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. 9,808,596

Inter Partes Review No. IPR2019-00223

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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Inter Partes Review of USP 9,808,596

Petitioner C. R. Bard, Inc. ("Petitioner" or "Bard") respectfully petitions for *inter partes* review of claims 7-16, 21, and 22 of U.S. Patent No. 9,808,596 ("the '596 patent" (Ex.1001)) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. INTRODUCTION

The '596 patent is directed to a kit for storing medical devices such as a catheter and related medical devices. (Ex.1001, 1:31-36.) The tray comprises multiple compartments that hold multiple syringes and a catheter assembly. The catheter assembly comprises a Foley catheter, a fluid receptacle, and a coiled tube coupled to the fluid receptacle and the catheter.

The structure as well as the components of a catheter tray were well-known by 2009, the earliest purported priority date of the '596 patent. For example, Solazzo (Ex.1005) discloses a tray with multiple compartments, such as compartments 3 and 27, as shown in annotated Figure 1 below.

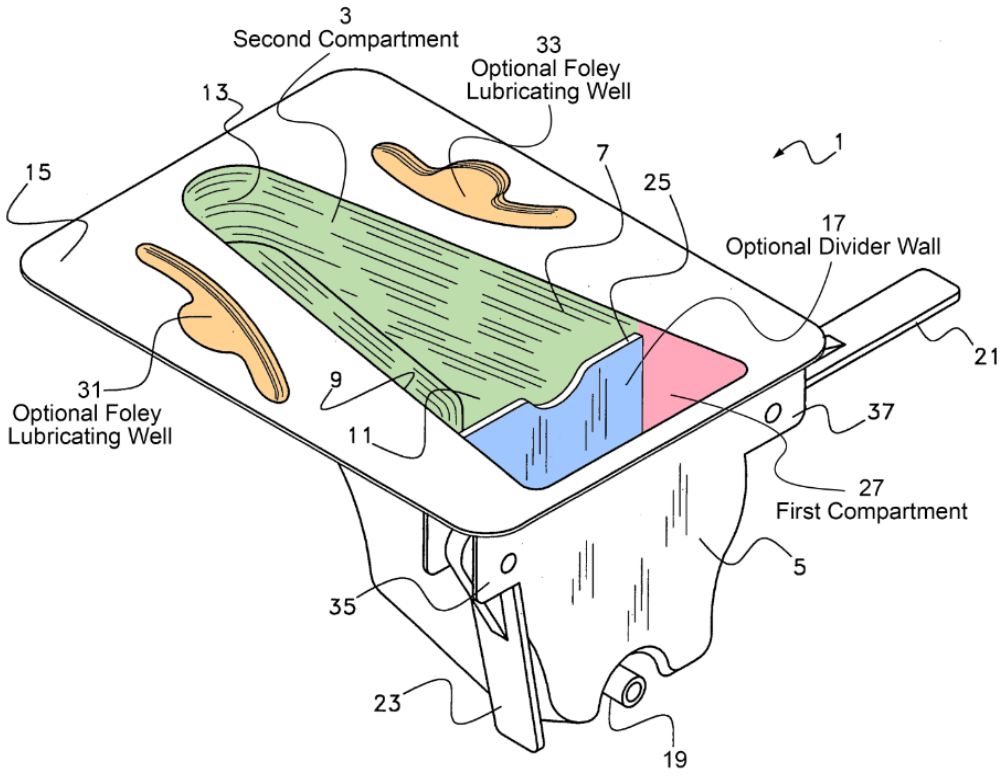


Fig. 1

The tray of Solazzo can hold a catheter and multiple syringes in separate compartments. (Ex.1005, 3:20-24.) Figure 8 (annotated) illustrates an embodiment of the tray with a Foley catheter 120 in a compartment 3 and an inflation syringe 110 in compartment 27. (*See also* Ex.1005, 3:17; 4:41-48.) A tube of lubricant 140, which could be substituted with a syringe of lubricant is in compartment 3.

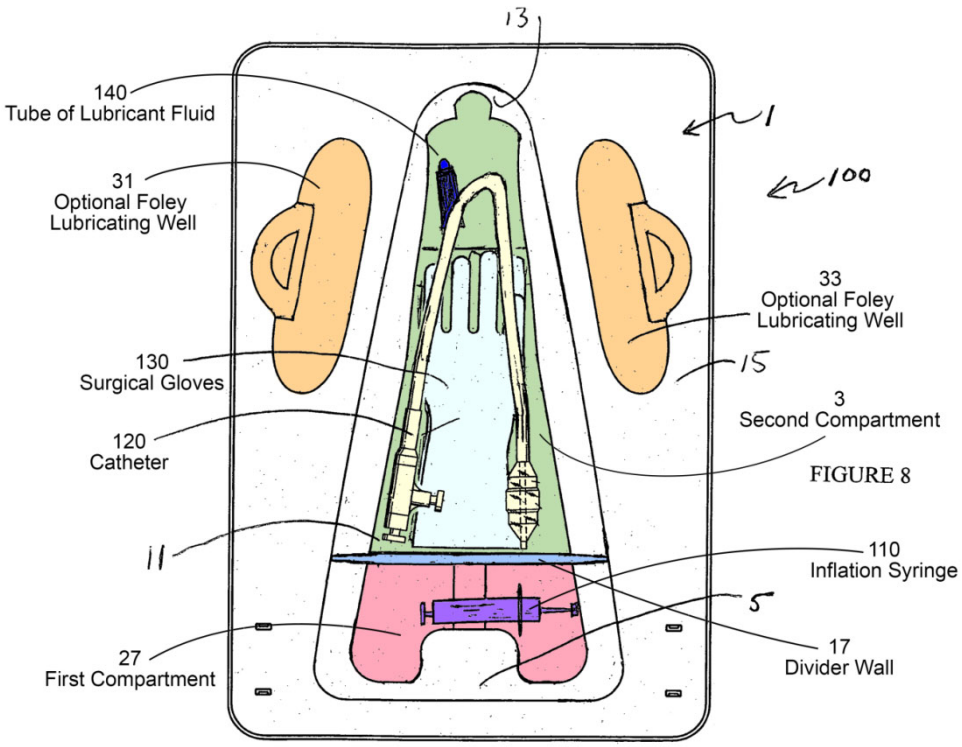


FIGURE 8

Solazzo does not explicitly disclose a coiled tube and a fluid receptacle with its Foley catheter. But catheters with these elements have been known, as Applicants admitted during the examination of a parent (U.S. Patent No. 9,808,400 (Exs. 1017, 1045)) of the '596 patent. (Ex.1046, 259, ¶33 (Meyst).) Moreover, Disston (Ex.1008), which issued in 1965 to Bard, is a well-known example of a closed-system Foley catheter with a coiled tube (drainage tubing 8) and a fluid receptacle (drainage bag 10):

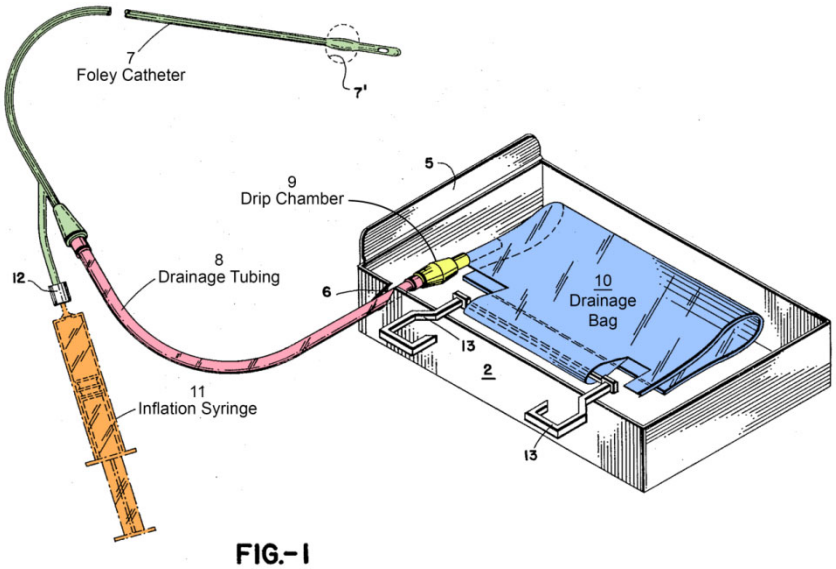


FIG.-1

As discussed in the accompanying Declarations of Michael Plishka (Ex.1002) and Dr. Edward Yun (Ex.1003), there are many reasons to utilize a closed-system Foley catheter in Solazzo. Specficially, closed-systems reduce the risk of CATUIs as noted by Nursing Standard and are "ready for use" as Disston explains.

Accordingly, Bard respectfully submits that the challenged claims are unpatentable for the reasons set forth in this Petition.

II. THE STATE OF THE ART

By 2009 (the earliest purported priority date of the '596 patent), the packaging of medical devices, in particular the packaging of Foley catheters and related medical devices, was extremely well-developed. To place the purported

inventions of the ’596 patent in context, Bard 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. 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 ’596 patent. (Ex.1002, ¶44.) 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 a single level tray that holds a Foley catheter pre-connected to a drainage bag (*see* annotated Figure 1 below) and related components such as an inflation syringe. (Ex.1008, 2:15-26; Figs. 1-2; Ex.1002, ¶¶45-48.)

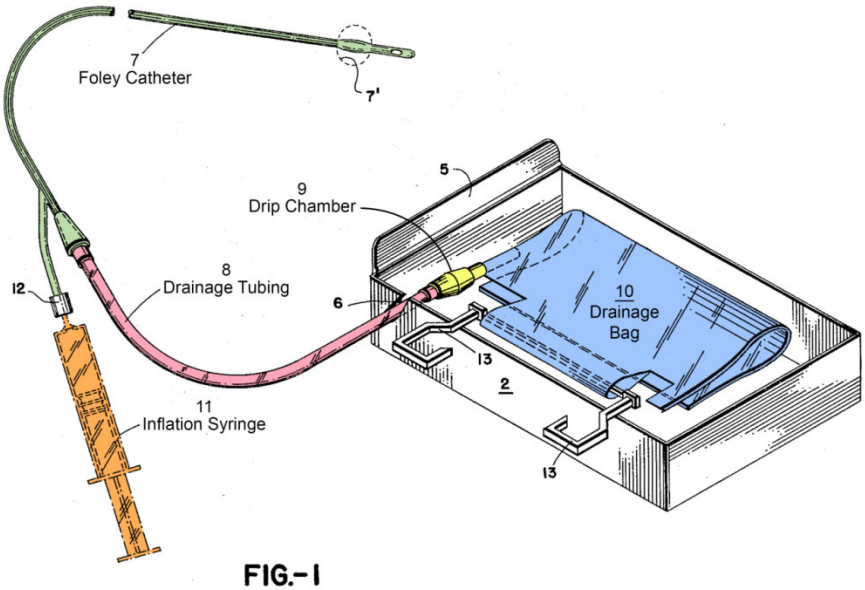
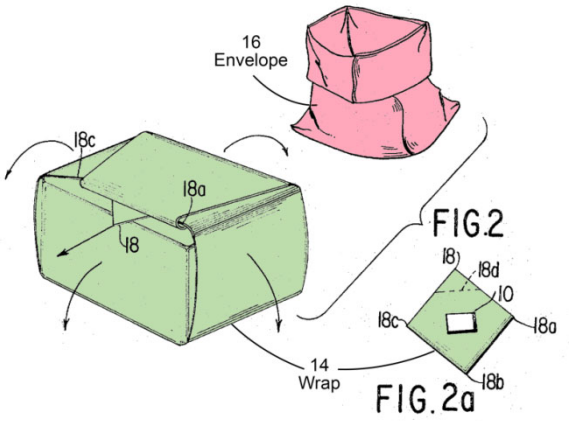
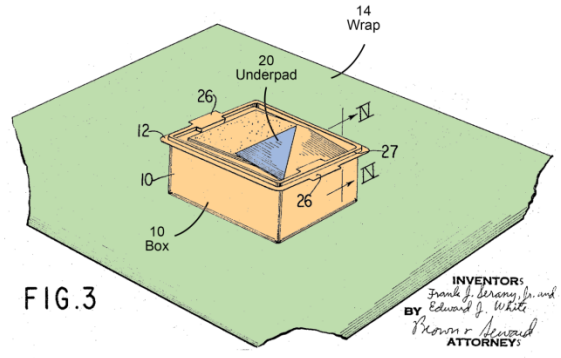


FIG.-1

Typically, a medical device tray is wrapped in a bag or outer wrap to allow shipment while holding components inside the tray. (Ex.1002, ¶55.) 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, ¶55.) 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. (Ex.1002, ¶56.)

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, ¶57.)





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, ¶¶60-83.)

Foley Catheter. Solazzo**,** Disston, and Serany all disclose trays with Foley catheters. (Ex.1002, ¶¶63-67.) Foley catheter kits have long been available. (Ex.1003, ¶¶12-15.)

Closed System Foley Catheter. "Reducing the risks associated with urinary catheters," is an article published in *Nursing Standard*, Vol. 23, No. 29 on March 25, 2009 (referred to as the "Nursing Standard article" or "Nursing

Standard"; Exs.1010, 1025). It 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, ¶67.) Disston and Serany also disclose closed-system Foley catheters. (Ex.1002, ¶¶64-66.)

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, ¶81.)

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 "applying lubricant to [the catheter], 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 included lubricant. (Ex.1008, 1:32; Ex.1006, 3:3-4; Ex.1005, 3:18; Ex.1010, 52; Ex.1002, ¶82.) Lubricant may also be provided in a syringe. (Ex.1010, 52; Ex.1002, ¶83; Ex.1003, ¶12.)

Anti-reflux Device. Anti-reflux devices were introduced by the 1970s along with the rise of "flexible" urine collection bags which could lead to urine reflux back to a patient's bladder. (Ex.1002, ¶¶68-80) Anti-reflux devices were

ubiquitous with closed-system Foley catheters before the time of the invention. (Ex.1003, ¶¶46-47.). Applicants also admitted during prosecution of the '400 patent that anti-reflux devices were associated with Foley catheters. (Ex.1046, 262, ¶41 (Meyst).)

Catheterization And Irrigation Procedures. A Foley catheterization procedure (as of 2009) using a Foley catheter kit involved a well-known series of steps. The steps include a practitioner lubricating the Foley catheter inside the tray using an included lubricant solution. (Ex.1003, ¶¶20-21.) Alternatively, the practitioner squirts lubricant directly into the patient's urethra using the tapered tip of a lubricant syringe. (Ex.1003, ¶22 Ex.1010, 53.) The catheter is then inserted by the practitioner, followed by inflation of the balloon. (Ex.1003, ¶23; Ex.1010, 53.)

The practitioner attaches an inflation syringe (filled with sterile water) to the inflation port of the Foley catheter. (Ex.1003, ¶23; Ex.1010, 53.) In some facilities, this step may be performed earlier in the process to test whether the balloon of the Foley catheter inflates. (Ex.1003, ¶23.) The practitioner next inflates the balloon of the catheter. (Ex.1003, ¶23; Ex.1010, 53.)

An irrigation procedure is performed with a urethral catheter to remove blood clots, which reduce or inhibit the flow of urine. (Ex.1003, ¶26.) Irrigation procedures are often performed with patients that are already catheterized to

improve the flow of urine. (Ex.1003, ¶27.) In that case, the Foley catheter must be disconnected from the drainage tubing that connects it to the drainage bag. (Ex.1003, ¶27.) Using an irrigation syringe, the practitioner draws up 60mL of saline solution and injects the catheter. (Ex.1003, ¶27.) The fluid is withdrawn and dispensed into a collection tray. (Ex.1003, ¶27.)

C. Functional Aspects Of The Tray

Lubrication compartment. Compartments for lubricating catheters were well-known features of prior art trays. (Ex.1002, ¶¶84-92.) 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. (Ex.1008, 2:15-19; *see also* Ex.1006, 1:23-25; 1:31-35; Ex.1002, ¶¶93-98.)

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 the 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; *see also* Ex.1008, 2:15-23, 2:63-72; Ex.1002, ¶¶99-106.)

III. THE '596 PATENT

A. Summary

The '596 patent is entitled "Catheter Tray, Packaging System, And Associated Methods." The '596 patent is directed to a kit for storing medical devices such as a catheter and related medical devices. (Ex.1001, 1:31-36.) The '596 patent focuses on tray structure, components in the tray, and functional aspects of the tray. As discussed below, all these aspects were well-known in the art by 2009.

1. Tray structure

Figure 1 of the ’596 patent provides a depiction of a medical device tray with multiple compartments.

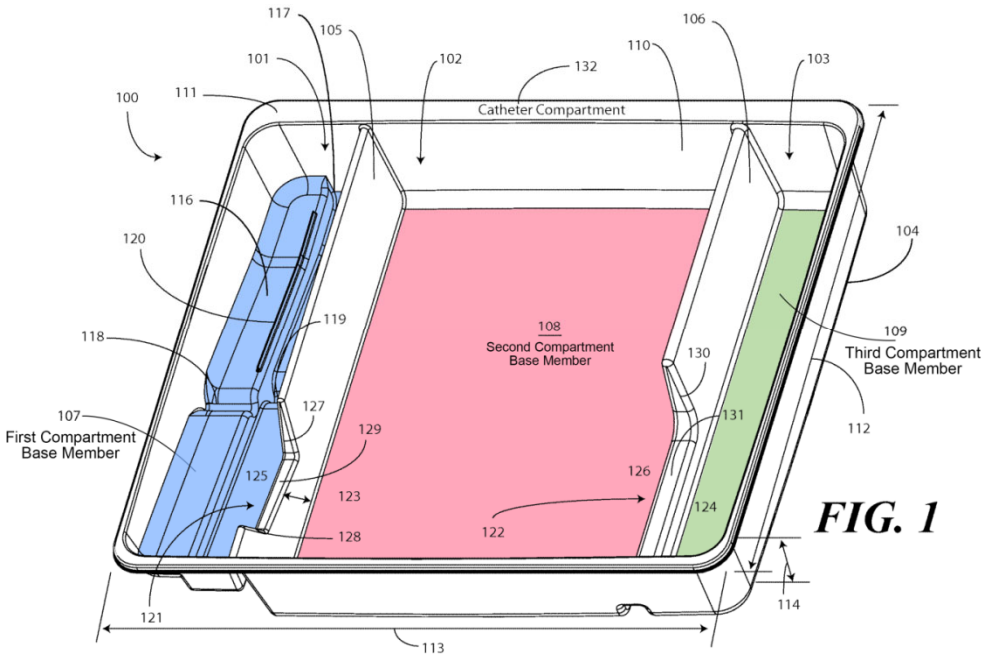


FIG. 1

The tray has a first compartment 101, a second compartment 102, and a third compartment 103, the compartments bounded on the sides by a perimeter wall 110. (Ex.1001, 4:44-46; 5:54-55.)

As shown in Figure 10 (annotated 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, 9:53-55, 10:51-52.)

