UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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C. R. BARD, INC.
Petitioner,

v.

MEDLINE INDUSTRIES, INC.
Patent Owner.

Patent No. 9,795,761

_____

Inter Partes Review No. IPR2019-00109

PETITION FOR *INTER PARTES* REVIEW

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

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

Exhibit List for *Inter Partes* Review of U.S. Patent No. 9,795,761

Exhibit Description	Exhibit #
U.S. Patent No. 9,795,761 to Lockwood et al.	1001
Declaration of Michael Plishka	1002
Declaration of Edward J. Yun, M.D.	1003
Prosecution History of U.S. Patent No. 9,795,761	1004
U.S. Patent No. 7,278,987 to Solazzo	1005
U.S. Patent No. 3,329,261 to Serany, Jr. et al.	1006
U.S. Patent No. 6,840,379 to Franks-Farah et al.	1007
U.S. Patent No. 3,166,189 to Disston	1008
U.S. Patent No. 5,931,303 to Salvadori	1009
Madeo M. and Roodhouse, A.J., Reducing the risks associated with urinary catheters, *Nursing Standard*, Vol. 23, No. 29, 47-55 (2009)	1010
Japanese Patent No. 2007-229520 to Imai et al.	1011
English Translation of Japanese Patent No. 2007-229520 to Imai et al.	1012
U.S. Patent No. 4,160,505 to Rauschenberger	1013
U.S. Patent No. 4,226,328 to Beddow	1014
Male Catheter Insertion Video, Uploaded to YouTube on February 7, 2008, Parts 1 and 2	1015A-B
Norman, Donald A., *The Design of Everyday Things*, 2002 ed. (Excerpt)	1016
Diagram of Medline Patent Portfolio	1017

Exhibit Description	Exhibit #
U.S. Published Application No. 2006/0009742 to Solazzo	1018
Notice of Allowability for U.S. Application No. 13/153,265	1019
Reserved	1020
Reserved	1021
E-mail from Medline's Counsel to Bard Concerning Proposed Claim Constructions Under Local Patent Rules (Case No. 17-7216)	1022
Medline's Responsive Claim Construction Brief (Case No. 16-3529)	1023
E-mail from Bard to Medline's Counsel Concerning Proposed Claim Constructions Under Local Patent Rules (Case No. 17-7216)	1024
Evidence of Public Availability of Nursing Standard Article	1025
Bard's Opening Claim Construction Brief (Case No. 17-7216)	1026
U.S. Patent No. 6,004,136 to Ehrenpreis	1027
U.S. Published Application No. 2004/0161732 to Stump et al.	1028
U.S. Published Application No. 2004/0271019 to Stoller et al.	1029
Medline's Final Infringement Contentions (Case No. 17-7216)	1030
Declaration of J. Tomes in U.S. Application No. 12/647,515	1031
2001 Bard Patient Instructions Pamphlet	1032
PTAB Decision (13/153,300) dated October 12, 2016	1033

Petitioner C. R. Bard, Inc. ("Petitioner" or "Bard") respectfully petitions for *inter partes* review of claims 1-19 and 22-25 of U.S. Patent No. 9,795,761 ("the '761 patent" (Ex.1001)) in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. INTRODUCTION

The '761 patent is directed to a patient aid for inclusion in a tray or container comprising compartments for a catheter and syringes. The compartments of the tray allow for the catheter and the syringes to be stored separately, as well as for the catheter to be lubricated. (*See*, *e.g.*, Ex.1001, Fig. 2.) The patient aid is for providing information to the patient relating to the catheter procedure, such as ensuring aseptic conditions ("If your caregivers don't clean their hands, it is o.k. to ask them to do so") and observing urine flow ("Tell somebody whenever the bag is more than half full"). (*See*, *e.g.*, Ex.1001, Fig. 19.)

All these elements—the structure and components of a catheter tray, as well as the inclusion of patient information and instructions relating to the catheter procedure—were well known by 2009, the earliest purported priority date of the '761 patent.

Solazzo (Ex.1005) discloses a tray with multiple compartments, such as compartments 3 and 27, as shown in annotated Figure 1 below.

