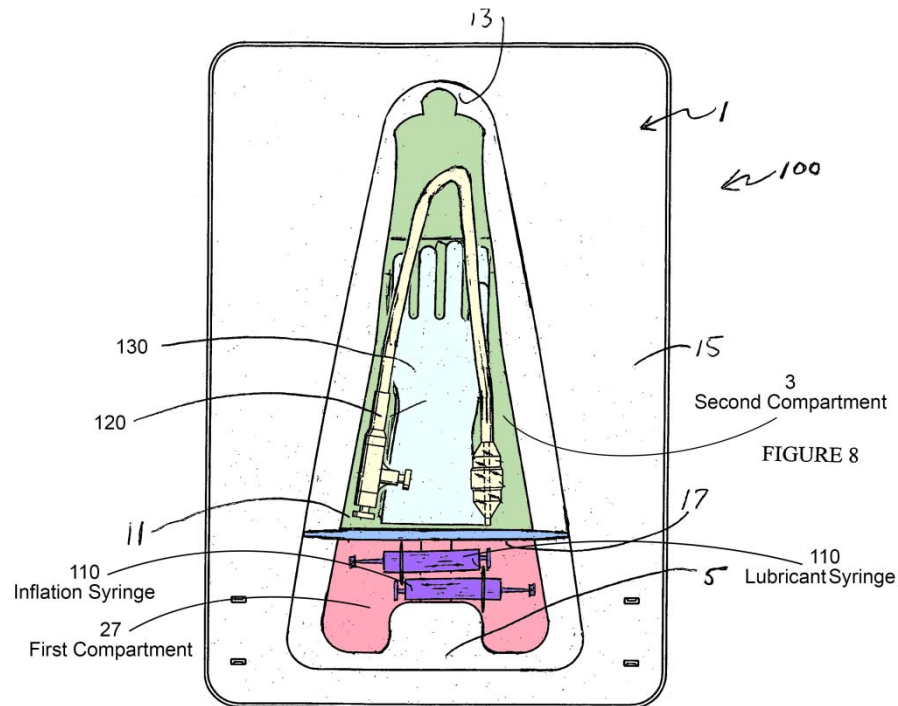
“Divider Wall” Embodiment

Solazzo discloses the tray 11 has a drain 19. To facilitate the drainage of the tray, the bottom 11 “has non-flat topography,” as shown in Figure 1. (Ex. 1005, 3:63-66; Figs. 1, 2, 5.)

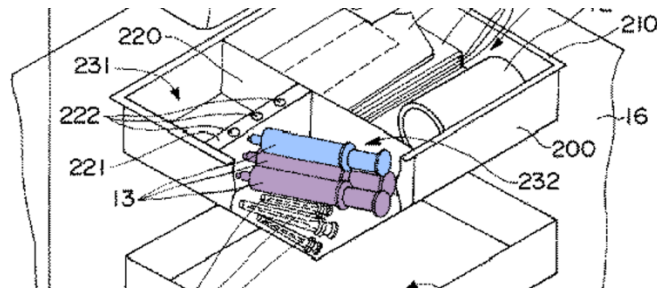


The bottom 11 extends to compartment 27, which Solazzo refers to as “low area 11A.” (Ex. 1005, 3:63-66; Fig. 2.) The bottom of compartment 27 is also inclined to facilitate drainage through drain 19. To the extent Solazzo does not explicitly disclose that the bottom of compartment 27 is inclined, it would have been obvious for it to be inclined to facilitate the drainage of the tray. (Ex. 1002, ¶¶ 294-295.) It is, in fact, called a drainage well. (Ex. 1005, claim 3.)

For the reasons set forth in claim 25[f], it would have been obvious to place lubricant 110 (replaceable with a syringe) and inflation syringe 140 in compartment 27. When placing multiple syringes in compartment 27, the syringe would be provided at different heights because the bottom member is inclined. Figure 8, below, has been modified to show two syringes placed in compartment 27 (and no “optional” lubricating wells):



Alternatively, the syringes could also be stacked on top of each other in compartment 27. For example, Figure 1 of Imai:



In either arrangement, the syringes are provided at different heights within compartment 27. Further, as originally configured, Solazzo presents the syringes at different heights because of the “terraced arrangement” of bottom 11. A POSITA would be motivated to maintain this same arrangement by height when placing a lubricant syringe and inflation syringe in compartment 27. Specifically, a lubricant syringe is placed higher within the tray because the catheter is lubricated before it is inflated. (See claim 1[e]; Ex. 1002, ¶¶ 296-298.)

An inflation syringe may also be used in certain Foley catheterization procedures before a lubricant syringe in order to inflate a test balloon. (Ex. 1003, ¶ 29.) Specifically, during such a procedure, an inflation syringe is used *before* the lubricant syringe (to inflate the test balloon) and *after* the lubricant syringe (to inflate the balloon once inserted). (Ex. 1003, ¶ 29.) The syringes therefore may alternatively be ordered in the tray such that the inflation syringe is presented first (e.g., supported at a higher height). A POSITA would have been motivated to arrange the syringes in that order when a catheterization procedure includes the step of inflating a test balloon. (Ex. 1002, ¶ 299.)