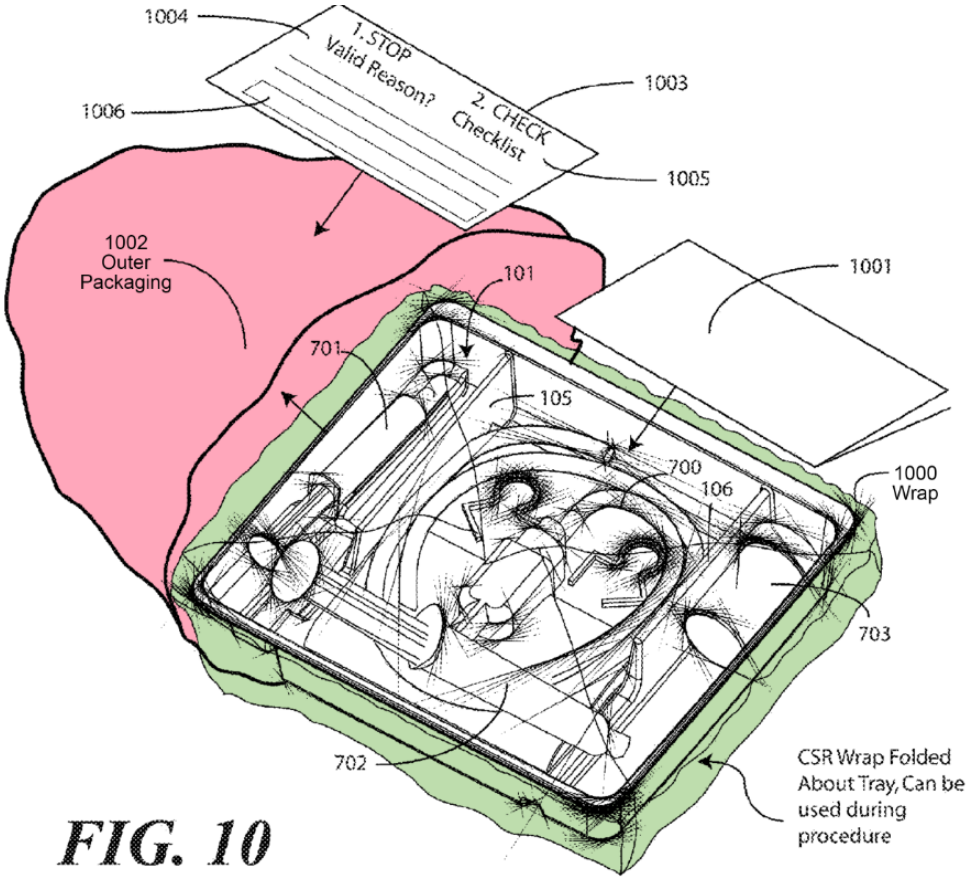


FIG. 10

2. Components of the tray

As shown in annotated Figure 7 (below), the tray accommodates, among other components, a pair of syringes (pink and green) containing sterile water or lubricants in the first compartment 101, and a catheter assembly 700 (blue) in the second compartment 102. (Ex.1001, 3:49-53.)

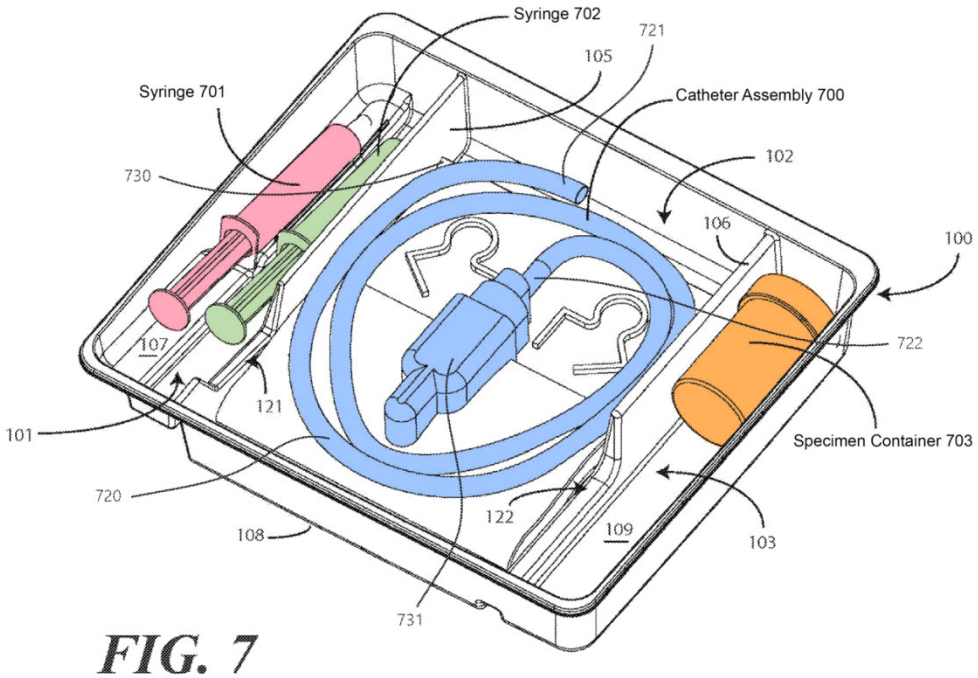


FIG. 7

3. Functional aspects of the tray

Compartments of the tray can have "multi-purpose functionality." (Ex.1001, 3:64-65.) For example, a compartment can both accommodate a syringe of lubricating jelly and be used as a lubricating jelly applicator. (Ex.1001, 3:66-4:2.)

The tray also orders objects "in accordance with their use during the procedure." (Ex.1001, 5:24.)

For example, the tray provides a "medical services provider with mnemonic devices instructing them in which order to use each device." (Ex.1001, 3:58-59.) 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, 3:60-63.) This arrangement serves 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, 5:49-53.)

B. Effective Filing Date

Application no. 61/183, 629, filed on June 3, 2009, is the earliest-filed application listed on the face of the '596 patent. (*See also* Ex.1030, 3.) Bard assumes—for this Petition only—that the challenged claims are entitled to a priority date of June 3, 2009. Bard reserves the right to challenge this priority date.

C. Prosecution History Of '596 Patent

Initial Filing. The '596 patent was filed on March 11, 2016, with an earliest priority claim through CIP chain to U.S. application no. 61/183,629, filed on June 3, 2009. (Ex.1004, 53-57, 61-62.)

Office Action. Examiner Richard Poon issued a non-final Office Action on June 14, 2016 rejecting the claims based on U.S. Published App. No. 2004/0004019 to Busch (Ex.1038) with other references (Exs.1042-44).

Final Rejection. After Applicants responded, Examiner Poon issued a final Office Action on January 13, 2017. (Ex.1004, 183-185.) Examiner Poon remarked that "since Busch discloses the compartment having the structure as

recited, then it would be capable of receiving lubricant jelly from the syringe to lubricate the catheter." (Ex.1004, 195.)

RCE. On June 22, 2017, Applicants submitted amended claims to recite "the first syringe containing an inflation fluid," "a second syringe disposed within the first compartment of the single level container, the second syringe containing a lubricating jelly," and "a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle, the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter." (Ex.1004, 222, 227.) New independent claim 25 (corresponding to issued claim 14) was added with similar recitations.

Notice of Allowability. On August 23, 2017, Examiner Poon issued a Notice of Allowance. No reasons for allowance were provided. (Ex.1004, 281.)

D. Prosecution History Of '400 Patent

A parent to the '596 patent—the '400 patent—was being examined at the same time by Examiner Poon. (Ex. 1017.) During that examination, Examiner Poon questioned whether many of the claim elements were illustrated or described in the original application, e.g., an indwelling catheter, and a fluid receptacle

coupled to the indwelling catheter via a coiled tube. Illustrations or descriptions of these elements were added during examination, but only after Applicants *admitted* that these elements were well-known.

RCE/Declarations. On July 10, 2017, Applicants amended the specification and drawings relating to an indwelling catheter, a fluid receptacle and an anti-reflux device. Because the application did not illustrate or describe an indwelling catheter coupled to a fluid receptacle via a coiled tube, or refer to an element as anti-reflux device, Applicants further submitted two declarations as "additional evidence to show that a POSITA would understand that the applicant was in possession of the claimed subject matter." (Ex.1046, 213.) The declarations were by Barbara Weintraub (a nurse) and Richard Meyst and had been submitted in *Medline II* (discussed below). (Ex.1046, 212-213.) In submitting these declarations, Applicants endorsed a number of admissions made by Ms. Weintraub and Mr. Meyst regarding what was known in the art:

- "Foley catheters are typically pre-connected to a drainage receptacle via a long coiled tubing." (Ex.1046, 259, ¶33 (Meyst).)
- "An anti-reflux chamber is a device that is designed to stop fluid from the bag from flowing back into the patient's bladder and is associated with a Foley catheter." (Ex.1046, 262, ¶41 (Meyst).)

- "Healthcare service providers familiar with administering catheters (including me) knew in 2009 that CAUTI is caused by Foley catheters." (Ex.1046, 239, ¶29 (Weintraub).)

Office Action. On August 24, 2017, Examiner Poon issued a non-final Office Action. Examiner Poon found that a fluid receptacle including an anti-reflux device coupled to a coiled tube was known. (Ex.1046, 73-76, 106-108.) Examiner Poon further noted that the feature of the fluid receptacle beneath the coiled tube was also admitted art. (Ex.1046, 73-76, 106-108.) Applicants never challenged any of these findings of Examiner Poon. (Ex.1046, 73-76, 106-108.)

E. Level Of Ordinary Skill

A person of ordinary skill in the art ("POSITA") in the field of the '596 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 POSITA would have 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 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.)

F. Litigation And Other Matters

Patent Owner has asserted the '596 patent against Bard in a co-pending litigation: *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:17-cv-07216 (N.D. Ill.), referred to herein as *Medline III*. 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 ’596 patent should be accorded their ordinary and customary meanings as understood by one of ordinary skill in the art and consistent with the ’596 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. (Ex.1022; Ex.1023, 13-14.)

Claim Term	Patent Owner Construction
Mnemonic device	feature intended to assist the memory, such as ordering items left to right or top to bottom
Barrier	structure that separates one compartment from another and prevents or blocks movement between the two
Lubricating jelly application chamber/compartment	a compartment or channel where lubrication is applied
Reveal	to make visible or to make (something that was hidden) able to be seen
Perimeter wall	a wall along the perimeter of the tray

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 district court. (Ex.1026.)

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:

- "the first compartment *configured to receive the lubricating jelly from the syringe*" (claim 14; *see also* claims 9 and 21 with similar recitations); and
- "a *mnemonic* device indicating that the first syringe should be removed from the first compartment before the second syringe during a catheterization procedure" (claim 15).

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 "catheterization 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)). For example, if the prior art discloses all the recited chambers or compartments, as does Solazzo, then a chamber that is "configured to receive the lubricating jelly from the syringe" does not differentiate claim 14 from Solazzo. What is applied to the chamber is directed to how the chamber is used. Examiner Poon made a similar point during the

examination of the ’596 patent. (Ex.1004, 195.) Applicants never challenged that determination.

VI. PRECISE REASONS FOR RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.104(b), Bard respectfully requests cancellation of claims 7-16, 21, and 22 of the ’596 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. 3,166,189 to Disston	“Disston” (Ex.1008)
U.S. Patent No. 3,965,900 to Boedecker	“Boedecker” (Ex.1034)

The statutory grounds for the challenge of each claim are set forth below. All of the statutory citations are pre-AIA.

Petition			
Ground	**35 U.S.C. §**	**Claim**	**References**
1	103(a)	7, 9-16, 21, 22	Solazzo, Serany
2	103(a)	8	Solazzo, Serany, Boedecker
3	103(a)	7, 9, 11-16, 22	Solazzo, Disston
4	103(a)	8	Solazzo, Disston, Boedecker
5	103(a)	10, 21	Solazzo, Disston, Serany

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 (Claims 7, 9-16, 21, 22) - 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 '596 patent under at least 35 U.S.C. § 102(b).

Solazzo is directed to a single layer catheterization/irrigation tray. The tray of Solazzo includes an "optional divider wall 17" creating "two separate compartments." (Ex.1005, 2:61-63; Fig.1; Ex.1002, ¶112.)

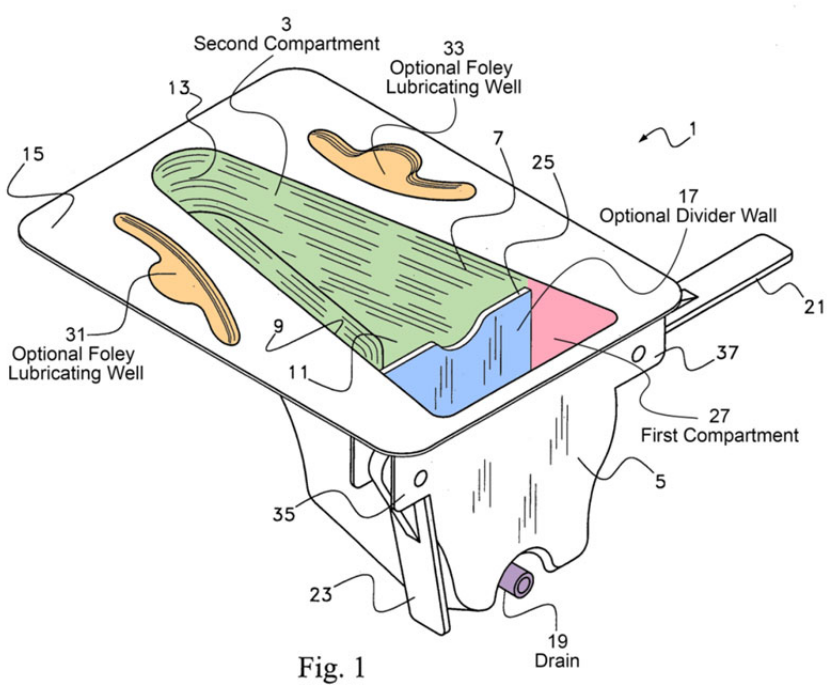


Fig. 1

As shown in annotated Figure 1 above, a first compartment ("compartment 27") and a second compartment ("recessed area 3") are formed in the tray. (Ex.1005, 2:61-63; 4:15-20; Figs. 1-3.) Figure 3, annotated below, provides a top down view of the tray:

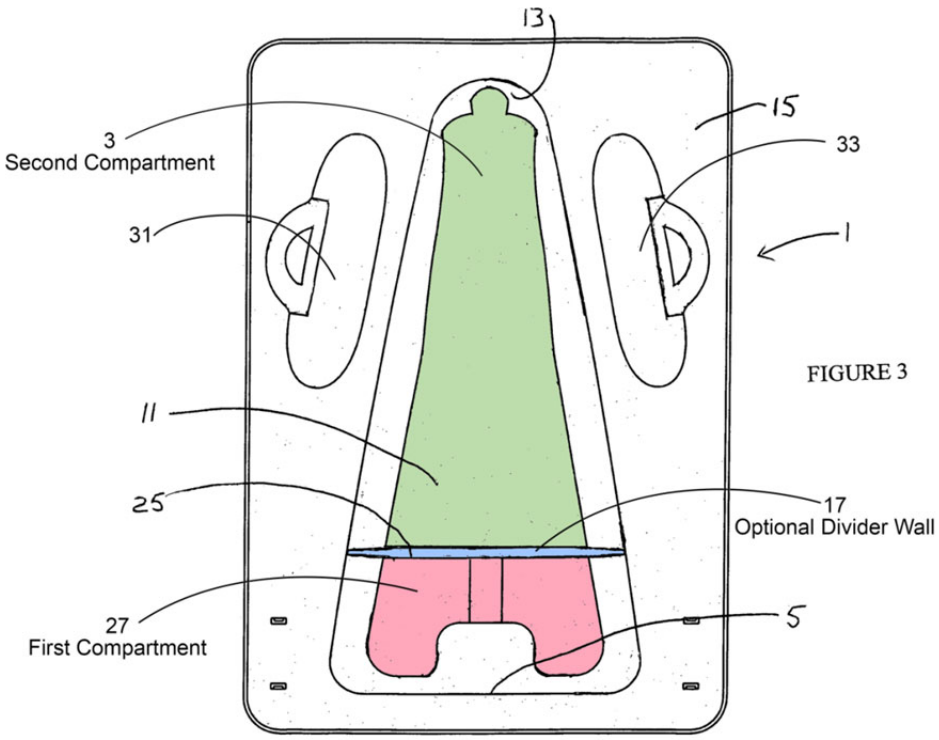


FIGURE 3

Bottom area 11a – a "low area" – and bottom area 11b – a "shallow area" – are shown in Figure 2 (annotated).

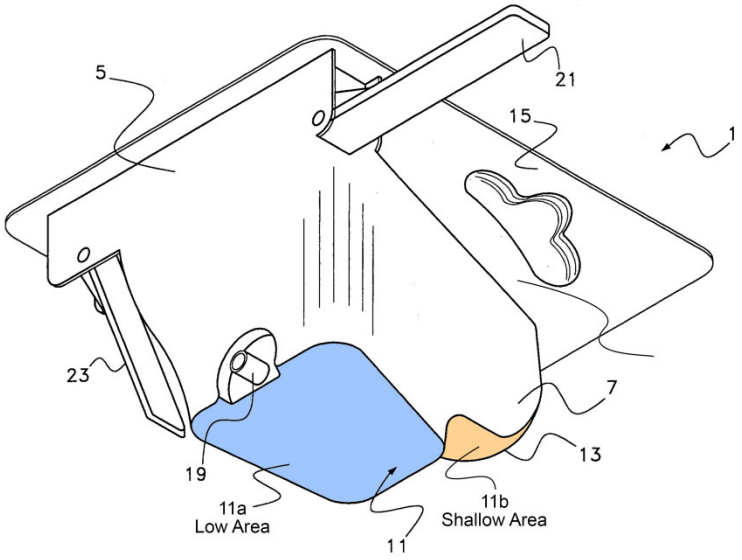


Fig. 2

Solazzo further discloses his invention in the context of a kit as shown in annotated Figure 8 below. The recessed area 3 and compartment 27 store medical devices included in tray kit 100, including a Foley catheter 120, urinary tract lubricant 140, surgical gloves 130, inflation syringe 110, irrigation syringe, and evacuation tubing. (Ex.1005, 3:14-24, 4:1-8; Fig. 8; Ex.1002, ¶¶117-19.)