Furthermore, ordering components within a Foley catheter tray in accordance with their use during a catheterization procedure was well-known in the art. For example, Serany discloses a tray that provides “components in their preferred order of use” and “proper order of use.” (Ex. 1006, 1:9-12; 1:23-25.) Serany further describes an object of the invention as making it easier for physicians to perform a catheterization procedure because “all the components [are] arranged in logical step-by-step order to facilitate the nurses or physicians task.” (Ex. 1006, 1:31-35.)

In view of Serany, a POSITA would have been motivated to arrange the components of Solazzo, including the syringes, in their order of use. Serany provides motivation for arranging components in their order of use by teaching components that are “arranged in logical step-by-step order to facilitate the nurses or physicians task.” (Ex. 1006, 1:9-35; Ex. 1002, ¶¶ 300-303.)

Accordingly, Serany discloses this claim element. To the extent Patent Owner might argue that Solazzo does not disclose this claim element, the combination of Solazzo in view of Serany discloses this claim element.

Solazzo in view of Serany therefore renders claim 25 obvious.

2) Claim 26

For the reasons set forth in claim 25[e], Solazzo discloses “*the first syringe and the second syringe ordered within the tray in accordance with their use during the catheterization procedure.*”

Solazzo in view of Serany therefore renders claim 26 obvious.

3) Claim 27

Solazzo discloses “*further comprising one or more of an instruction set, one or more medical devices, or combinations thereof.*”

Solazzo discloses a kit containing multiple medical devices: “[t]he kit includes: ... (b.) a Foley catheter; (c.) a urinary tract lubricant; (d.) surgical gloves; (e.) an inflation syringe for inflation of a catheter with fluid; (f.) irrigation syringe; (g.) evacuation tubing; and, (h.) antiseptic solutions.” (Ex. 1005, 3:15-24.)

Accordingly, Solazzo discloses this claim element. Solazzo in view of Serany therefore renders claim 27 obvious.

4) Claim 28

Claim 28 requires “*the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a Foley catheter.*”

“No Divider Wall” Embodiment

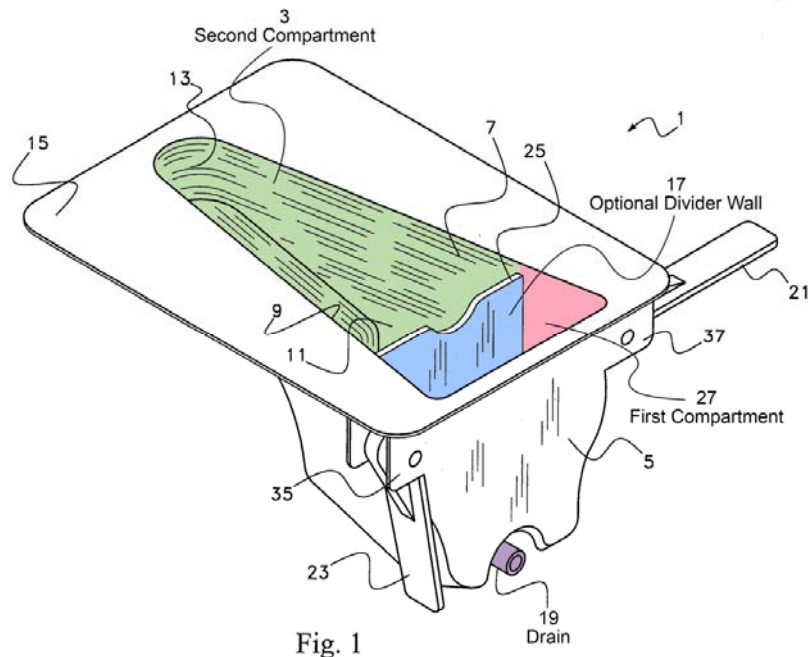
For the reasons set forth in claim 7, Solazzo discloses “*the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a*

Foley catheter” when compartment 3/27 is the first compartment. (Ex. 1002, ¶ 310.)

“Divider Wall” Embodiment

For the reasons set forth in claim 7, “low area 11A” of compartment 17 necessarily functions as “*lubricating jelly application chamber to lubricate at least a portion of a Foley catheter*” because it forms a channel where lubricant could be dispensed. The same is true when the divider wall 17 is provided in the tray. In fact, the divider wall would further serve to provide a confined space to lubricate the catheter without messing up the other components of the tray. Thus, a POSITA would have necessarily recognized that the first compartment 27 functions as a “*lubricating jelly application chamber to lubricate at least a portion of a Foley catheter.*” (Ex. 1002, ¶ 311.)

Furthermore, when divider wall 17 is present, Solazzo may have only *two* compartments as the “optional Foley catheter lubricating wells 31 and 33” can be removed. (Ex. 1005, 4:21.) Modified Figure 1 shows a tray without compartments 31 and 33:



The absence of the lubricating wells in this Solazzo embodiment provides further motivation to lubricate within compartment 27. Additionally, for the reasons set forth in claim 25[f], it would have been obvious to support the lubricant syringe in the compartment 27 along with the inflation syringe. (Ex. 1002, ¶ 313.)

As described at claim 25[f] and 25[g], within compartment 27, the lubricant syringe could be supported at a higher height (i.e., in the same ordering taught by Solazzo in Figure 8 and in line with the procedural steps taught by Solazzo). Alternatively, the inflation syringe may be provided at a higher height because it is used first in catheterization procedures that include the step of inflating a test balloon. (Ex. 1003, ¶ 29.) This arrangement would also facilitate the lubrication of the syringe in the first compartment after the inflation syringe has been removed

from the compartment. Thus, A POSITA would have been motivated to arrange the syringes in either order within the first compartment, depending on the type of Foley catheterization procedure performed (i.e., whether a test balloon is inflated). (Ex. 1003, ¶¶ 28-29; Ex. 1002, ¶¶ 314-319.)

Accordingly, Solazzo discloses this claim element. Solazzo in view of Serany therefore renders claim 28 obvious.

5) Claims 29, 39

For the reasons set forth in claim 6, Solazzo discloses, “*the first compartment defining one or more contours for accommodating flanges of one or more of the first syringe or the second syringe.*”

Solazzo in view of Serany therefore renders claims 29 and 39 obvious.

6) Claim 30

For the reasons set forth in claim 8 and 25[g], Solazzo discloses (or renders obvious in combination with Serany) “*the first compartment to support the first syringe at a shallower depth within the tray than the second syringe.*”

Solazzo in view of Serany therefore renders claim 30 obvious.

7) Claim 31

For the reasons set forth in claim 10 and 25[g], Solazzo discloses (or renders obvious in combination with Serany) “*wherein a higher of the first syringe or the*

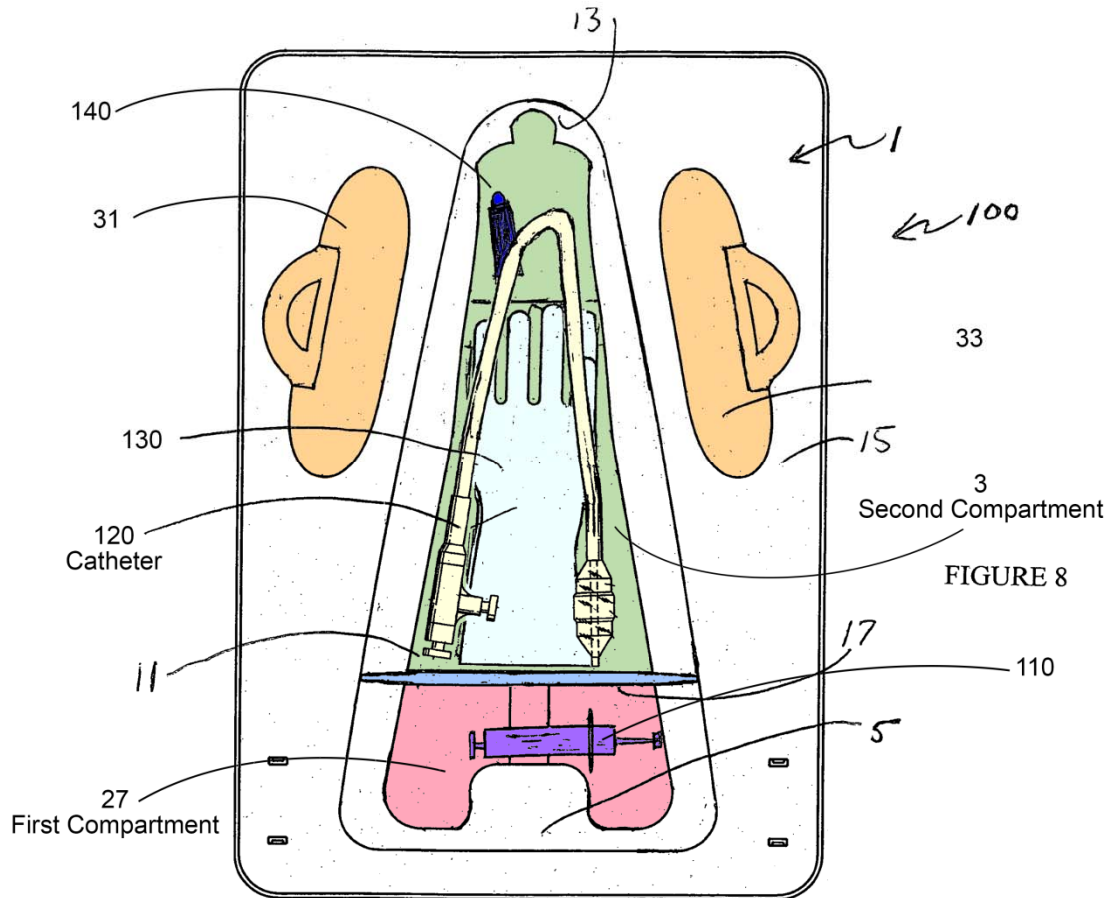
second syringe is for use in the catheterization procedure before a lower of the first syringe or the second syringe.”