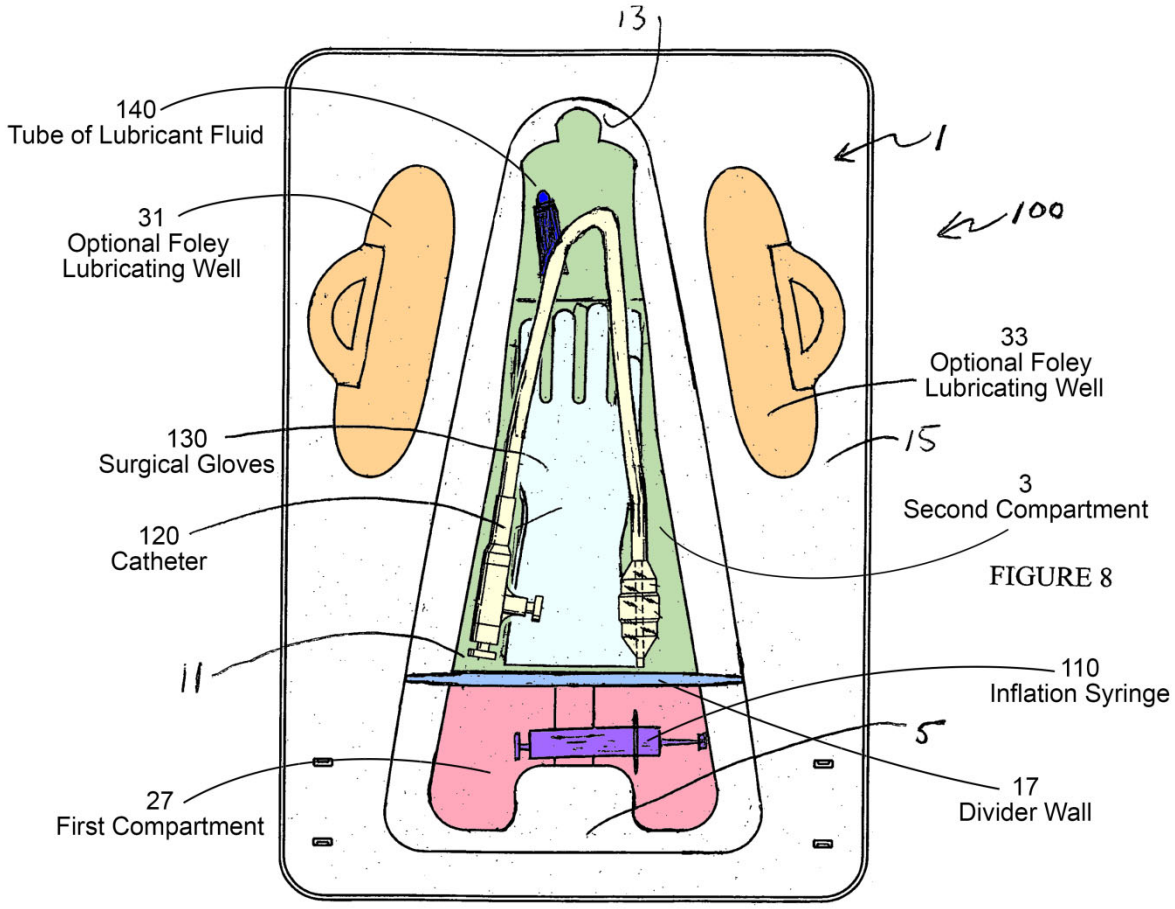


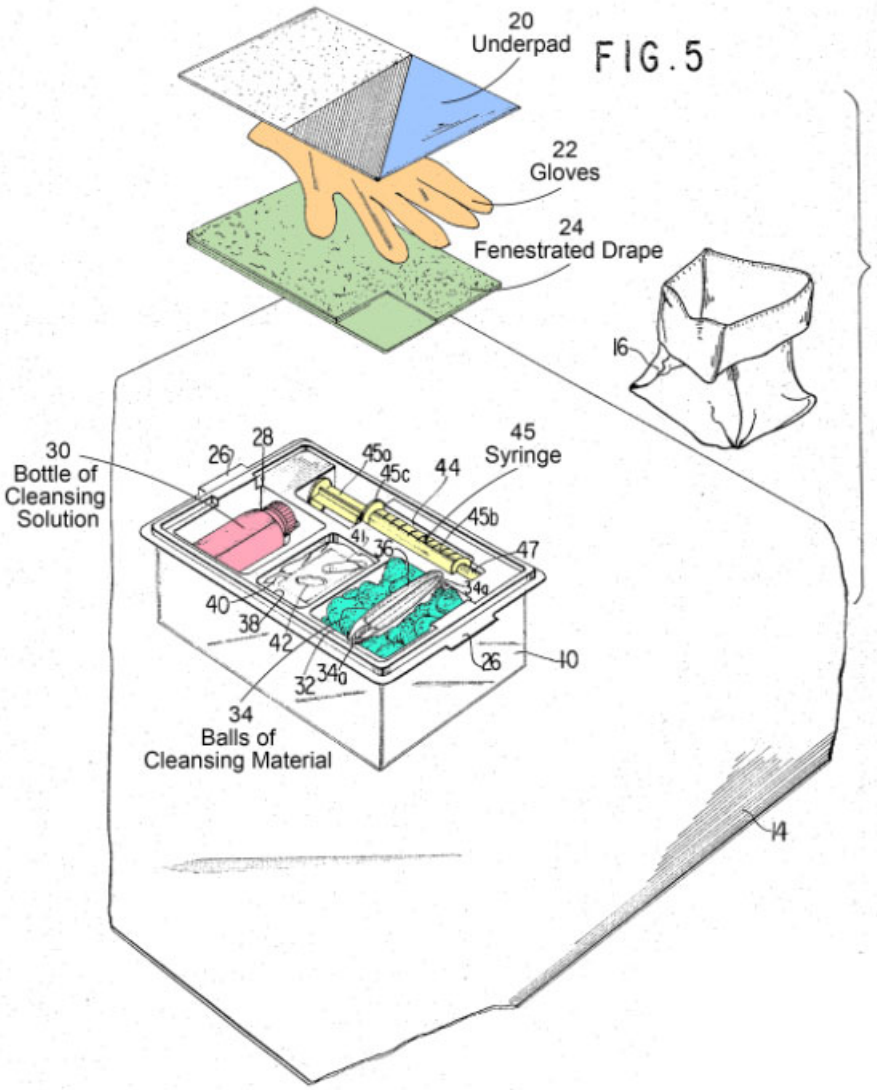
FIGURE 8

2. Summary of Serany

Serany issued on July 4, 1967. Serany is therefore prior art to the '596 patent pursuant to at least 35 U.S.C. § 102(b).

Serany is directed to a double-wrapped, sterile package providing catheterization components, including a Foley catheter 48, "ready for use" and in the order needed. (Ex.1006, 1:8-16, 1:60-63, 3:23-26; 63-4:2; Figs. 1-3, 5-6; Ex.1002, ¶¶131-32.) As shown in annotated Figures 5 and 6 below, the package includes a multi-compartment tray 12 mounted on a box 10 and enclosed with an

inner wrap 14 that unfolds to provide a sterile field work area. (Ex.1006, 1:60-72, 2:17-20; Figs. 1-5.)



The package includes a collapsible drainage bottle 46 that is made of flexible plastic material and can be folded flat for storage. (Ex.1006, 3:26-29.) Annotated Figure 6 below shows the bottle 46 partially expanded and preconnected to a detachable connection fitting 50, drainage tubing 49, and the catheter 48.

(Ex.1006, 3:26-36; Fig. 6.) The catheter 48 and tubing 49 are coiled about the bottle 46. (Ex.1006, 3:32-34, 4:37-40; Fig. 6.)

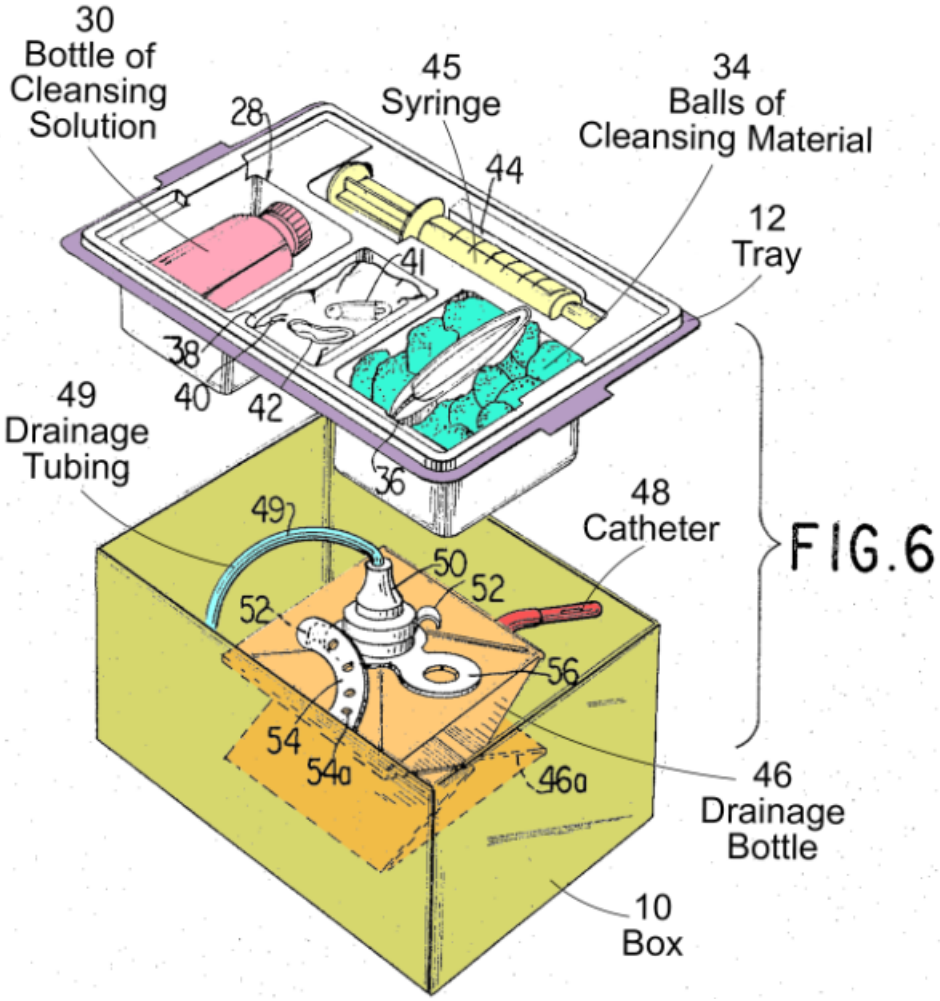


FIG.6

3. The Combination

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

1) Claim 7

a. ***Preamble and 7[a]:*** *"A catheterization kit comprising: a single level container…"*

Solazzo discloses "*[a] catheterization kit comprising: a single level container defining a first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the single level container defining a second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall*."

As shown in Figure 1, Solazzo discloses a *single level container* with a first and second compartment:

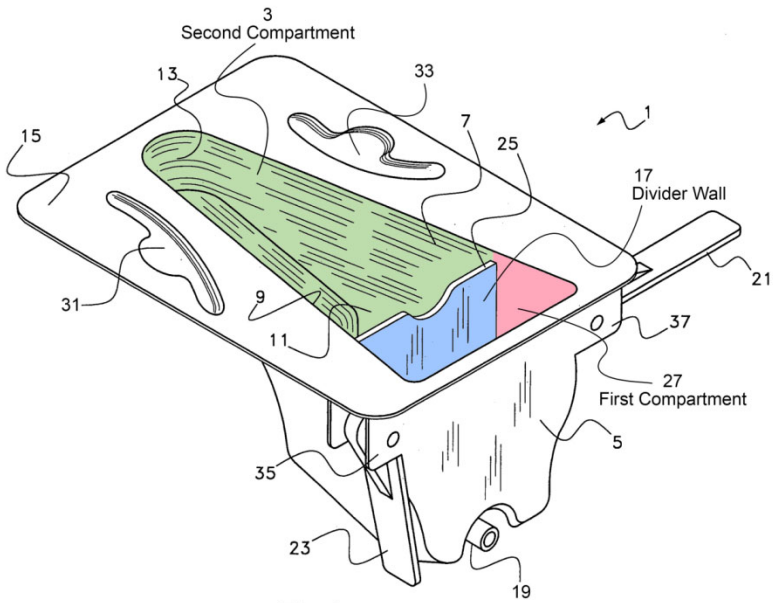


Fig. 1

Specifically, Solazzo discloses a tray with a first compartment (compartment 27) and second compartment (recessed area 3) separated by a barrier (divider wall 17) as shown in Figure 1 above. (Ex.1005, 2:61-63.)

The tray of Solazzo has a *perimeter wall* that extends along the outside of the tray including a "front 5," "back 13," and "side walls 7 and 9." (Ex.1005, 3:56-4:1.) As shown in Figures 2 and 5 below, the perimeter wall extends along the side of the tray (e.g., side wall 7).

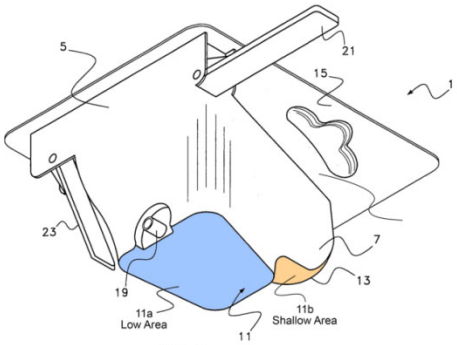


Fig. 2

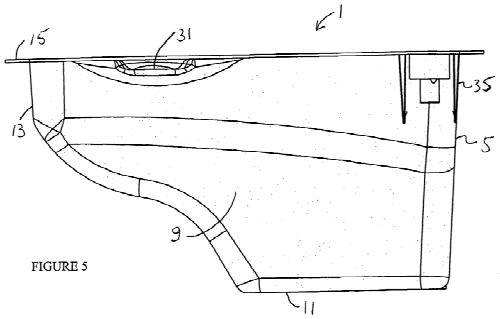


FIGURE 5

Thus, the first compartment (compartment 27) is bounded by multiple portions of the perimeter wall: "front 5" and "opposing side walls 7 and 9." The second compartment (compartment 3) is bounded by multiple portions of the perimeter wall: "back 13" and "opposing side walls 7 and 9." (Ex.1002, ¶¶152-54.)

The first and second compartments are also bounded by base members. (Ex.1002, ¶155.) Specifically, Solazzo discloses a base member (bottom 11) that comprises a base member (11A) and a base member (11B): "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:

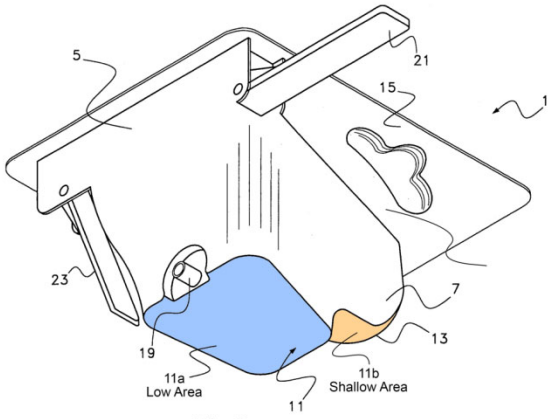


Fig. 2

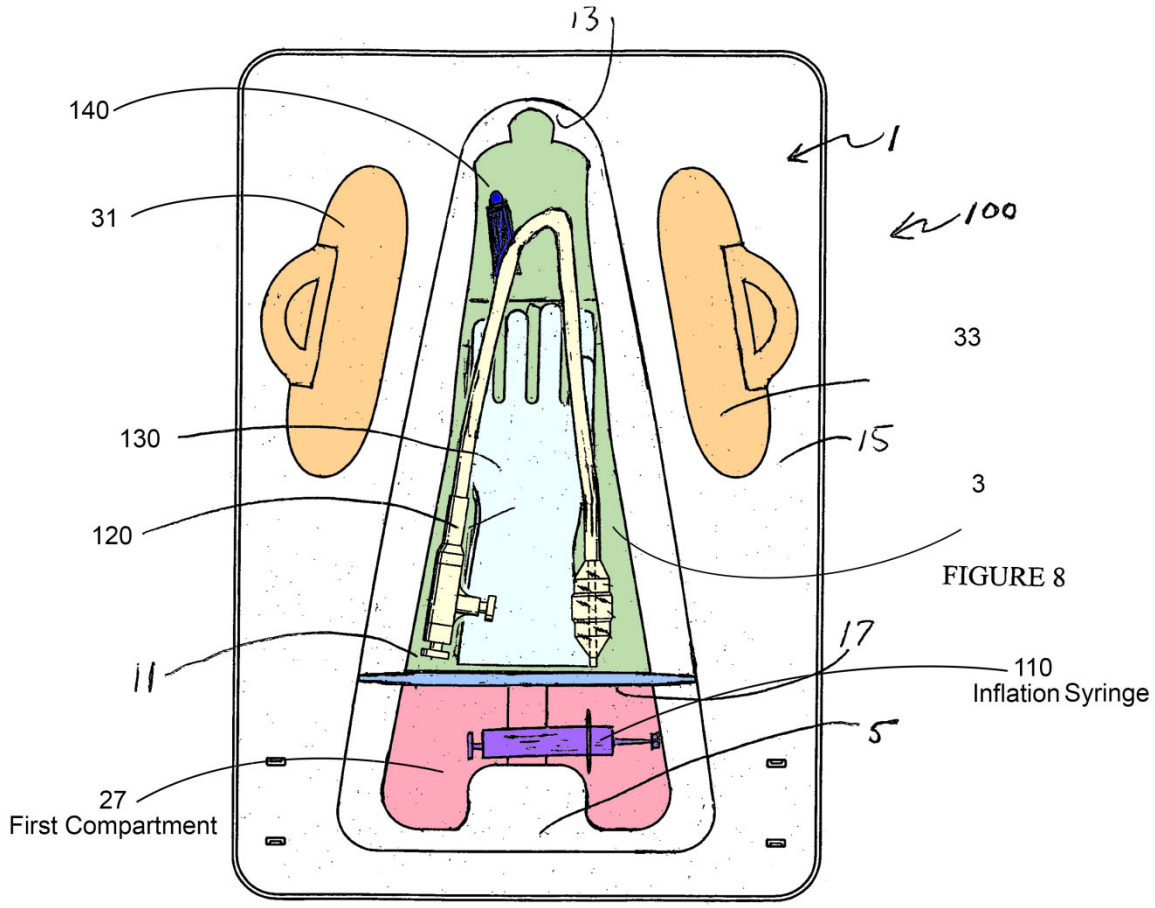
The low area 11A is a *first compartment base member* because it bounds the bottom surface of the first compartment (compartment 27). (Ex.1005, 3:63-66; Figs. 1, 2, 8.) The shallow area 11B is a *second compartment base membe*r because it bounds, "*at least in part*," the bottom surface of a portion of the second compartment (compartment 3). (Ex.1005, 3:63-66; Figs. 1, 2, 8.)

Accordingly, Solazzo discloses this claim element. (Ex.1002, ¶¶ 48-57.)

b. ***7[b]:*** *"a first syringe disposed within the first compartment …"*

Solazzo discloses "*a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid*."