Solazzo in view of Serany therefore renders claim 31 obvious.

8) Claim 32

Solazzo discloses “*the at least two compartments further comprising a second compartment, further comprising a Foley catheter disposed within the second compartment.*”

As shown in annotated Figure 8, Solazzo discloses a Foley catheter disposed within the second compartment (compartment 3) when divider wall 17 is present. (Ex. 1002, ¶¶ 326-328.)



Accordingly, Solazzo discloses this claim element. Solazzo in view of Serany therefore renders claim 32 obvious.

9) Claims 36, 40

Solazzo discloses “*the tray comprising a single tray.*” Solazzo discloses a single tray (“catheterization/irrigation tray 1”). (Ex. 1005, Figs. 1-6, 8; 3:52-56).

Accordingly, Solazzo discloses this claim element. Solazzo in view of Serany therefore renders claims 36 and 40 obvious.

10) Claim 37

(a) Preamble and 37[a]: “A medical procedure kit ...”

For the reasons set forth in claim 1[a], Solazzo discloses “[a] medical procedure kit, comprising: a tray having a compartment for receiving a medical assembly.”

(b) 37[b]: “a first syringe and a second syringe ...”

For the reasons set forth in claim 1[b], Solazzo discloses “a first syringe and a second syringe disposed within the tray.”

(c) 37[c]: “at least one layer of wrap material ...”

For the reasons set forth in claim 1[c], the combination of Solazzo in view of Serany discloses “at least one layer of wrap material enclosing the tray within one or more folds of the at least one layer of wrap material.”

(d) 37[d]: “an outer packaging ...”

For the reasons set forth in claim 1[d], the combination of Solazzo in view of Serany discloses “an outer packaging disposed about both the tray and the at least one layer of wrap material.”

(e) 37[e]: “the first syringe and the second syringe are ordered ...”

For the reasons set forth in claim 1[e], Solazzo discloses “*the first syringe and the second syringe are ordered within the tray in accordance with their use during a catheterization procedure.*”

(f) 37[f]: “... a first compartment to support the first syringe and the second syringe”

For the reasons set forth in claim 25[f], Solazzo discloses “*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) 37[g]: “... use a higher of the first syringe or the second syringe ...”

For the reasons set forth in claims 25[g] and 31, Solazzo discloses “*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.*”

11) Claim 38

For the reasons set forth in claim 28, Solazzo discloses “*the first compartment defining a lubricating jelly application chamber to lubricate at least a portion of a catheter assembly.*”

12) Claim 41

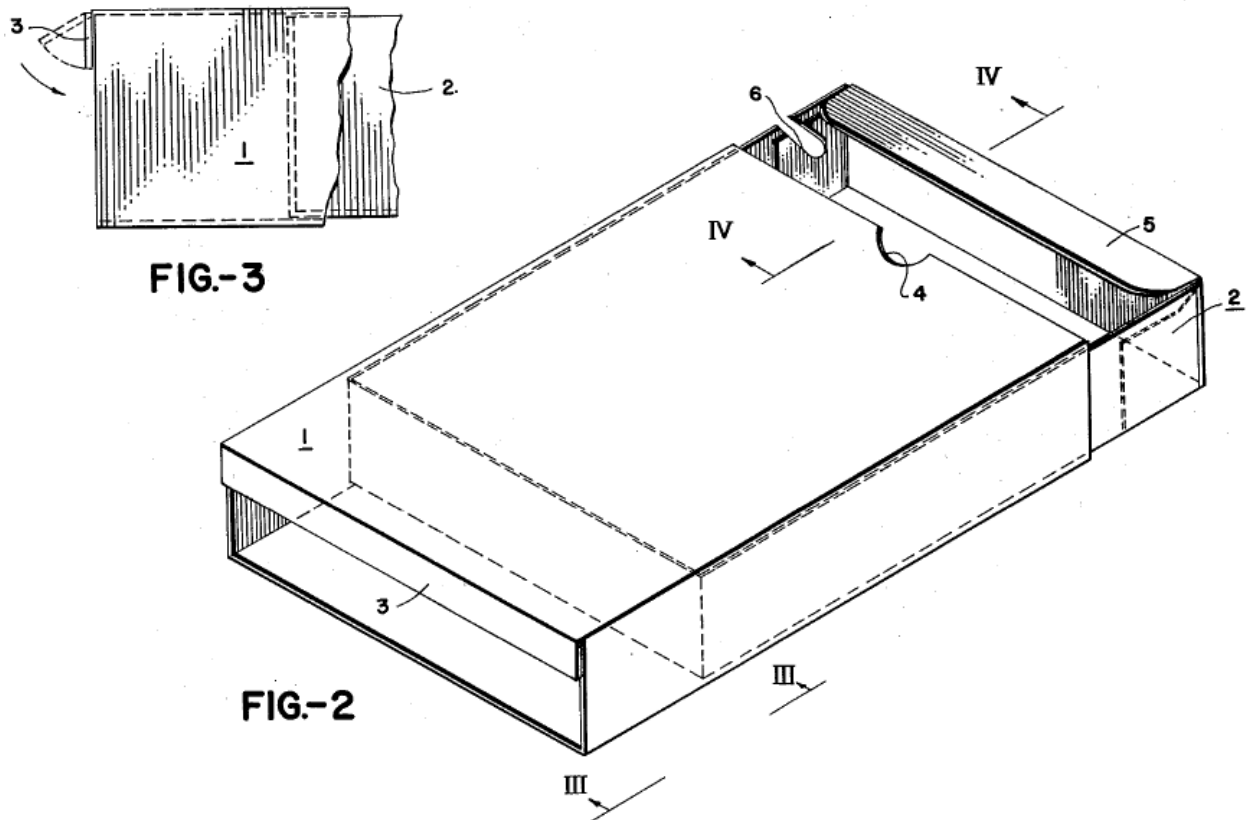
For the reasons set forth in claim 32, Solazzo discloses “*the tray comprising a surface defining a second compartment, further comprising a Foley catheter disposed within the second compartment.*”

D. Ground 4 – Obvious Based on Solazzo, Serany, and Disston

1. Summary of Disston

Disston issued on January 19, 1965. Disston is therefore prior art to the '088 patent pursuant to at least 35 U.S.C. § 102(b).

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.” (Ex. 1008, 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. (Ex. 1008, 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.” (Ex. 1008, 1:26-35, 2:41-52; Fig. 1.) The pre-assembly “not only saves time and trouble but practically eliminates the danger of faulty connections and loss of sterility, inherent in the former system.” (Ex. 1008, 1:42-46; Ex. 1002, ¶¶ 143-144.)

2. The Combination

As set forth below, Solazzo in view of Serany and Disston discloses all the elements in the claims in this ground and renders those claims as obvious.

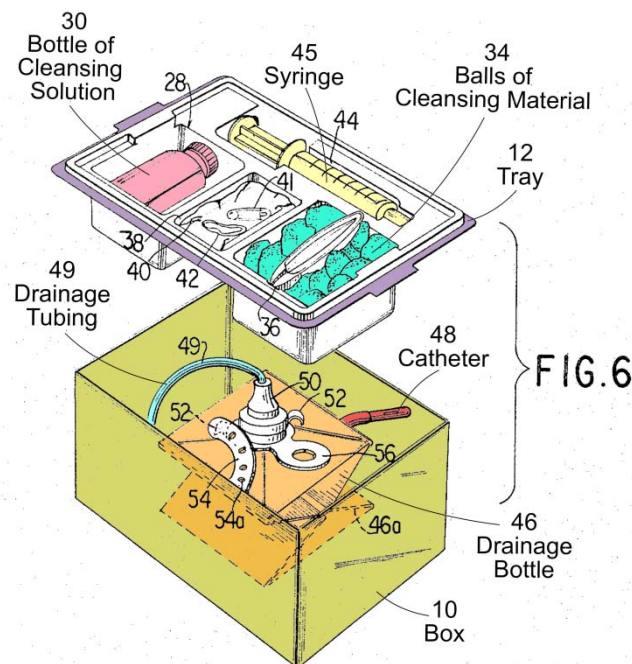
1) Claim 33

Claim 33 requires “*the Foley catheter coupled to a fluid bag.*”

Solazzo discloses a Foley catheter 120, but does not expressly mention a closed-system Foley catheter, i.e., a Foley catheter that is *pre-connected* to a drainage bag via flexible tubing.

Solazzo discloses a “urological catheterization/irrigation tray.” The tray may be used to “evacuate the bladder of its contents, urine and/or clots.” (Ex. 1005, 4:26-33.) A Foley catheter is an *indwelling* catheter (as opposed to an intermittent or ‘in’-and-‘out’ catheter”). (Ex. 1003, ¶ 11.) Solazzo teaches a catheterization kit, including catheterization devices such as a Foley catheter and inflation syringe. (Ex. 1003, ¶¶ 30-31.) Solazzo notes that a patient may “discharge or be relieved into the tray.” (Ex. 1005, 2:42-46.) However, discharge of urine into the tray is not a long-term solution for an indwelling Foley catheter that remains in a patient for a period of time, because the tray has an open top. ((Ex. 1003, ¶ 36.) A closed container (e.g., a drainage bag) is required for a long-term catheterization solution. (Ex. 1003, ¶ 36; Ex. 1002, ¶ 342.)