Solazzo discloses: "The kit includes … "an inflation syringe for inflation of a catheter with fluid." (Ex.1005, 3:15-24.) The inflation syringe is stored in first compartment of the tray as shown in annotated Figure 8 below:



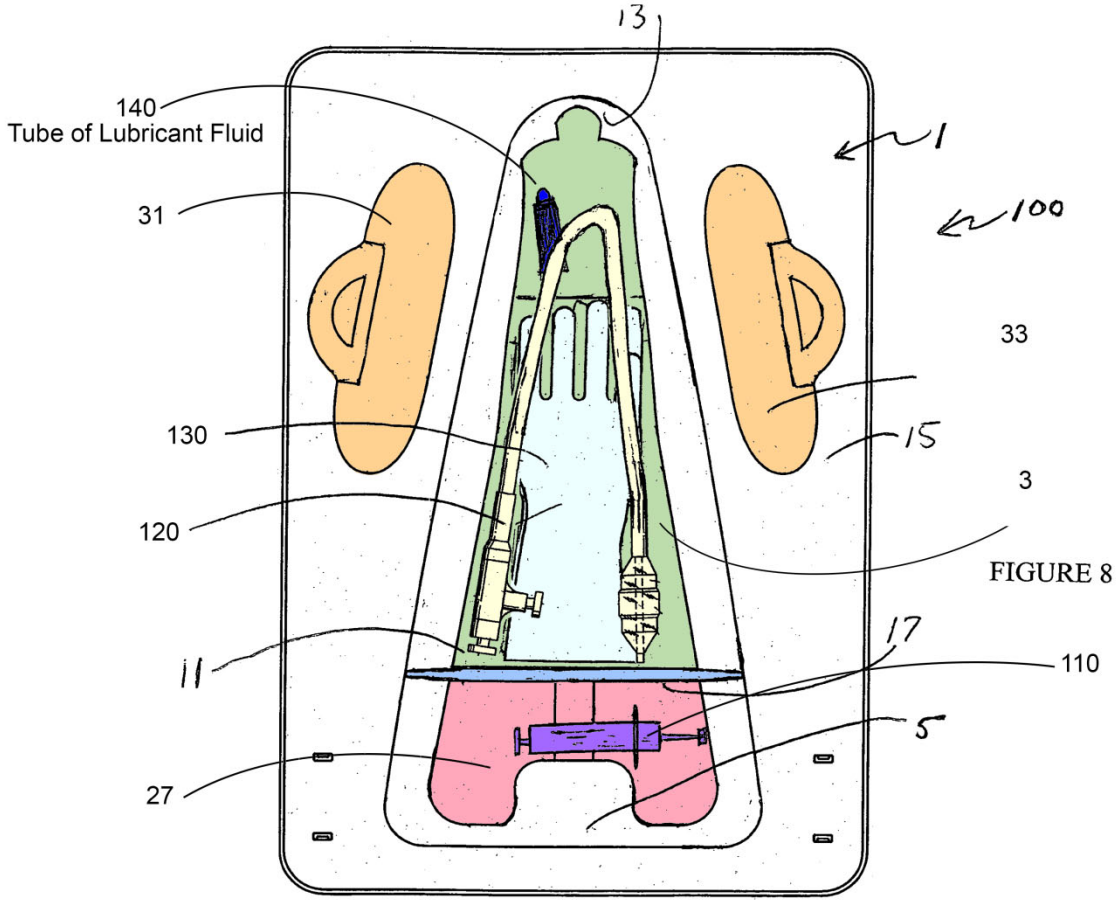
Accordingly, Solazzo discloses this claim element. (Ex.1002, ¶¶158-60.)

c. ***7[c]***: *"a second syringe disposed within the first compartment of the single level container…"*

Claim 7[c] requires "*a second syringe disposed within the first compartment of the single level container, the second syringe containing a lubricating jelly*."

(i) ***"a second syringe disposed within the first compartment of the single level container"***

Solazzo's kit includes "a tube of lubricant fluid 140" disposed within the single level tray as shown in annotated Figure 8 below:

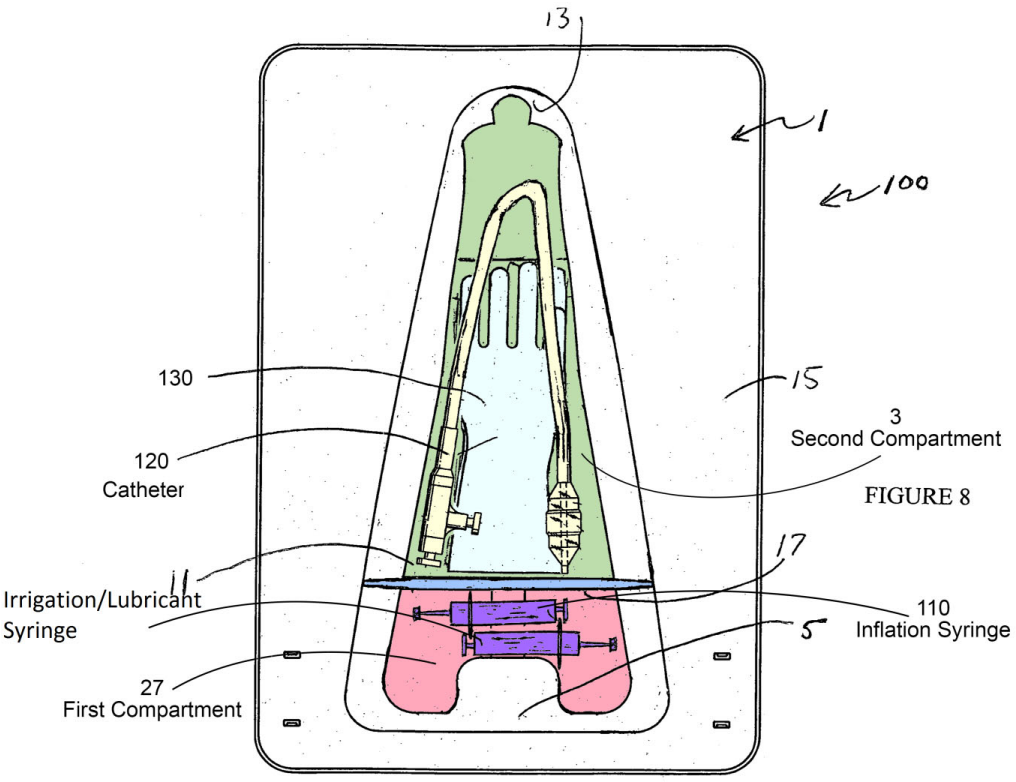


(Ex.1005, 4:41-46.)

Solazzo discloses the lubricant tube (replaceable with a syringe, as discussed below) stored in compartment 3. But compartment 27 (a first compartment) is also a natural place to store the lubricant syringe because it already holds the inflation syringe. Further, compartment 27 also is structured such that it could hold the tube

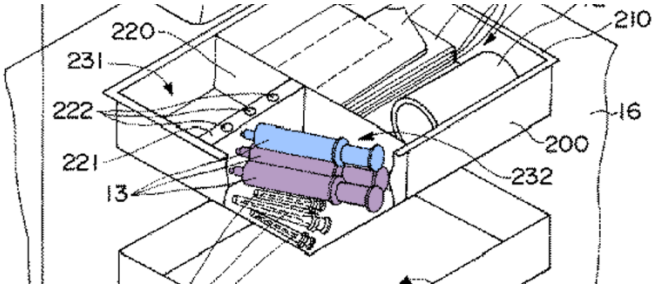
of lubricant 110 (replaceable with a syringe) in compartment 27 as well. (Ex.1002, ¶163.)

Modified Figure 8 below shows the first compartment accommodating two syringes: an inflation syringe 110 and a lubrication syringe:



It was well-known in the art to group like items in the same compartment of a tray. For example, Serany discloses grouping multiple balls of cleansing material in the same compartment. (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 nurse's or physician's task." (Ex.1006, 1:31-35; Ex.1002, ¶165.)

Additionally, Imai (Exs.1011-1012) discloses grouping syringes in the same compartment of a catheter tray, as shown in Figure 1 below:



As shown by Imai, compartment 27 could hold all three syringes (which could be inflation, irrigation, and lubricant syringes) in a stacked configuration. (Ex.1002, ¶¶166-67.)

Accordingly, a POSITA would have been motivated to group a first and second syringe in the first compartment of Solazzo to arrange them in a "logical step-by-step order to facilitate the nurse's or physician's task." A POSITA would have further been motivated to group the syringes together in the first compartment to remove the lubricant 110 from the second compartment (compartment 3), which contains the Foley catheter, because this would ensure the lubricant syringe does not damage the Foley catheter during shipment of the tray. (Ex.1002, ¶¶168-69.)

Thus, Solazzo in view of Serany discloses providing at least two syringes in a first compartment (compartment 27). (Ex.1002, ¶¶162-170.)

(ii) "*the second syringe containing a lubricating jelly*"

It would have 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, ¶¶172-174.) Indeed, the Board has found such a substitution to be obvious in one of the *Medline I* IPRs. (*See* IPR2015-00513, Institution Decision (Paper 9), 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.").)

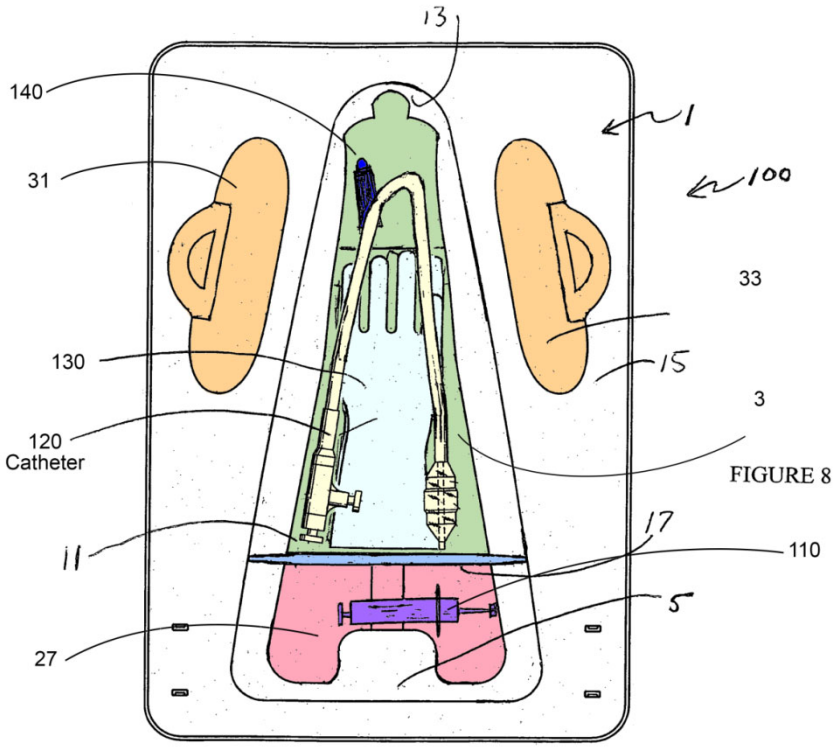
Accordingly, Solazzo in view of Serany discloses these claim elements. (Ex.1002, ¶¶162-75.)

d. ***7[d]:*** *"a coiled medical device disposed within the second compartment of the single level container…"*

(i) *"…a coiled medical device…"*

Claim 7[d][i] requires "*a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle.*"

Solazzo discloses a catheter (i.e., Foley catheter 120) disposed in the second compartment (compartment 3). (Ex.1005, 3:17; Fig. 8.)



Solazzo does not expressly mention a Foley catheter that is *pre-connected* to a drainage bag via coiled tubing. But Applicants admitted during the examination

of the related '400 patent that such an arrangement was well-known. (Ex.1046, 259, ¶33 (Meyst) ("Foley catheters are typically pre-connected to a drainage receptacle via a long coiled tubing.").) Indeed, this arrangement has been known for over 50 years, as evidenced by Serany.

Serany discloses "*a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle.*" Specifically, Serany discloses coiled tubing 49 coupled between a Foley catheter 48 and a fluid receptacle ("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.)

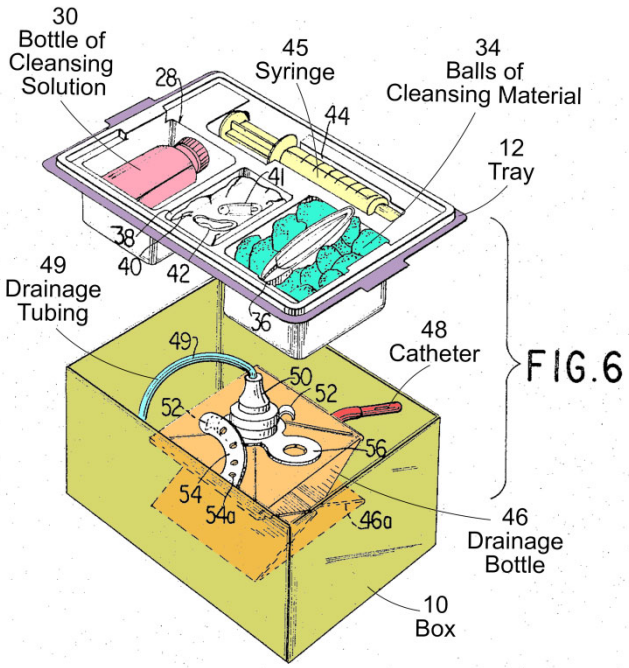


FIG.6

Serany expressly states the tubing 49 is "coiled": "The catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." (Ex.1006, 3:33-35.)

In view of Serany, a POSITA would have been motivated to include a closed-system Foley catheter in the tray of Solazzo for multiple reasons. (Ex.1002, ¶185.)

First, Serany teaches pre-connected systems that are "ready for use." (Ex.1006, 3:26.) Including a pre-connected Foley system that is "ready for use" in the tray of Solazzo 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; Ex.1006, 1:20-23.)

Second, as Applicants admitted in a related prosecution, it was known by 2009 that Foley catheters (such as shown by Solazzo) caused CAUTI. (Ex.1046, 239, ¶29 (Weintraub).) It was further known in the art that closed-system Foley catheters (i.e., Foley catheters that are pre-connected to a drainage bag via tubing) reduce the risk of infection. The Nursing Standard article, which was published in March 2009, notes that providing a "closed system" catheter in a catheterization tray kit, such as in Serany, was a standard practice: "Catheters should be connected to a sterile catheter bag or valve, creating a closed system." (Ex.1010, 52; Ex.1002, ¶183.) Nursing Standard also states "[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 indeed describes that "an object of this invention is to provide a catheterization package which reduces the rate of infection." (Ex.1006, 1:31-32; 3:23-36). Thus, reducing the risk of infection would have motivated a POSITA to utilize Serany's closed-system Foley catheter in Solazzo's tray. (Ex.1002, ¶185.)

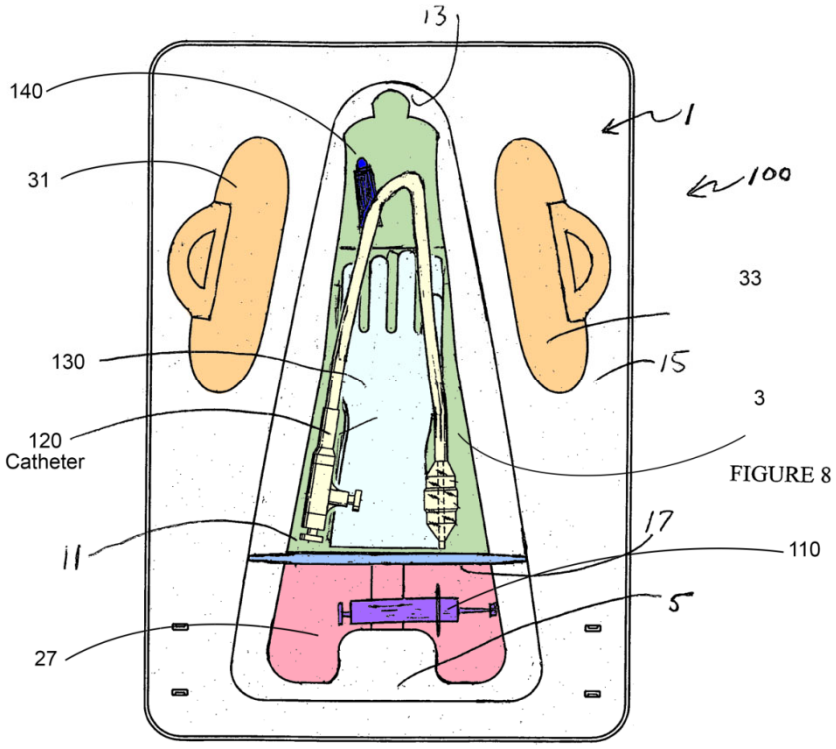
Furthermore, placing the closed-system Foley catheter in Solazzo's tray does not eliminate the catheterization and irrigation features of the tray. (Ex.1002, ¶186.) As explained by Dr. Yun, the tray can be best utilized for both purposes when a closed-system Foley catheter is provided in the tray of 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.)

Accordingly, Solazzo in view of Serany discloses claim 7[d][i]. (Ex.1002, ¶¶176-186.)

(ii) "*…the fluid receptacle is between the second compartment base member and the Foley catheter.*"

Claim 7[d][ii] requires *"the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter*."

Solazzo discloses a catheter "*disposed within the second compartment of the single level tray*." Specifically, Foley catheter 120 is disposed in a second compartment (almost up to its top edge) of the single-level tray of Solazzo:



Serany discloses "*the fluid receptacle is between the second compartment base member and the Foley catheter*" as shown in Figure 6:

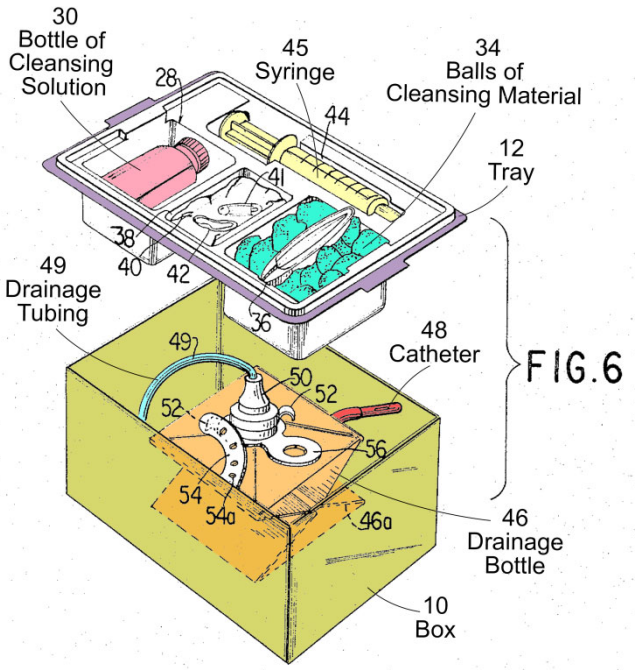


FIG.6

Serany notes that the Foley catheter and tubing are coiled around the fluid receptacle (bottle 46): "The catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." (Ex.1006, 3:33-35.) When stored in its collapsed position, the *fluid receptacle* is between the bottom of box 10 (a base member) and the Foley catheter and attached tubing. (Ex.1006, 3:26-32.) This arrangement is well-known, and Applicants never challenged Examiner Poon's finding that this arrangement was admitted art, as discussed above in Section III.D. (Ex.1046, 73-76, 106-108.)

Specifically, the drainage bag of Serany is designed to fit in a catheter tray in a collapsed form on the bottom of a tray with the Foley catheter and tubing

wrapped around the drainage receptacle. The second compartment of Solazzo would hold the closed-system Foley catheter of Serany with this same configuration, i.e., with the second compartment base member of Solazzo (**"**shallow area 11B**"**) beneath the fluid bag and the attached tubing and Foley catheter wrapped around and/or on top of the bag. (Ex.1002, ¶194.)

Serany provides further motivation to arrange "components in their preferred order of use" and "proper order of use." (Ex.1006, 1:9-12; 1:23-25.) It would have been obvious to a POSITA to arrange the items of a closed-system Foley catheter in a top-to-bottom arrangement such that the drainage receptacle is on the bottom of the tray and the Foley catheter is provided on top of the receptacle because the Foley catheter is used before the drainage receptacle. (Ex.1002, ¶195.) Specifically, a healthcare provider needs access to the Foley catheter in order to lubricate and insert it before the receptacle is accessed. Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Solazzo such that "*the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter*." (Ex.1002, ¶195.)

Accordingly, Solazzo in view of Serany discloses claim 7[d][ii]. (Ex.1002, ¶¶189-96.) Thus, Solazzo in view of Serany renders claim 7 obvious.

2) Claim 9

Solazzo discloses "*wherein the first compartment is configured to receive the lubricating jelly from the second syringe to lubricate a tip of the Foley catheter when the tip is placed into the first compartment.*"

(i) "*wherein the first compartment is configured to receive the lubricating jelly from the second syringe*"

Solazzo discloses "*optional* Foley catheter lubricating wells 31 and 33" to lubricate the Foley catheter. (Ex.1005, 4:21-25 (emphasis added).) A POSITA would further have recognized that other compartments of the tray of Solazzo, including compartment 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, ¶¶ 21-22.)