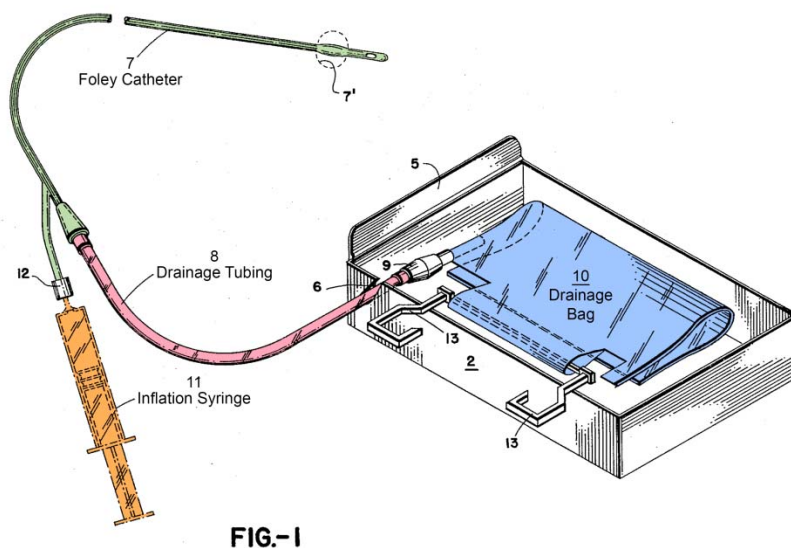
Serany discloses “*the Foley catheter coupled to a fluid bag.*” Specifically, Serany discloses a “Foley catheter 48” coupled to a “drainage bottle 46: “Included in the box 10 beneath the tray 12 are a collapsible drainage bottle 46 and a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use.” (Ex. 1006, 3:23-26; Ex. 1002, ¶¶ 343-344.)



While Serany refers to catheter as being connected to a “drainage *bottle*,” it describes the “bottle” as being made out of a “flexible plastic material” that can be collapsed inside the box. (Ex. 1006, 3:26-32.) A POSITA would understand Serany to therefore also teach a drainage/fluid *bag*. (Ex. 1002, ¶ 344.) To the extent Patent Owner argues that Serany does not teach a bag, it would have further been obvious to substitute the “bottle” of Serany with the “bag” of Disston. (Ex.

1002, ¶ 344.) Doing so would merely involve a simple substitution of one container (a “bottle”) for another known type of container (a “bag”) to produce predictable results.

Disston discloses “*the Foley catheter coupled to a fluid bag.*” Specifically, Disston discloses “a pre-assembled catheter-tube-bag assembly,” including a Foley catheter 7, drainage tube 8, and drainage bag 10. (Ex. 1008, 2:15-23; Fig. 1; Ex. 1002, ¶ 345.)



Disston is analogous art to Solazzo and Serany because all three references teach Foley catheter trays.

Thus, it was well-known in the art (by the 1960s) to provide closed-system Foley catheters in Foley catheter kits. The Nursing Standard article, which was

published in March 2009, notes that “[c]atheters should be connected to a sterile catheter bag or valve, creating a closed system” because “[t]he risk of infection with an open system is 97% but this falls to between 8% and 15% when a sterile closed system is adopted.” (Ex. 1010, 51.)

Serany further describes a pre-connected catheterization system and that “an object of this invention is to provide a catheterization package which reduces the rate of infection.” (Ex. 1005, 1:31-32; 3:23-36). Similar, Disston discloses “the drainage system is pre-assembled” and “ready for use.” (Ex. 1008, 2:72, 3:1.)

In view of Serany and Disston, a POSITA would have been motivated to include a closed-system Foley catheter, including a fluid/drainage bag, in Solazzo’s tray for multiple reasons. First, Serany and Disston teach pre-connected systems that are “ready for use.” Including a pre-connected Foley system that is “ready for use” in Solazzo’s tray reduces the steps in a Foley catheterization procedure because a fluid/drainage bag does not need to be fetched and connected to the Foley catheter. (Ex. 1003, ¶ 35.) Second, it was known in the art that closed-system Foley catheter (i.e., Foley catheters that are pre-connected to a drainage bag via tubing) reduce the risk of infection. (Ex. 1002, ¶ 349; Ex. 1003, ¶ 35; Ex. 1010, 51.)