The '596 patent describes the "first compartment" as being "a lubricant applicator for the catheter" when the first compartment is *stair-stepped*. (Ex.1001, 7:1-7.) Specifically, lubricating jelly may be "spread" along the "second step portion 117," which forms a "channel" as it is lower in the tray than the "first step portion 116. (Ex.1001, 7:8-20.)

Solazzo discloses the same essential structure as the '596 patent. The bottom 11 of the tray of Solazzo 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.)

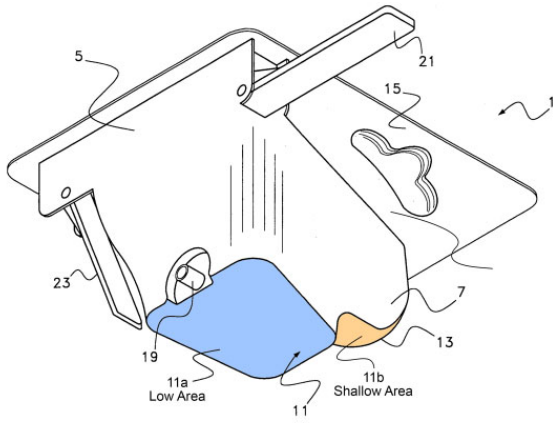


Fig. 2

Thus, the first compartment of Solazzo *is configured to receive the lubricating jelly*. Indeed, during prosecution of the '596 patent, the Examiner remarked that although the applied art was silent to a compartment receiving lubricant jelly to lubricate the catheter, the prior art compartment includes the structure as recited and therefore would be capable of receiving lubricant as recited:

> Applicant further argues that Busch is silent with the compartment receiving lubricant jelly to lubricate the catheter. However, since Busch discloses the compartment having the structure as recited, then it would be capable of receiving lubricant jelly from the syringe to lubricate the catheter.

(Ex.1004, 195.)

The "terraced arrangement" of the bottom member of Solazzo would necessarily function as a lubrication compartment to lubricate the catheter for the same reason a "stair-stepped" base member functions as a lubricating jelly application chamber. (Ex.1002, ¶201.) Specifically, the "low area 11A" which includes compartment 27 would function as a "channel" where lubricant may be spread to lubricate the catheter. Notably the tip of the Foley catheter is located nearby the low area and oriented towards the low area (as shown in Figure 8), making it easy for a practitioner to dip the tip of the catheter in lubricant that is spread in the low area. Moreover, the divider wall provides a confined space within compartment 27 to lubricate the catheter without messing up the other components of the tray. (Ex.1002, ¶201.)

Further, Solazzo expressly teaches Foley catheter lubricating wells that are "optional." (Ex.1005, 4:21-25 (emphasis added).) Modified Figure 1 shows a tray without these optional compartments:

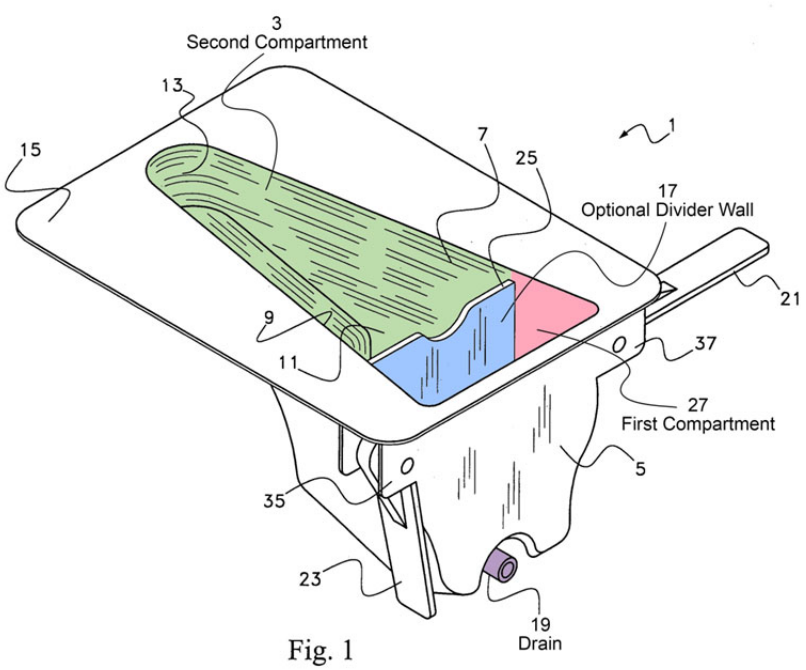


Fig. 1

The absence of the lubricating wells in this Solazzo embodiment would have provided further motivation to lubricate within compartment 27. (Ex.1006, 4:2-8; Ex.1002, ¶¶204-05.)

Accordingly, Solazzo discloses claim 9[i]. (Ex.1002, ¶¶189-207.)

(ii) "*to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray*"

Solazzo further discloses "*…to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray*." Specifically, Solazzo discloses a Foley catheter situated in the second compartment (compartment 3) that is passed from the second compartment to the first compartment (compartment 27) when the catheter is lubricated. Figure 8 shows

the Foley catheter situated in the second compartment with the tip of the catheter – the portion that is lubricated – next to the first compartment:

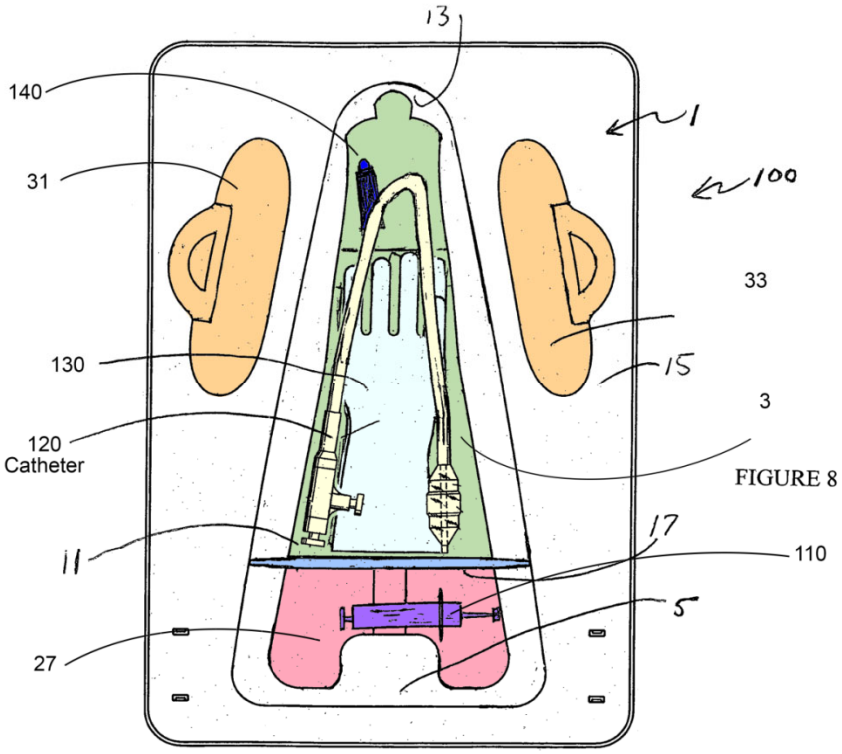


FIGURE 8

The Foley catheter may be passed from the second compartment into the first compartment when lubricating it because divider wall 17 is designed to be provided at a lower height than the flange 15 in case of overflow. (Ex.1005, 4:15-20; Ex.1002, ¶209.)

Further, as shown in Figure 1 below, there is a notch in the divider wall 17 that would further aid in allowing the catheter to be passed from the second compartment into the first compartment when lubricating the catheter. The catheter or attached drainage tubing would rest on the notch during lubrication to

keep the catheter in place when lubricating it. (Ex.1002, ¶210.)

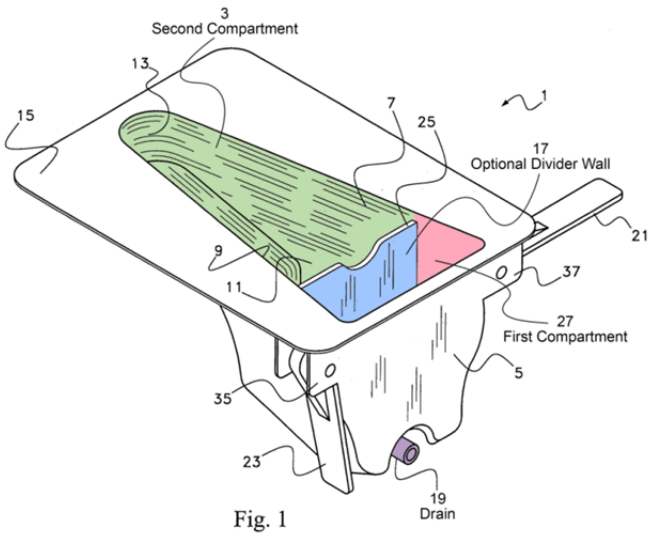


Fig. 1

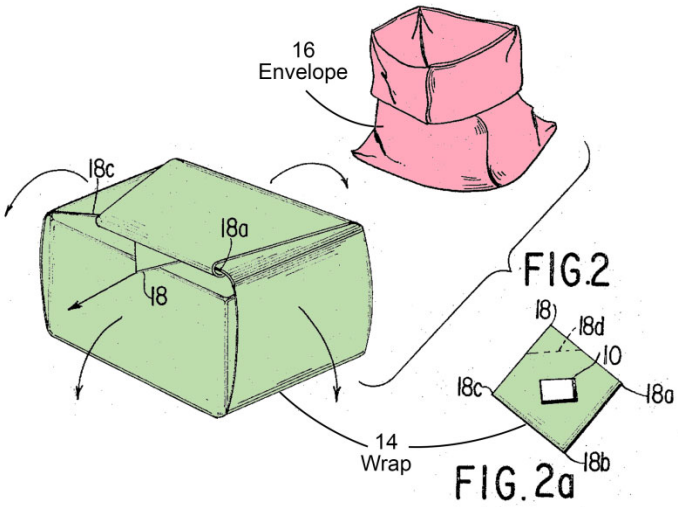
Accordingly, Solazzo discloses claim 9[ii]. Thus, Solazzo in view of Serany also renders claim 9 obvious. (Ex.1002, ¶¶208-12.)

3) Claim 10

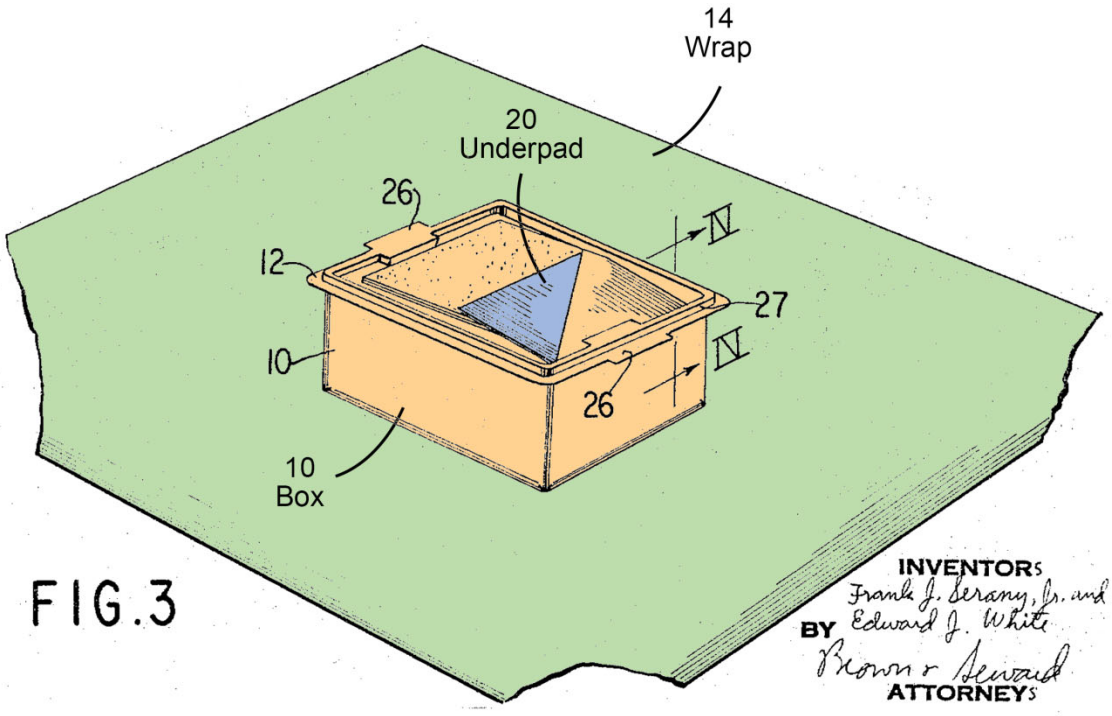
Claim 10 requires "*a wrap folded about the single level container so as to enclose the single level container within the wrap, the wrap configured to be unfolded to A) reveal the first compartment and the second compartment and B) provide a sterile field to accommodate the single level container during use.*"

Solazzo discloses a single level tray with a top opening, but does not describe how the tray is packaged for shipping.

Serany discloses a Foley catheter tray with "*a wrap disposed about the tray*." Specifically, Serany discloses a tray that is "enclosed within a wrap 14," as shown in green in Figure 2 (below). (Ex.1006, 1:60-63.)



The wrap 14 ensures that "components are maintained sterile until the package is opened." (Ex.1006, 1:13-16.) Serany's wrap 14 is a sterile wrap such that a "sterile field may be maintained as the components are removed from the package and used." (Ex.1006, 1:13-16; 2:1-20.)



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, ¶¶218-19.)

Furthermore, a POSITA would have been motivated to enclose the tray of Solazzo in a wrap in view of Serany. (Ex.1002, ¶220.) Solazzo teaches sterile components such as "a Foley catheter" and "surgical gloves." (Ex.1005, 3:15-24.) Serany teaches preserve the sterility of the components both *before* the package is opened and *after* the package is opened with a wrap. Specifically, the wrap 14 (along with the envelope 16) ensures that the "components are maintained sterile until the package is opened" and the wrap 14 also serves as a "sterile field" after opening the tray. (Ex.1006, 1:13-16; Ex.1002, ¶210-11) Thus, wrapping the tray of Solazzo in Serany's wrap would preserve the sterility of Solazzo's components provided inside the tray.

Solazzo discloses a tray with a top opening:

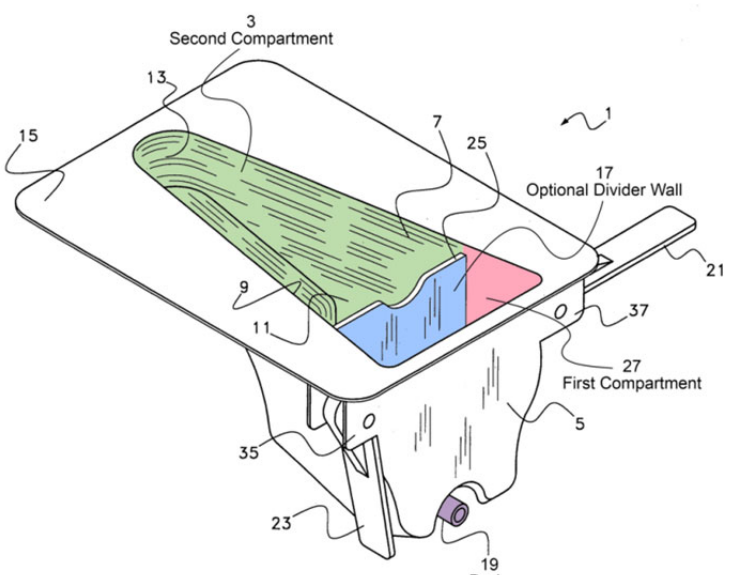


Fig. 1

"*When the sterile wrap is unwrapped from about the top opening*" of the tray of Solazzo, the components shown in Figure 8 are revealed, because Solazzo has an open top and does not teach any obstruction between the opening and the components shown in Figure 8 that would obstruct the view. (Ex.1002, ¶224.)

Serany also teaches 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.) When the wrap 14 of Serany is applied to the tray of Solazzo, it would likewise "*provide a sterile field to accommodate the single level container during use."* (Ex.1002, ¶225.)

Accordingly, Solazzo in view of Serany discloses these elements and therefore renders claim 10 obvious. (Ex.1002, ¶¶213-26.)

4) Claim 11

Claim 11 requires "*wherein the first syringe and the second syringe are positioned at different elevations within the first compartment, the different elevations being associated with an order of use of the first syringe and the second syringe during a catheterization procedure.*"

For the reasons at claims 7[b] and [c], it would have been obvious for the first compartment to hold a first syringe (inflation syringe 110) and a second syringe (lubricant 140).

Solazzo presents the lubrication tube 110 and inflation syringe 140 at different heights because of the "terraced arrangement" of bottom 11. (Ex.1005, 3:63-66.) Figure 2 shows the *terraced* bottom of the tray:

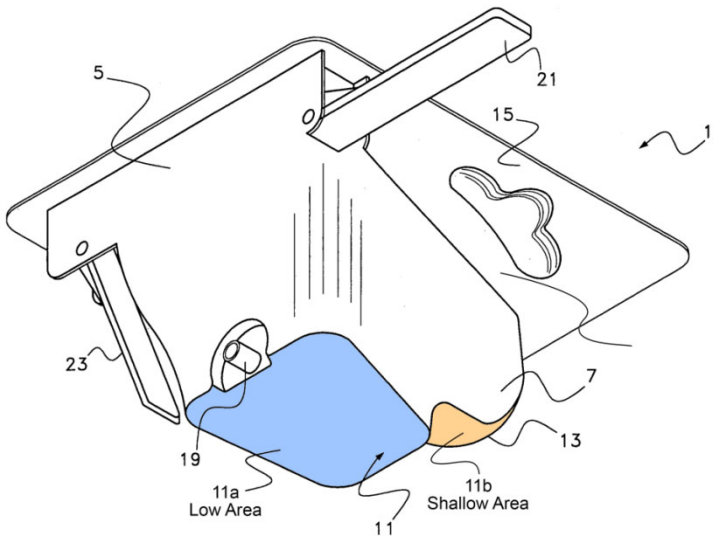


Fig. 2

Specifically, a first syringe (lubricant fluid 140, modified to be a syringe) 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, which is inclined for drainage through drain 19. (Ex.1002, ¶¶230-31.)