Furthermore, placing the closed-system Foley catheter in Solazzo’s tray does not eliminate the catheterization and irrigation features of the tray. The tray of

Solazzo can be still be used for catheterization and irrigation procedures. (Ex. 1003, ¶ 38.) As explained by Dr. Yun, the tray can be best utilized for both purposes when a closed-system Foley catheter is provided in the tray of Solazzo. (Ex. 1003, ¶¶ 41-42.) For example, a practitioner may use the tray to catheterize a patient. The tray can be later used to perform an irrigation procedure, as necessary, for example if the patient is unable to urinate due to the formation of clots. (Ex. 1003, ¶¶ 41-42; Ex. 1002, ¶ 350.)

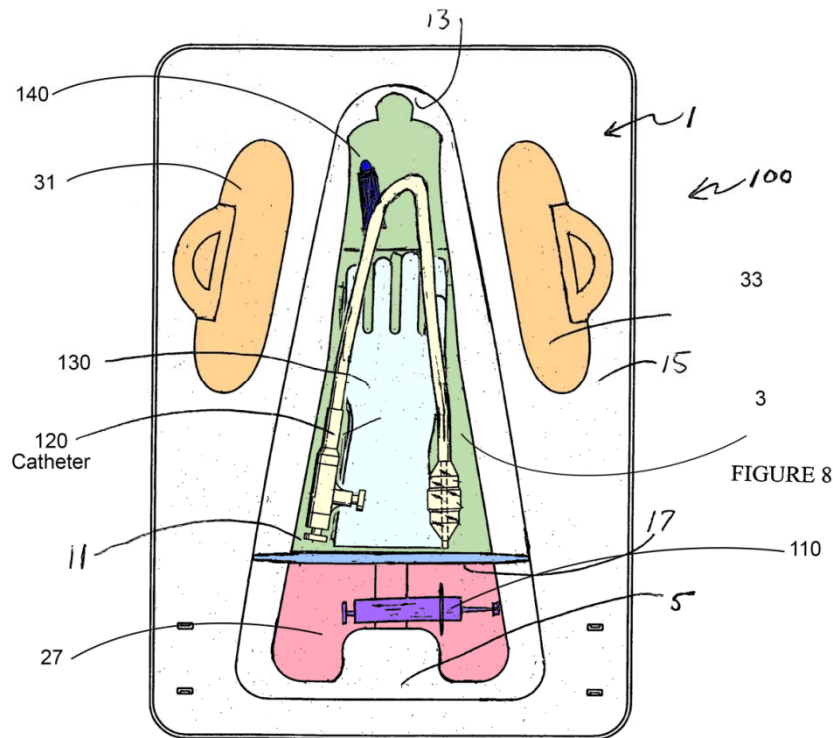
A POSITA would further have been motivated to combine the closed-system Foley catheter (including a drainage bag) taught by Serany and Disston with the tray of Solazzo because it involves applying a known technique (a closed-system Foley catheter) to a known device (a Foley catheter kit) ready for improvement to yield predictable results (providing a “ready for use” catheterization solution and a closed-system to reduce CAUTIs). (Ex. 1002, ¶ 351.)

Thus, claim 33 is obvious based on Solazzo in view of Serany and Disston.

2) Claim 34

Solazzo discloses “*the fluid bag disposed within the second compartment.*”

Solazzo teaches an embodiment with a divider wall 17 that forms two compartments, including a *first* compartment (3) and *second* compartment (27). Solazzo further teaches providing a Foley catheter 120 in the second compartment, as shown in Figure 8.



When providing a closed-system Foley catheter in Solazzo's tray as discussed in claim 33, it would have been obvious to put the Foley catheter with the pre-connected fluid bag in the second compartment where catheter 120 already resides. (Ex. 1002, ¶¶ 352-355.)

3) Claim 42

For the reasons set forth in claim 34, Solazzo discloses “*further comprising a fluid bag disposed within the second compartment.*”

E. Ground 5 – Obvious Based on Solazzo, Serany, and Franks-Farah

Claim 35 requires “*further comprising printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment.*”

Because claim 35 is directed to printed matter, the claim lacks patentable weight and is invalid for the same reason as claim 32. (*See* Section VI of this Petition.)

For the reasons set forth in claims 18 and 19, Solazzo in view of Serany and Franks-Farah discloses “*further comprising printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment.*”

F. Ground 6 – Obvious Based on Solazzo, Serany, Disston, and Franks-Farah

1. The Addition of Franks-Farah and Disston

The claims under this ground merely add printed instructions in the context of a tray with a Foley catheter. As a result, the ground utilizes both Franks-Farah and Disston together. As discussed below, to the extent printed instructions are even deserving of patentable weight, the combination of these two references would have been obvious to a POSITA.

2. The Combination

As set forth below, Solazzo, in view of Serany, Disston, and Franks-Farah discloses all the elements in the claims in this ground and renders those claims as obvious.

1) Claim 43

Claim 43 requires “*further comprising printed instructions for using the tray.*”

Because claim 43 is directed to printed matter, the claim lacks patentable weight and is invalid for the same reason as claim 42. (*See* Section VI.)