A POSITA would be motivated to arrange the syringes by height when placing lubricant 110 (replaceable with a syringe) in compartment 27 along with the existing inflation syringe. Such an arrangement merely requires placing the syringes on the inclined, bottom surface of compartment 27. (Ex.1002, ¶¶233-35.) The bottom surface of compartment 27 is inclined for drainage of fluid through drain 19. (Ex.1002, ¶¶ 233-34.) For example, modified Figure 8 shows such an arrangement:

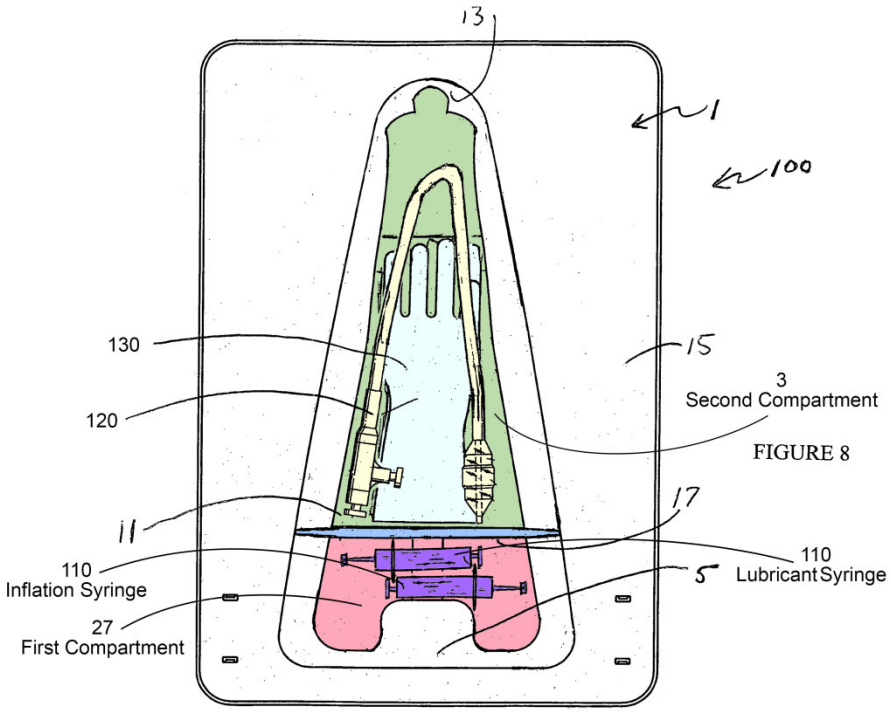
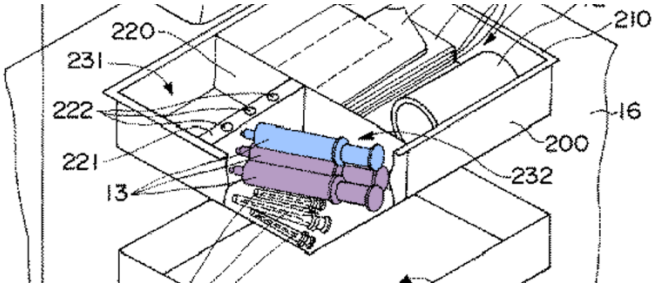


FIGURE 8

Alternatively, the syringes could be stacked on top of each other, which would also present them at different heights within compartment 27 (for example, as shown in Figure 1 of Imai). (Exs.1011-1012.)



In either configuration, the syringes are supported "*at different heights based upon order of use in a Foley catheterization procedure*." If a lubricant syringe is placed at higher elevation, the syringes are arranged based upon an order of use because a lubricant syringe may be used first in a Foley catheterization procedure. (Ex.1002, ¶¶235-37; Ex.1003, ¶28.) If an inflation syringe is placed at higher elevation, the syringes are arranged based upon an order of use because certain Foley catheterization procedures involve the inflation of test balloon, as discussed at claim 12. (Ex.1002, ¶239.)

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; Ex.1002, ¶238.)

Accordingly, Solazzo in view of Serany discloses these elements and therefore renders claim 11 obvious.

5) Claim 12

Claim 12 requires "*wherein the first syringe is positioned within the first compartment at a higher elevation than the second syringe.*"

An inflation syringe is used first in Foley catheterization procedures when a test balloon is inflated. (Ex.1003, ¶ 29) The inflation of test balloons was common when performing a Foley catheterization at the time of the invention. (Ex.1003, ¶ 25.)

A POSITA would have been motivated to arrange the syringes in such an order—with the inflation syringe presented at higher elevation—when a catheterization procedure includes the step of inflating a test balloon. (Ex.1002, ¶¶242-43.) Serany provides motivation by teaching "components in their preferred order of use," and some practitioners preferred using an inflation syringe first to inflate a test balloon at the time of the invention. (Ex.1006, 1:9-12; 1:23-25; Ex.1003, ¶ 29.) This arrangement would also facilitate the lubrication of the catheter in the first compartment after the inflation syringe has been removed from the compartment. (Ex.1002, ¶243.)

Accordingly, Solazzo in view of Serany discloses these elements and therefore renders claim 12 obvious.

6) Claim 13

Solazzo discloses "*wherein a length of the first compartment extends along a side length of the single level container.*"

Solazzo discloses a single level container with a first compartment (compartment 27) that is bounded on the sides by "opposing side walls 7 and 9" as shown in Figures 2 and 5. (Ex.1005, 3:56-61.)

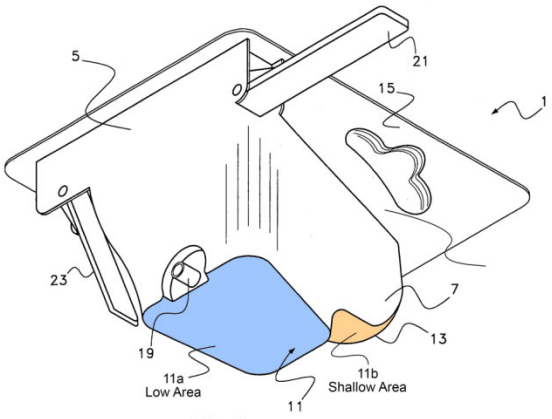
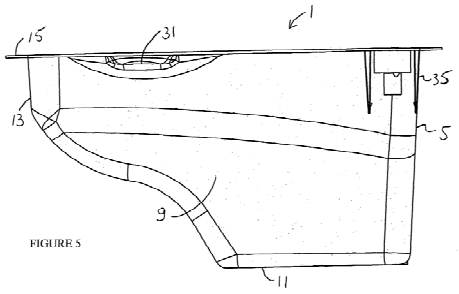


Fig. 2



As shown in Figures 2 and 5 above, a length of the first compartment extends along a side length of the container (i.e., along side wall 7 or 9).

Accordingly, Solazzo discloses this element. (Ex.1002, ¶¶245-49.) Thus, Solazzo in view of Serany renders claim 13 obvious.

7) Claim 14

a. ***Preamble and 14[a]:*** *"A catheterization kit comprising: a single level container…"*

For the reasons at claim 7[a], Solazzo discloses "*a single level tray defining a first compartment and a second compartment, the first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall, the single level tray including a barrier separating the first compartment from the second compartment*."

b. ***14[b]:*** *"a first syringe disposed within the first compartment …"*

For the reasons at claim 7[b], Solazzo discloses "*a first syringe disposed in the first compartment of the single level tray at a first elevation, the first syringe containing an inflation fluid*."

c. ***14[c]:*** *" a second syringe disposed within the first compartment…"*

Claim 14[c] requires "*a second syringe disposed within the first compartment of the single level tray at a second elevation, the second elevation below the first elevation relative to a top of the single level tray, the second syringe containing a lubricating jelly, the first compartment configured to receive the lubricating jelly from the syringe*."

For the reasons at claim 7[c], Solazzo discloses "*a second syringe disposed within the first compartment of the single level tray*" and "*the second syringe containing a lubricating jelly*."

For the reasons at claims 11 and 12, Solazzo in view of Serany discloses "*a second syringe disposed within the first compartment of the single level tray at a second elevation, the second elevation below the first elevation relative to a top of the single level tray*."

For the reasons at claim 9, Solazzo discloses "*the first compartment configured to receive the lubricating jelly from the syringe*."

Accordingly, Solazzo in view of Serany discloses claim 14[c]. (Ex.1002, ¶¶252-56.)

d. ***14[d]:*** *"a coiled medical device disposed within the second compartment of the single level container…"*

Claim 14[d] requires "*a coiled medical device disposed within the second compartment of the single level tray, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle, a tip of the Foley catheter configured to be placed within first compartment to lubricate a tip of the Foley catheter when the lubricating jelly has been dispensed from the second syringe into the first compartment.*"

For the reasons at claim 7[d], Solazzo in view of Serany discloses "*a coiled medical device disposed within the second compartment of the single level tray, the*

coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle."

For the reasons at claim 9, Solazzo discloses "*a tip of the Foley catheter configured to be placed within first compartment to lubricate a tip of the Foley catheter when the lubricating jelly has been dispensed from the second syringe into the first compartment.*"

Accordingly, Solazzo in view of Serany discloses claim 14[d]. (Ex.1002, ¶¶257-60.) Thus, Solazzo in view of Serany renders claim 14 obvious.

8) Claim 15

Claim 15 requires "*wherein the single level tray defines a mnemonic device indicating that the first syringe should be removed from the first compartment before the second syringe during a catheterization procedure.*"

For the reasons set forth in claims 7[c] and 9, it would have been obvious to substitute the *tube* of lubricant 140 with a *syringe* of lubricant and the inflation and lubricant syringes could be ordered by height in the first compartment 27 due to that compartment's inclined nature. (Ex.1002, ¶¶262-66.)

The structure of the Solazzo tray necessarily functions as a mnemonic device limitation because it has an inclined (and terraced) base member. (Ex.1002, ¶¶263-65.) 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.) 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 the tray of Solazzo, which would include placing a *first* syringe at a higher height than a *second* syringe, as a design affordance. (Ex.1002, ¶267.)

Accordingly, Solazzo in view of Serany discloses claim 15. (Ex.1002, ¶¶261-69.)

9) Claim 16

Claim 16 requires "*wherein the first compartment defines one or more contours to accommodate a flange of at least one of the first syringe or the second syringe.*"

As shown in Figure 8 (annotated), Solazzo discloses a contour in the first compartment of the tray. That contour accommodates the flanges of syringe 110:

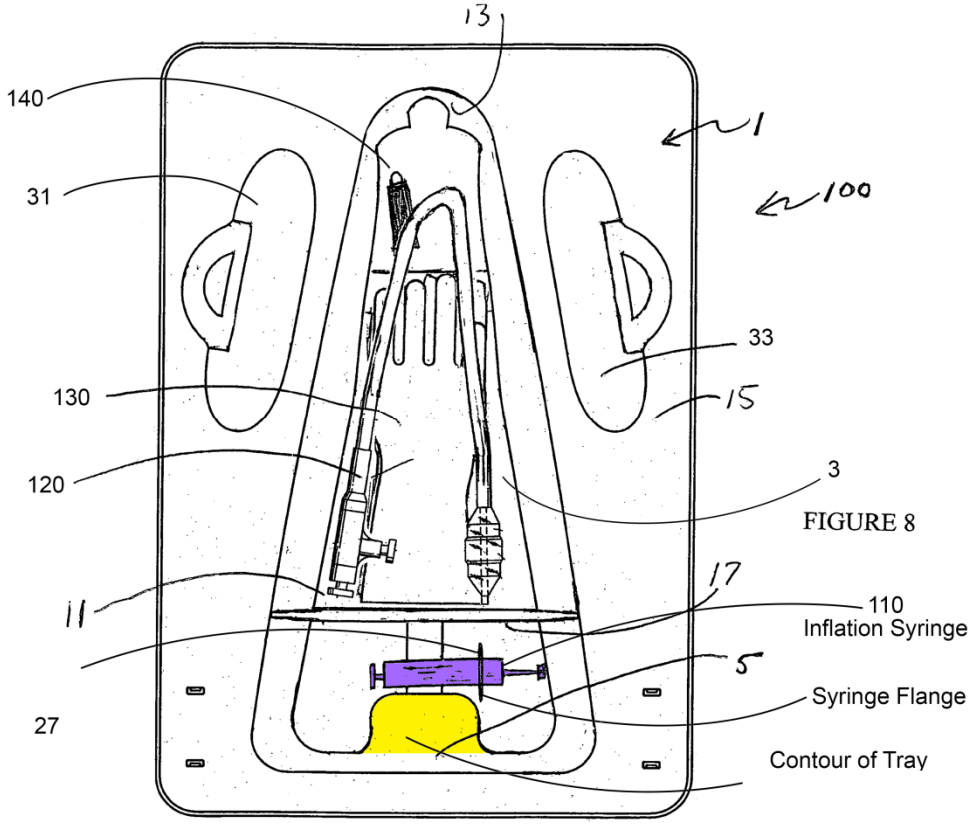


FIGURE 8

Additionally, Serany discloses "the tray 12 has compartments or depressions therein to suitably accommodate components for catheterization," including a compartment that is contoured to "accommodate the flange [] of the syringe" such that a syringe plunger "may be easily grasped for removal of the syringe from the tray." (Ex.1006, 2:40-41; 3:16-22.) In view of Serany, a POSITA would have been motivated to contour the compartments of Solazzo to accommodate the components of the tray, including a syringe and its flanges for storage and to allow the syringe to be easily grasped and removed from the tray. (Ex.1002, ¶272.)

Accordingly, Solazzo, alone or combined with Serany, discloses this element. (Ex.1002, ¶¶270-74.) Thus, Solazzo in view of Serany renders claim 16 obvious.

10) Claim 21

a. ***Preamble and 21[a]:*** *"The catheterization kit of claim 7, further comprising: a wrap folded about the single level container…"*

For the reasons at claim 10, Solazzo in view of Serany discloses "*a wrap folded about the single level container so as to enclose the single level container within the wrap, the wrap configured to be unfolded to A) reveal the first compartment and the second compartment and B) provide a sterile field to accommodate the single level container during use*."

b. ***21[b]:*** *"the first syringe being positioned above the second syringe within the first compartment,…"*

Claim 21[b] requires "*the first syringe being positioned above the second syringe within the first compartment, the first compartment configured to receive a tip of the Foley catheter and the lubricating jelly from the second syringe to lubricate the tip after the first syringe and the second syringe have been removed from the first compartment*."

For the reasons at claim 9, Solazzo discloses "*the first compartment configured to receive a tip of the Foley catheter and the lubricating jelly from the second syringe*." When a test balloon is inflated, the inflation syringe is removed

from the first compartment before the lubricated syringe is used to lubricate the catheter. Lubricating the catheter also requires removing the lubricant syringe from the first compartment. Additionally, Serany discloses a tray that provides "components in their preferred order of use." (Ex.1006, 1:9-12; 1:23-25.) Thus, Solazzo in view of Serany further discloses "*to lubricate the tip after the first syringe and the second syringe have been removed from the first compartment*." (Ex.1002, ¶¶277-78.)

For the reasons at claims 11 and 12, Solazzo in view of Serany discloses "*the first syringe being positioned above the second syringe within the first compartment*."

Therefore, Solazzo in view of Serany renders claim 21 obvious.

11) Claim 22

For the reasons at claim 7[d][ii], Solazzo in view of Serany discloses "*wherein the coiled medical device is positioned within the second compartment such that the fluid receptacle is beneath the Foley catheter.*"

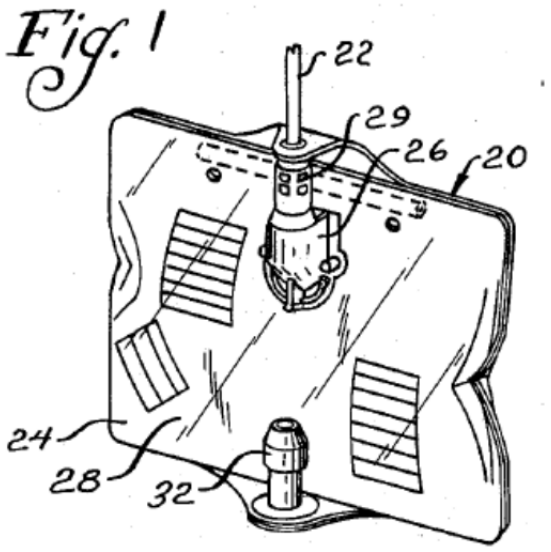
Thus, Solazzo in view of Serany renders claim 22 obvious.

B. Ground 2 (Claim 8) – Obvious Based on Solazzo, Serany, and Boedecker

1. Summary of Boedecker

Boedecker issued on June 29, 1976. Boedecker is therefore prior art to the '596 patent under at least 35 U.S.C. § 102(b).

Boedecker teaches an anti-reflux device for use with a flexible collection receptacle during urinary catheterization. (Ex.1034, 1:5-9, Figs. 1-2.)



Boedecker describes that pressure exerted against the flexible walls of such receptacles may cause urine to back up into the drainage tube, catheter, and/or patient's bladder, which may cause trauma or retrograde bacterial movement to the bladder. (Ex.1034, 1:19-35.)

To prevent urine reflux, Boedecker's collection bag 24 provides an anti-reflux device at its inlet opening. The anti-reflux device includes a flexible valve element 34 covering the inlet opening such that when urine flows into the bag, the valve element 34 flexes open to permit passage of urine into the bag. (Ex.1034, 2:54-3:3, 3:20-23; Figs. 1-2, 5; Ex.1002, ¶125.)

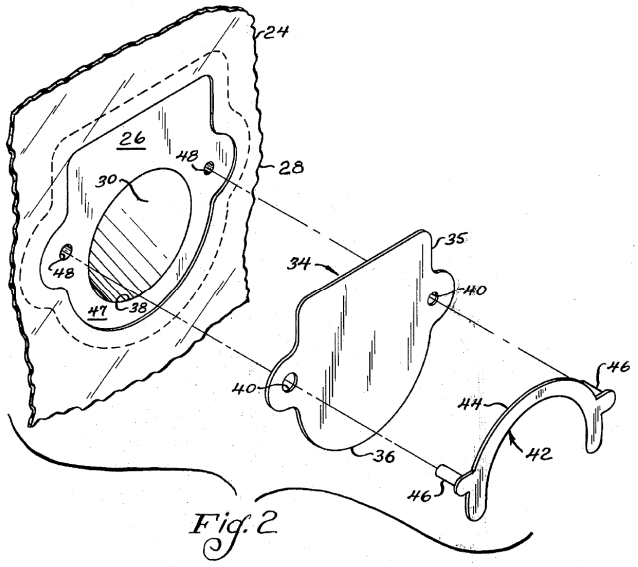


Fig. 2

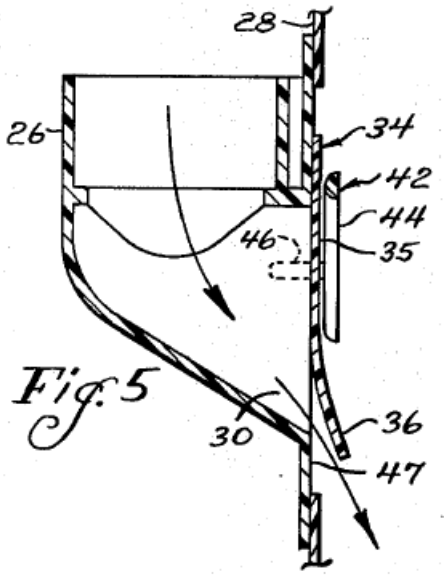


Fig. 5

When pressure is exerted onto the valve element 34 from inside the bag 24 (e.g., by inadvertent squeezing), the flexible valve element 34 seals the inlet opening shut to prevent reflux. (Ex.1034, 3:23-33; Ex.1002, ¶¶286-88.)

2. The Combination

As discussed below, Solazzo in view of Serany and Boedecker discloses all the elements in the claim in this ground and renders the claim as obvious.

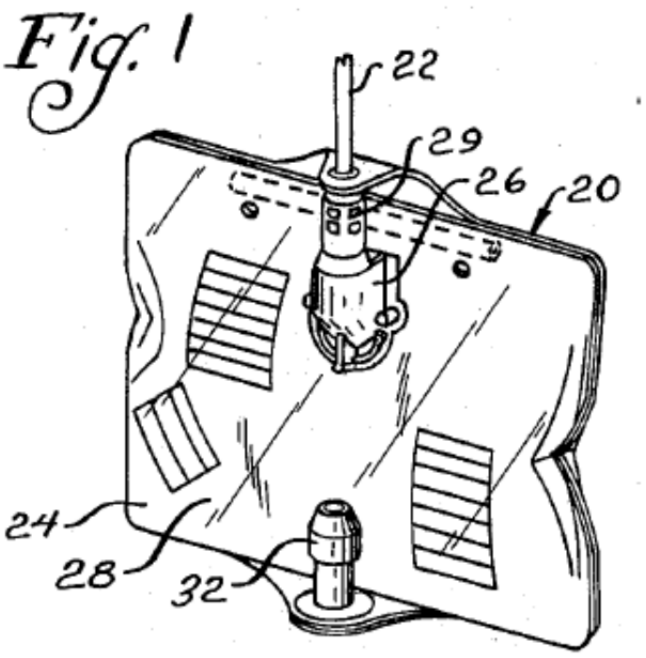
1) Claim 8

Claim 8 requires "*wherein the tube is attached to the fluid receptacle via an anti-reflux device*."

For the reasons at claim 7[d][i], it would have been obvious to include a closed-system Foley catheter (such as the catheter assembly of Serany) in the tray of Solazzo.

As discussed above in Section III.D, Applicants admitted that anti-reflux devices were associated with Foley catheters, and they never challenged Examiner Poon's finding that a fluid receptacle including an anti-reflux device coupled to a coiled tube was known. (Ex.1046, 73-76, 106-108, 262, ¶41 (Meyst).) It was also well-known in the art to include such a device with a flexible fluid receptacle, such as disclosed in Serany. (Ex.1006, 3:26-32, Fig. 6.) Boedecker is an example of a prior art anti-reflux device.

Boedecker issued in the 1970s and describes that pressure exerted against the flexible walls of such receptacles may cause urine to back up into the drainage tube, catheter, and/or patient's bladder. (Ex.1034, 1:19-35.) Boedecker teaches "an anti-reflux device for a collection bag" that connects to "drainage tube 22." (Ex.1034, 1:45-47.)



The "drainage tube 22 is connected to and communicates with a connector or a drip chamber 26, which is secured to a wall 28 of the bag 24." (Ex.1034, 2:48-52; Ex.1002, ¶287.) Accordingly, Boedecker teaches "the *fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*." (Ex.1002, ¶¶180-82.)

It would have been obvious to a person of skill in the art to replace the flexible drainage receptacle 46 of Serany with the "liquid collection bag 24" of Boedecker, such that Serany's drainage tubing 49 would be connected to Boedecker's connector 26 of liquid collection bag 24. (Ex.1002, ¶¶289-92.) Serany and Boedecker are analogous art because both references teach a catheter connected to a flexible fluid receptacle via a drainage tube. Specifically, Serany shows this teaching through Figure 6, and Boedecker states: "During catherization, urine drains through the catheter and drainage tube to the receptacle for collection." (Ex.1034, 1:13-17.)

The motivation is expressly stated in Boedecker. Boedecker explains that "flexible receptacles or bags … may cause a reflux of urine from the bag into the drainage tube, and possibly the catheter and patient's bladder" due to the "pressure exerted against the side walls of the flexible bag." (Ex.1034, 1:19-25.) Further, "the refluxing urine dramatically increases the possibility of retrograde bacterial movement from the bag to the patient's bladder, with possible deleterious results to

the patient." (Ex.1034, 1:25-35.) To prevent the reflux of urine from the drainage receptacle of Serany into a patient's bladder through drainage tubing 49, a POSITA would have been motivated to substitute the drainage receptacle of Serany with the urine collection bag (including an anti-reflux device) as taught by Boedecker. (Ex.1002, ¶291.)

Furthermore, doing so would merely involve a simple substitution of one container (a urine collection receptacle as taught by Serany including connector 50) for another known type of container (a urine collection receptacle as taught by Boedecker including connector 26) to produce predictable results (preventing urine reflux). (Ex.1002, ¶291.)

Accordingly, Solazzo in view of Serany and Boedecker discloses claim 8. (Ex.1002, ¶¶283-293.)

C. Ground 3 (Claims 7, 9, 11-16, 22) - Obvious Based on Solazzo and Disston

1. Summary of Disston

Disston issued on January 19, 1965. Disston is therefore prior art to the '596 patent under at least 35 U.S.C. § 102(b).

Disston is directed to a single-level, wrapped catheterization tray package that "provide[s] for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled." (Ex.1008, 1:59-67, 2:60-63; 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.)

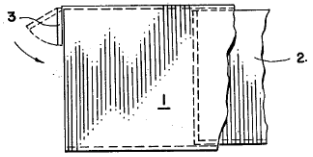


FIG.-3

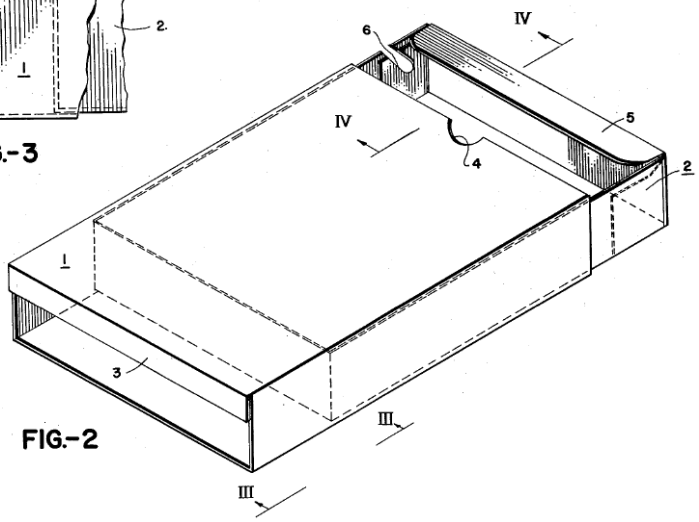


FIG.-2

The package includes "a pre-assembled catheter-drainage tube-drip chamber-drainage bag," with "suitable adapters being interposed, if necessary, between the catheter and tube and/ or between the drip chamber and bag." (Ex.1008, 1:33-34, 2:15-23; Fig. 1; Ex.1002, ¶311.)

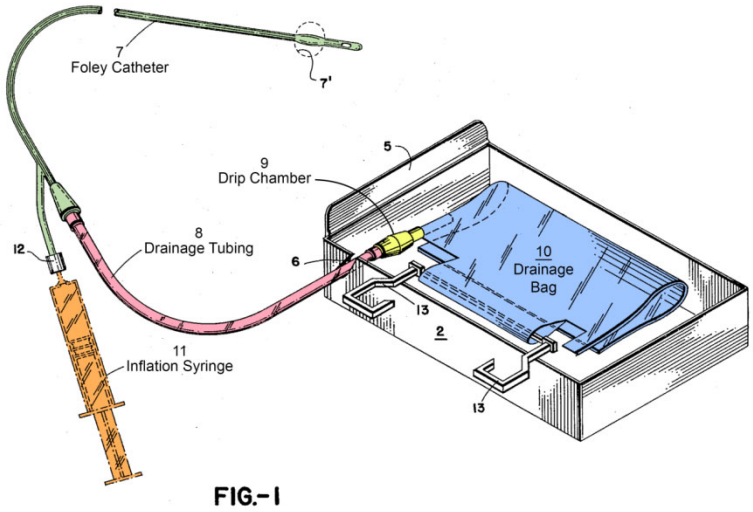


FIG.-1

Disston acknowledges that urine reflux is undesirable and instructs: "hold the drip chamber higher than the bag and prevent spillage or back flow when the catheter is first inserted and before the bag and its support have been installed on the bed rail." (Ex.1008, 1:35-42; Ex.102, ¶387.)

2. The Combination

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

1) Claim 7

a. ***Preamble and 7[a]:*** *"A catheterization kit comprising: a single level container…"*

For the reasons at Ground 1, claim 7[a], Solazzo discloses "*a single level container defining a first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the single level container*

defining a second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall."

b. ***7[b]:*** *"a first syringe disposed within the first compartment …"*

For the reasons at Ground 1, claim 7[b], Solazzo discloses "*a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid*."

c. ***7[c]****: "a second syringe disposed within the first compartment of the single level container…"*

Claim 7[c] requires "*a second syringe disposed within the first compartment of the single level container, the second syringe containing a lubricating jelly*."

(i) ***"a second syringe disposed within the first compartment of the single level container"***

Solazzo's kit includes "a tube of lubricant fluid 140" disposed within the single level tray as shown in annotated Figure 8 below:

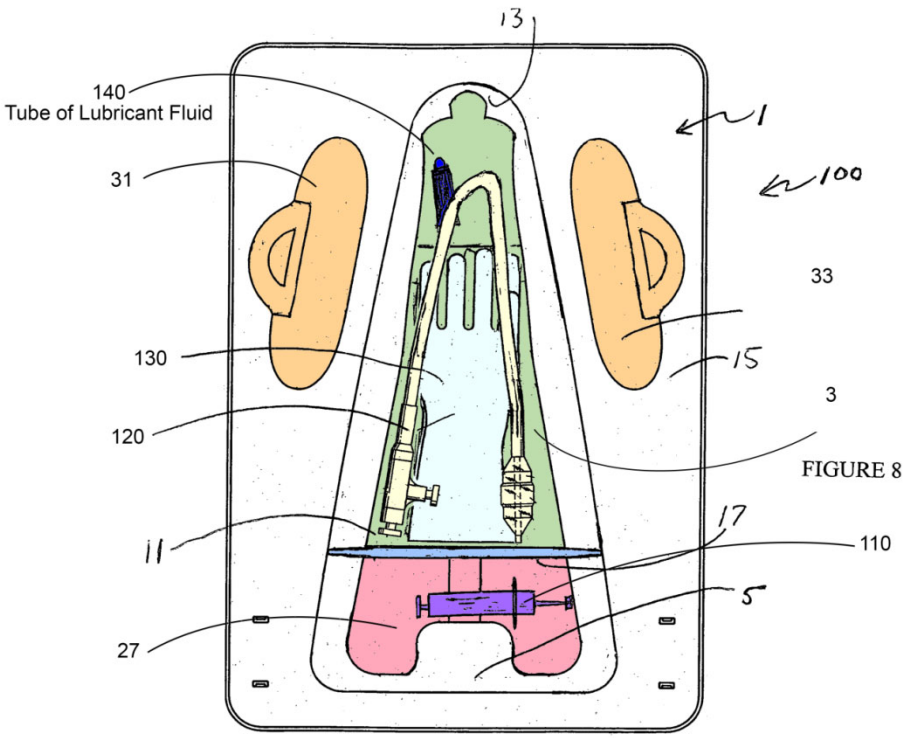


FIGURE 8

Solazzo discloses the lubricant tube (replaceable with a syringe, as discussed below) stored in compartment 3. But compartment 27 (a first compartment) is also a natural place to store the lubricant syringe because it already holds the inflation syringe. Further, compartment 27 also is structured such that it could hold the tube of lubricant 110 (replaceable with a syringe) in compartment 27 as well. (Ex.1002, ¶298.)

Modified Figure 8 below shows the first compartment accommodating two syringes: an inflation syringe 110 and lubrication syringe:

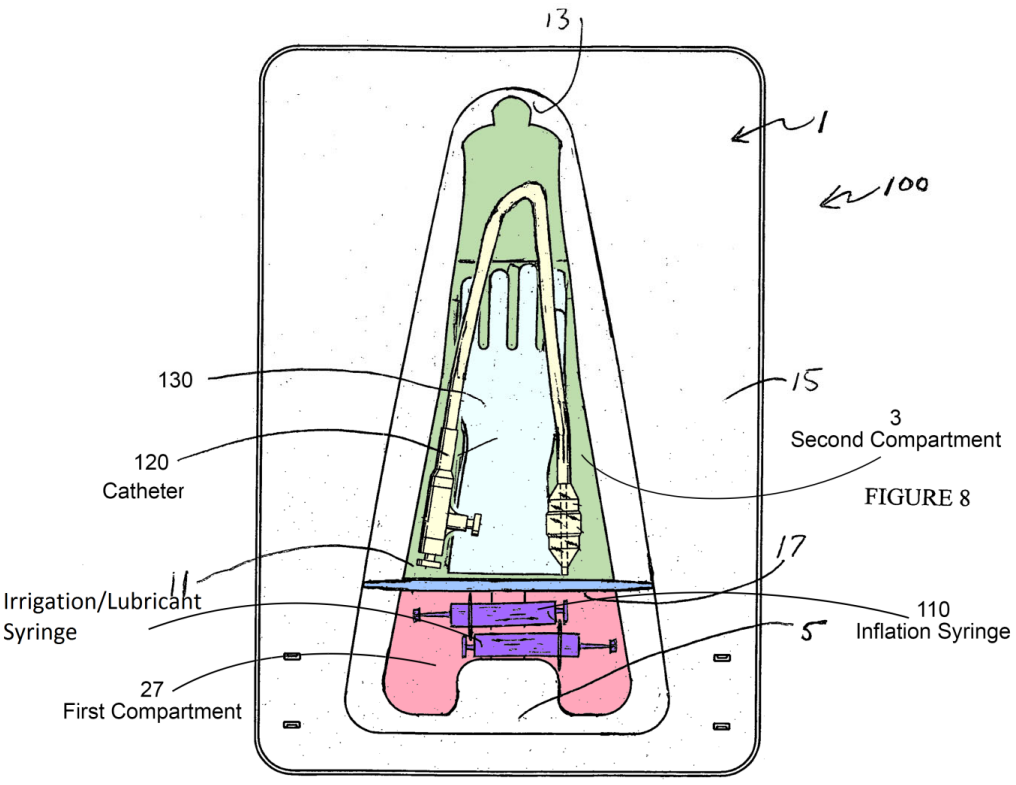
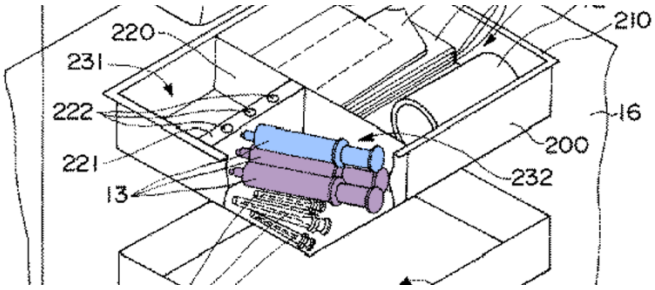


FIGURE 8

It was well-known in the art to group like items in the same compartment of a tray. For example, Imai discloses grouping syringes in the same compartment of a catheter tray, as shown in Figure 1 below:



As shown by Imai, compartment 27 could hold all three syringes (which could be inflation, irrigation, and lubricant syringes) in a stacked configuration. (Exs.1011-1012.)

Further, in view of Disston, a POSITA would have been motivated to group the first and second syringe in the first compartment of Solazzo such that they are "arranged in such order as to be most conveniently available when the container is opened." (Ex.1008, 2:15-19; Ex.1002, ¶303.)

A POSITA would have further been motivated to group the syringes together in the first compartment to remove the lubricant 110 from the second compartment (compartment 3), which contains the Foley catheter. This would ensure the lubricant 110 does not damage the Foley catheter during shipment of the tray. (Ex.1002, ¶304.)

Thus, Solazzo in view of Disston discloses claim 7[c][i]. (Ex.1002, ¶¶297-305.)

(ii) "*the second syringe containing a lubricating jelly*"

For the reasons at Ground 1, claim 7[c][ii], Solazzo renders obvious "*the second syringe containing a lubricating jelly*."

d. ***7[d]:*** *"a coiled medical device disposed within the second compartment of the single level container…"*

(i) "*…a coiled medical device…*"

Claim 7[d][i] requires "*a coiled medical device disposed within the second compartment of the single level container, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle.*"

For the reason at Ground 1, claim 7[d], Solazzo discloses an indwelling catheter including an inflatable portion (i.e., Foley catheter 120) disposed in the second compartment (compartment 3), but does not expressly mention a Foley catheter that is *pre-connected* to a drainage bag via coiled tubing. (Ex.1002, ¶¶309-10.) This arrangement has been known for over 50 years, as evidenced by Applicants' admission during the examination of the '400 patent and by Disston. (Ex.1046, 259, ¶33 (Meyst).)

Specifically, Disston discloses a "ready for use" "pre-assembled catheter-tube-bag assembly," including a Foley catheter 7, drainage tube 8, and drainage bag 10. (Ex.1008, 2:15-23; 2:72-3:1; Fig. 1.)

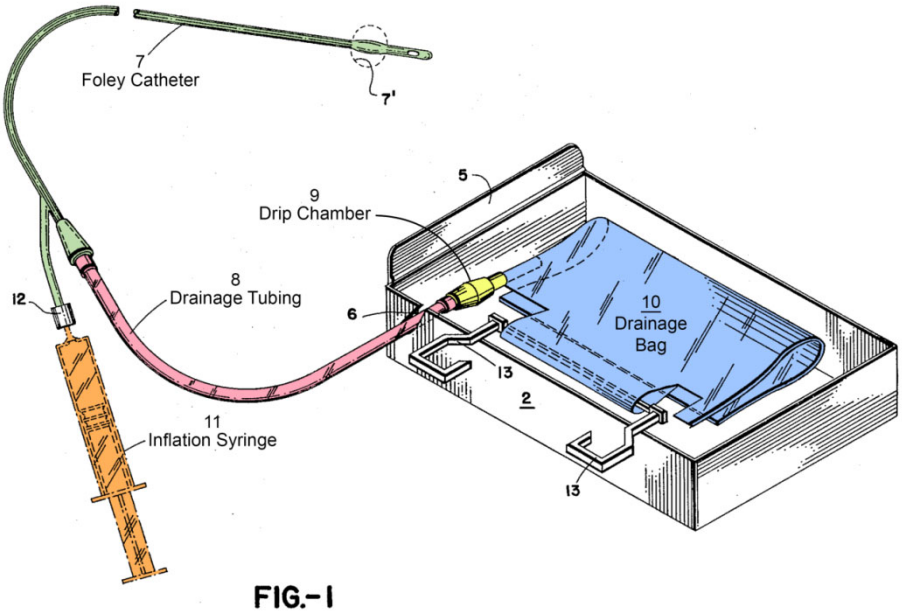


FIG.-1

The drainage tube 8 is coiled as shown in Figure 1. The drainage tube of Disston would also be coiled around a drainage bag when stored in the tray of Solazzo to fit the tubing in the box and prevent kinks. (Ex.1002, ¶312.)

First, Disston teaches pre-connected systems that are "ready for use." (Ex.1008, 1:35.) Including a pre-connected Foley system that is "ready for use" in the tray of Solazzo 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; Ex.1002, ¶314.)

Second, as Applicants admitted in a related prosecution, it was known by 2009 that Foley catheters (such as shown by Solazzo) caused CAUTI. (Ex.1046,

239, ¶29 (Weintraub).) It was further known in the art that closed-system Foley catheters (i.e., Foley catheters that are pre-connected to a drainage bag via tubing) reduce the risk of infection. Nursing Standard notes that providing a "closed system" was a standard practice and dramatically reduced infection rates. (Ex.1010, 51-52; Ex.1002, ¶390.) Thus, reducing the risk of infection would have motivated a POSITA to utilize Disston's closed-system Foley catheter in Solazzo's tray. (Ex.1002, ¶316.)