For the reasons set forth in claim 18, Solazzo in view of Franks-Farah discloses “*further comprising printed instructions for using the tray.*”

2) Claim 44

Claim 44 requires “*the printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment.*”

Because claim 44 is directed to printed matter, the claim lacks patentable weight and is invalid for the same reason as claim 43. (*See* Section VI.)

For the reasons set forth in claims 18 and 19, Solazzo in view of Serany and Franks-Farah discloses “*the printed instructions instructing application of lubricating jelly to the Foley catheter using the first compartment.*”

VIII. SECONDARY CONSIDERATIONS

While secondary considerations of non-obviousness must be taken into account when present, Patent Owner offered no such evidence during the prosecution of the '088 patent. To the extent Medline raises alleged evidence of non-obviousness in response to Bard's Petition, Bard should be afforded the opportunity to respond.

IX. SECTION 325(d) IS INAPPLICABLE

Neither the original examination of the '088 patent (or other Medline patents), nor the *inter partes* reviews in *Medline I* raised substantially the same art or arguments as the current Petition. Thus, § 325(d) is inapplicable to this proceeding. See *Becton, Dickinson and Company v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017).

A. Original Examination

The primary reference in this Petition—Solazzo—is materially different and not cumulative of the art discussed in the Examiner's Notice of Allowability. With respect to claims 1, 25 and 37, the closest art (Paikoff) lacked:

- A mnemonic device or a base member that defines a mnemonic device; and
- Compartments that support multiple syringes at different heights according to their order of use in a catheterization procedure.

Solazzo has all these features as discussed above. Moreover, Solazzo was included in an IDS listing of 375 references or so. While it was considered along with the hundreds of other references, the Examiner never mentioned Solazzo in the entire examination, including in the Notice of Allowability. Indeed, none of the art referenced in the grounds of this Petition was discussed by the Examiner

during the original examination. Thus, no factor in *Becton* favors application of § 325(d).

B. Original Examination Of U.S. Patent No. 9,795,761

The '088 patent is part of a complex patent portfolio. (Ex. 1017.) In application no. 13/153,265, now U.S. Patent No. 9,795,761, the Examiner identified the published application of Solazzo (Ex. 1018; “Solazzo Publication”) as one of the closest prior art in the Notice of Allowability (Ex. 1019). (He had not raised it before.) The Examiner noted that the Solazzo Publication discloses a Foley catheter, syringes and a lubricant. The Examiner, however, allowed the claims over the Solazzo Publication, because it did not teach or suggest such elements with a patient aid—a feature that the Examiner had added through an Examiner’s amendment. A “patient aid” is not claimed in any of the challenged claims of the '088 patent. Accordingly, the arguments in this Petition and the distinguishing feature over the Solazzo Publication in the '761 patent examination differ.

C. IPRs In *Medline I*

Section 325(d) should not be applied in view of the IPRs in *Medline I*. None of the grounds of the IPRs utilized Solazzo. Nor would Solazzo be considered cumulative of the art raised in any of the grounds of the IPRs. In particular,

Solazzo provides a single level Foley catheter tray that includes multiple syringes, in contrast to the art raised in the IPR.

X. NOTICES AND STATEMENTS

Pursuant to 37 C.F.R. § 42.8(b)(1), C. R. Bard, Inc. and Becton, Dickinson and Company are the real parties-in-interest.

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following related matters: (i) *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:17-cv-07216 (N.D. Ill.) and (ii) an accompanying *inter partes* review petition directed to claims 45-58, 60-74, 76-90 and 92 of the '088 patent.

Pursuant to 37 C.F.R. § 42.8(b)(3), Petitioner identifies the following counsel (and a power of attorney accompanies this Petition).

Lead Counsel for Petitioner	Backup Counsel for Petitioner
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Pursuant to 37 C.F.R. § 42.8(b)(4), service information for lead and back-up counsel is provided above. Petitioner consents to electronic service by email to 48010-Medline@mofo.com.

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '088 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

XI. CONCLUSION

Bard respectfully requests that the Board initiate *inter partes* review of the challenged claims.

The USPTO is authorized to charge any required fees, including the fee as set forth in 37 C.F.R. § 42.15(a) and any excess claim fees, to Deposit Account No. **03-1952** referencing Docket No. **480100000019**.

Dated: October 4, 2018

Respectfully submitted,

By /Mehran Arjomand/
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Certification of Word Count (37 C.F.R. § 42.24)

I hereby certify that this Petition for *Inter Partes* Review has 13,766 words (as counted by the “Word Count” feature of the Microsoft Word™ word-processing system), exclusive of “a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.”

Dated: October 4, 2018

By /Mehran Arjomand/
Mehran Arjomand

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by UPS, which is a means at least as fast and reliable as U.S. Express Mail, on the Patent Owner at the correspondence address indicated for U.S. Patent No. 9,745,088.

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Dated: October 4, 2018

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