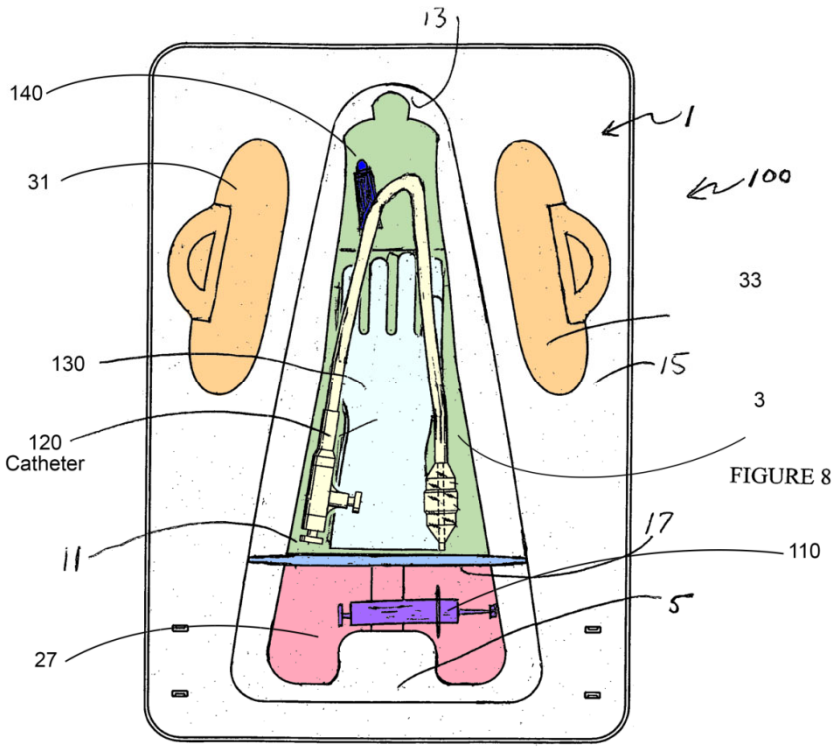
Furthermore, placing the closed-system Foley catheter in Solazzo's tray does not eliminate the catheterization and irrigation features of the tray. (Ex.1002, ¶315.) As explained by Dr. Yun, the tray can be best utilized for both purposes when a closed-system Foley catheter is provided in the tray of Solazzo. (Ex.1003, ¶¶41-42.)

Accordingly, Solazzo in view of Disston discloses claim 7[d][i]. (Ex.1002, ¶¶308-317.)

(ii) "*…the fluid receptacle is between the second compartment base member and the Foley catheter. …*"

Claim 7[d][ii] requires *"the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter*."

Solazzo discloses a catheter "*disposed within the second compartment of the single level tray*." Specifically, Foley catheter 120 is disposed in a second compartment (almost up to its top edge) of the single-level tray of Solazzo:



Disston discloses *"the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter*."

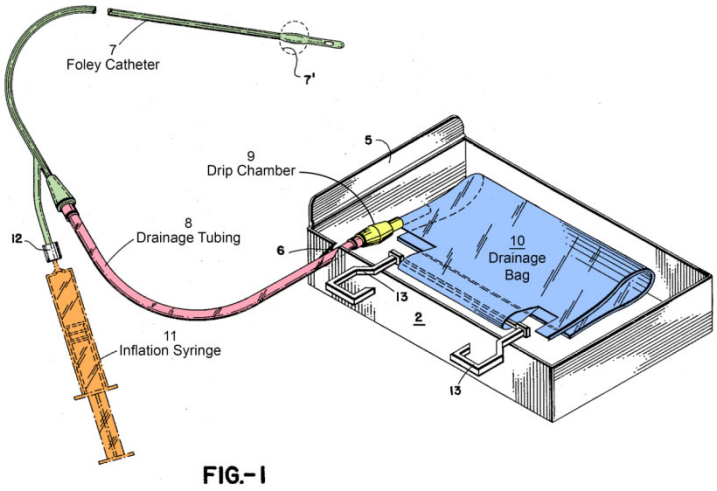


FIG.-1

As shown in Figure 1 above, Disston discloses the *fluid receptacle* (drainage bag 10) is between the bottom of tray portion 2 (a base member) and the Foley catheter 7. (Ex.1002, ¶322.) Examiner Poon further noted that the feature of the fluid receptacle beneath the coiled tube was admitted art. As discussed above in Section III.D, Applicants never challenged this finding. (Ex.1046, 73-76, 106-108.)

Therefore, when the closed-system Foley catheter of Disston is added to the second compartment of Disston where the Foley catheter is placed, the following limitation is met: "*the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter*." Specifically, the drainage bag of Disston is designed to fit in the bottom of a catheter tray, and the Foley catheter

can be placed on top of and/or wrapped around the drainage receptacle. The second compartment of Solazzo would hold the closed-system Foley catheter of Disston with this same configuration, i.e., with the second compartment base member of Solazzo (**"**shallow area 11B**"**) beneath the fluid bag and the attached tubing and Foley catheter wrapped around and/or on top of the bag. (Ex.1002, ¶323.)

Disston provides further motivation to arrange the items of a closed-system Foley catheter such that the drainage receptacle is on the bottom of the tray. (Ex.1002, ¶324.) Specifically, Disston discloses catheterization components that are "arranged in such order as to be most conveniently available when the container is opened…." (Ex.1008, 2:15-19.) A healthcare provider needs access to a Foley catheter to lubricate it and insert it before the drainage receptacle is accessed.

Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Solazzo such that "*the Foley catheter and the fluid receptacle positioned within the second compartment such that the fluid receptacle is between the second compartment base member and the Foley catheter*." (Ex.1002, ¶¶322-25.)

Accordingly, Solazzo in view of Disston discloses claim 7[d][ii]. (Ex.1002, ¶¶318-25.) Thus, Solazzo in view of Disston renders claim 7 obvious.

2) Claim 9

For the reasons at Ground 1, claim 9, Solazzo discloses "*wherein the first compartment is configured to receive the lubricating jelly from the second syringe to lubricate a tip of the Foley catheter when the tip is placed into the first compartment.*"

Thus, Solazzo in view of Disston renders claim 9 obvious.

3) Claim 11

For the reasons at Ground 1, claim 11, Solazzo discloses "*wherein the first syringe and the second syringe are positioned at different elevations within the first compartment, the different elevations being associated with an order of use of the first syringe and the second syringe during a catheterization procedure.*"

As mentioned at Ground 1, claim 11, Serany teaches items in their "order of use." Disston provides the same teaching and therefore the same motivation to arrange syringe in their order of use: catheterization components are "arranged in such order as to be most conveniently available when the container is opened…." (Ex.1008, 2:15-19; Ex.1002, ¶¶327-38.)

Thus, Solazzo in view of Disston renders claim 11 obvious.

4) Claim 12

For the reasons at Ground 1, claim 12, and Ground 3, claim 11, Solazzo discloses "*wherein the first syringe is positioned within the first compartment at a higher elevation than the second syringe."* (Ex.1002, ¶¶353-63.)

Thus, Solazzo in view of Disston renders claim 12 obvious.

5) Claim 13

For the reasons at Ground 1, claim 13, Solazzo discloses "*wherein a length of the first compartment extends along a side length of the single level container.*"

Thus, Solazzo in view of Disston renders this claim obvious.

6) Claim 14

a. ***Preamble and 14[a]:*** *"A catheterization kit comprising: a single level container…"*

For the reasons at Ground 1, claim 7[a], Solazzo discloses "*a single level tray defining a first compartment and a second compartment, the first compartment bounded by a first compartment base member and at least a first portion of a perimeter wall, the second compartment bounded, at least in part, by a second compartment base member and at least a second portion of the perimeter wall, the single level tray including a barrier separating the first compartment from the second compartment*."

b. ***14[b]:*** *"a first syringe disposed within the first compartment …"*

For the reasons at Ground 1, claim 7[b], Solazzo discloses "*a first syringe disposed in the first compartment of the single level tray at a first elevation, the first syringe containing an inflation fluid*."

c. ***14[c]:*** *" a second syringe disposed within the first compartment…"*

Claim 14[c] requires "*a second syringe disposed within the first compartment of the single level tray at a second elevation, the second elevation below the first elevation relative to a top of the single level tray, the second syringe containing a lubricating jelly, the first compartment configured to receive the lubricating jelly from the syringe*."

For the reasons at Ground 3, claim 7[c], Solazzo discloses "*a second syringe disposed within the first compartment of the single level tray*" and "*the second syringe containing a lubricating jelly*."

For the reasons at Ground 3, claims 11 and 12, Solazzo disclose "*a second syringe disposed within the first compartment of the single level tray at a second elevation, the second elevation below the first elevation relative to a top of the single level tray*."

For the reasons at Ground 1, claim 9, Solazzo discloses "*the first compartment configured to receive the lubricating jelly from the syringe*."

d. ***14[d]:*** *"a coiled medical device disposed within the second compartment of the single level container…"*

Claim 14[d] requires "*a coiled medical device disposed within the second compartment of the single level tray, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid*

receptacle, a tip of the Foley catheter configured to be placed within first compartment to lubricate a tip of the Foley catheter when the lubricating jelly has been dispensed from the second syringe into the first compartment."

For the reasons at Ground 3, claim 7[d], Solazzo in view of Disston discloses "*a coiled medical device disposed within the second compartment of the single level tray, the coiled medical device including a Foley catheter, a fluid receptacle, and a tube coupling the Foley catheter to the fluid receptacle*."

For the reasons at Ground 1, claim 14[d], Solazzo discloses "*a tip of the Foley catheter configured to be placed within first compartment to lubricate a tip of the Foley catheter when the lubricating jelly has been dispensed from the second syringe into the first compartment.*"

Thus, Solazzo in view of Disston renders claim 14 obvious.

7) Claim 15

For the reasons at Ground 1, Claim 15, Solazzo discloses "*wherein the single level tray defines a mnemonic device indicating that the first syringe should be removed from the first compartment before the second syringe during a catheterization procedure.*"

As mentioned at Ground 1, claim 11, Serany teaches items in their "order of use." Disston provides the same teaching and therefore the same motivation to arrange syringe in their order of use: catheterization components are "arranged in

such order as to be most conveniently available when the container is opened…." (Ex.1008, 2:15-19; Ex.1002, ¶¶369-77.)

Thus, Solazzo in view of Disston renders claim 15 obvious.

8) Claim 16

For the reasons at Ground 1, Claim 16, Solazzo discloses "*wherein the first compartment defines one or more contours to accommodate a flange of at least one of the first syringe or the second syringe.*"

9) Claim 22

For the reasons at Ground 3, claim 7[d][ii], Solazzo in view of Disston discloses "*wherein the coiled medical device is positioned within the second compartment such that the fluid receptacle is beneath the Foley catheter*."

D. Ground 4 (Claim 8) – Obvious Based on Solazzo, Disston, and Boedecker

1. The Combination

As discussed below, Solazzo in view of Disston and Boedecker discloses all the elements in the claim in this ground and renders the claim as obvious.

1) Claim 8

Claim 8 requires "*wherein the tube is attached to the fluid receptacle via an anti-reflux device*."

For the reasons at claim Ground 3, claim 7[d][i], it would have been obvious to include a closed-system Foley catheter (such as the catheter assembly of Disston) in the tray of Solazzo.

Disston teaches a *fluid receptacle* in the form of a flexible bag:

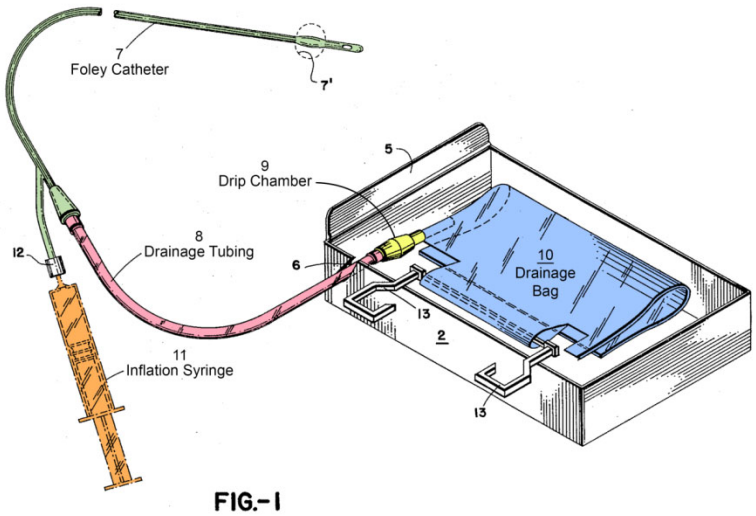
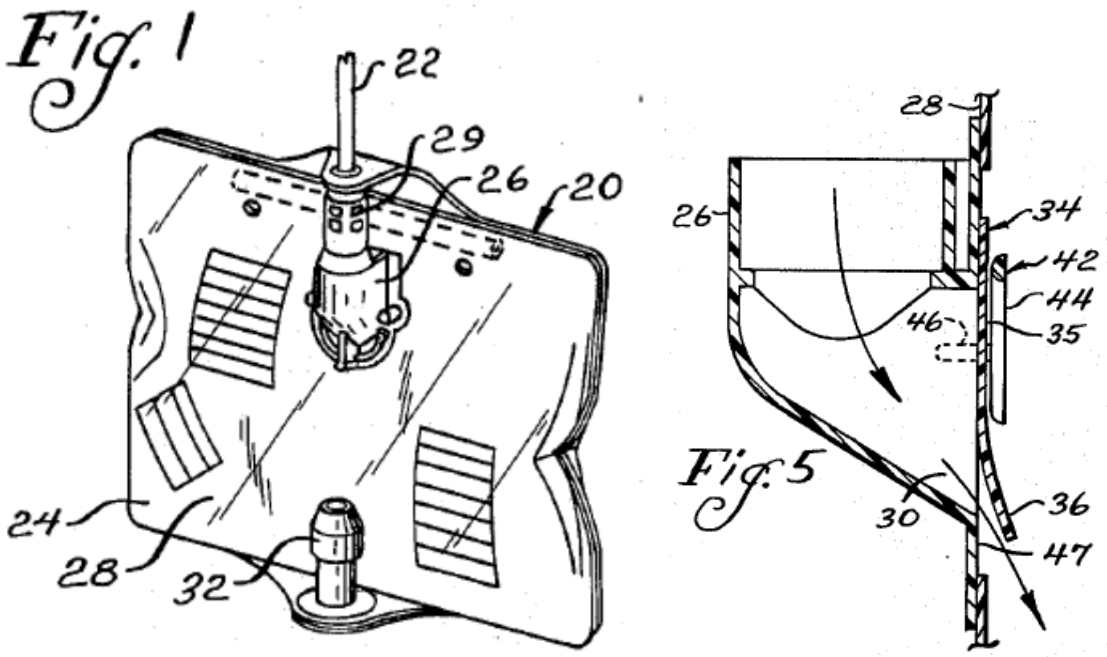


FIG.-1

Disston notes that drip chamber 9 is held higher than bag via a notch in the tray to prevent urine "back flow." (Ex.1008, 1:35-46; Ex.1002, ¶387.)

Boedecker teaches an anti-reflux device including a valve element 34 provided at an inlet opening of a liquid collection bag 24. (Ex.1034, 1:7-9, 2:63-3:3.) A connector or drip chamber 26 couples the inlet opening to a drainage tube 22, which further connects to a catheter. (Ex.1034, 2:49-60.) Boedecker's anti-reflux device flexes open at the inlet opening to permit urine flow to enter the bag,

and seals shut against the connector 26 to prevent the collected flow from escaping. (Ex.1034, 3:20-30; Ex.1002, ¶390.)



It would have been obvious to modify Disston in view of Boedecker. (Ex.1002, ¶¶394-95.) Disston addresses the problem of urine "back flow," but requires an extra step to accomplish: placing the tubing in a notch in the tray to keep the drip chamber 9 higher than drainage bag 10. The drip chamber 26 of Boedecker (including an anti-reflux device) prevents urine backflow without the need to keep the drip chamber higher than the drainage bag. It would thus have been obvious to a person of skill in the art to replace the drainage bag 10 of Disston with the "liquid collection bag 24" of Boedecker, such that Disston's drainage tubing 8 would be connected to Boedecker's connector 26 of liquid

collection bag 24. Such a modification would solve the problem of urine reflux while eliminating a step of the catheterization procedure. (Ex.1002, ¶¶394-95.)

Furthermore, Boedecker provides express motivation to add an anti-reflux device to Disston by noting that "*flexible* receptacles or bags … may cause a reflux of urine from the bag into the drainage tube, and possibly the catheter and patient's bladder" and "refluxing urine dramatically increases the possibility of retrograde bacterial movement from the bag to the patient's bladder, with possible deleterious results to the patient." (Ex.1034, 1:19-35.) To prevent the reflux of urine from the drainage bag of Disston into a patient's bladder through drainage tubing 8, a POSITA would have been motivated to substitute the drainage bag of Disston with the urine collection bag (including an anti-reflux device) as taught by Boedecker. (Ex.1002, ¶¶396-97.)

Finally, doing so would merely involve a simple substitution of one container (a urine collection receptacle as taught by Disston including connector 9) for another known type of container (a urine collection receptacle as taught by Boedecker including connector 26) to produce predictable results. (Ex.1002, ¶398.) Accordingly, Solazzo in view of Disston and Boedecker renders this claim obvious.

E. Ground 5 (Claims 10 and 21) – Obvious Based on Solazzo, Disston, and Serany

1. The Combination

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

1) Claim 10

For the reasons at Ground 1, claim 10, Solazzo in view of Serany discloses "*a wrap folded about the single level container so as to enclose the single level container within the wrap, the wrap configured to be unfolded to A) reveal the first compartment and the second compartment and B) provide a sterile field to accommodate the single level container during use."*

Thus, Solazzo in view of Disston and Serany renders claim 10 obvious.

2) Claim 21

a. ***Preamble and 21[a]:*** *"The catheterization kit of claim 7, further comprising: a wrap folded about the single level container…"*

For the reasons at Ground 1, claim 10, Solazzo in view of Serany discloses "*a wrap folded about the single level container so as to enclose the single level container within the wrap, the wrap configured to be unfolded to A) reveal the first compartment and the second compartment and B) provide a sterile field to accommodate the single level container during use*."

b. ***21[b]:*** *"the first syringe being positioned above the second syringe within the first compartment,…"*

For the reasons at Ground 1, claim 21(b), Solazzo discloses "*the first syringe being positioned above the second syringe within the first compartment, the first compartment configured to receive a tip of the Foley catheter and the lubricating jelly from the second syringe to lubricate the tip after the first syringe and the second syringe have been removed from the first compartment*."

Thus, Solazzo in view of Disston and Serany renders claim 21 obvious.

VII. 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 '596 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.

VIII. SECTION 325(d) IS INAPPLICABLE

Neither the original examination of the '596 patent, nor the *inter partes* reviews in *Medline I* raised substantially the same art or arguments in the same way 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 or applied during the original examination of the '596 patent. None of the references applied by the Examiner included a Foley catheter. (Exs. 1038, 1042-44.)

Solazzo, Serany and Disston all disclose a tray for holding a Foley catheter. But none of these references were mentioned by the Examiner. Boedecker teaches an anti-reflux device on a urinary collection bag. But this reference was not cited during the prosecution. Thus, no factor in *Becton* favors application of § 325(d).

B. 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 compartments and syringes, in contrast to the art raised in the IPRs.

IX. 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.); (ii) *inter partes* review petitions (IPR2019-00035 and -00036) for U.S. Patent No.

9,745,088; (iii) *inter partes* review petition (IPR2019-00109) for U.S. Patent No. 9,795,761; and (iv) *inter partes* review petition (IPR2019-00208) for U.S. Patent No. 9,808,400.

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 '596 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.

X. 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. **480100000023**.

Dated: November 7, 2018

Respectfully submitted,

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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 13,522 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: November 7, 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. 9,808,596.

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Dated: November 7, 2018

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