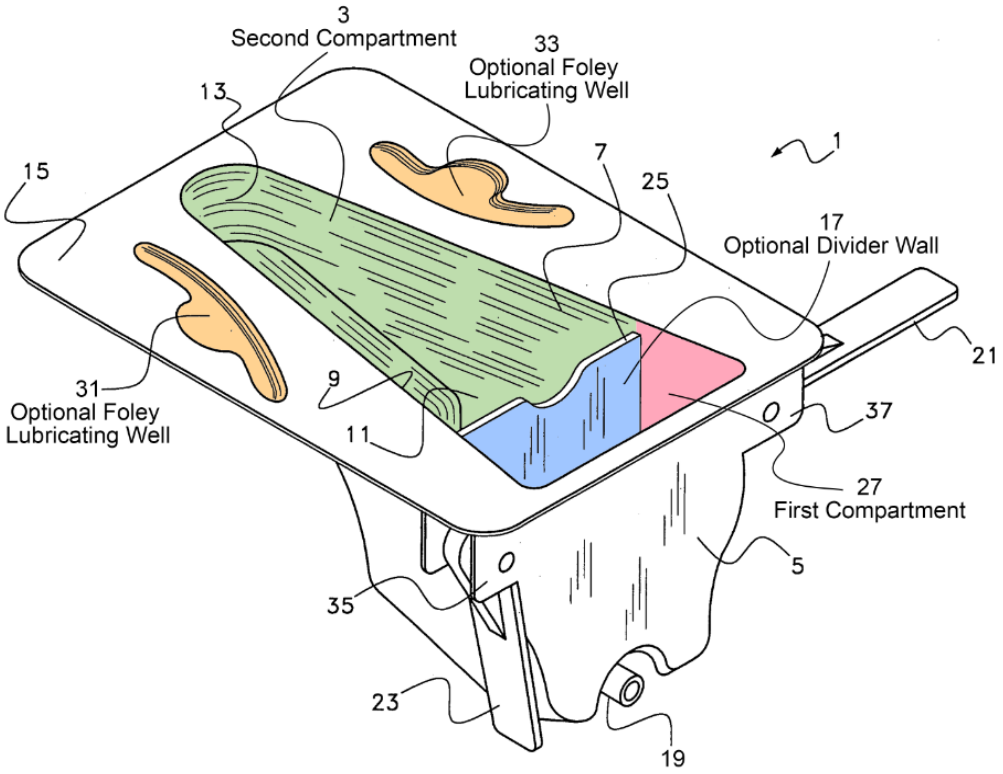


Fig. 1

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.) Solazzo discloses that the kit has another syringe (an irrigation syringe) which would have been obvious to place with syringe 110 in compartment 27. (Ex.1005, 3:22; Ex.1002, ¶¶168-175.)

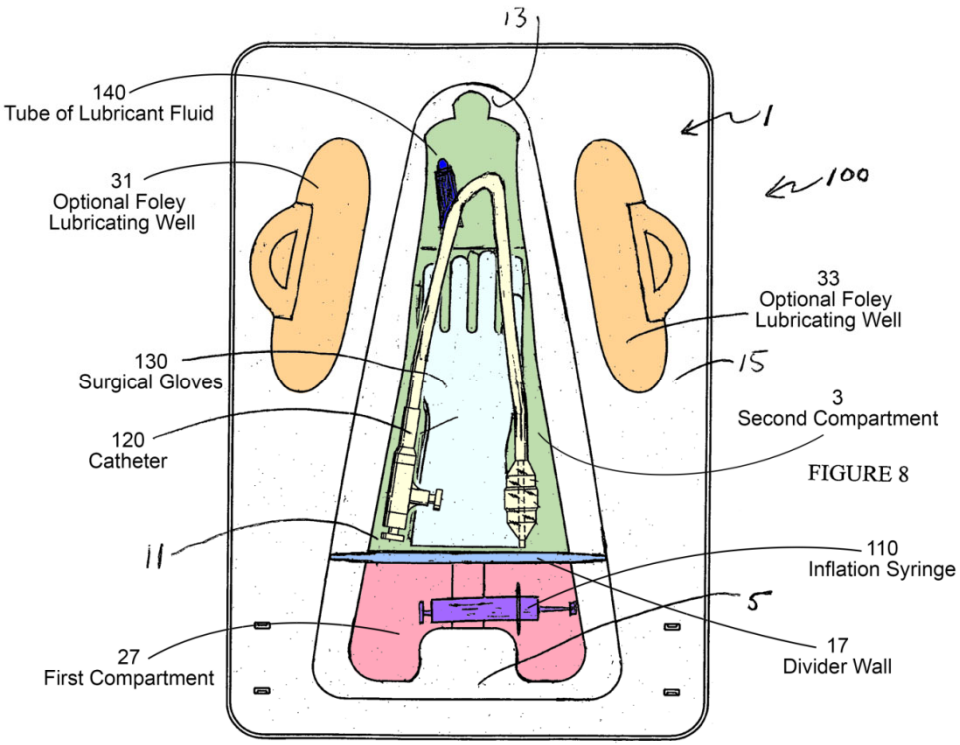


FIGURE 8

Aside from reciting a known tray structure, the challenged claims of the '761 patent recite a number of well-known components associated with a catheterization tray, such as a hand sanitizer, a wrap and a sealed bag.

Even the functional aspects of the tray—such as compartments for lubricating the catheter, and arranging components consistent with their order of use—were well-known. In any event, where the prior art, such as Solazzo, discloses the same structure, the manner of using the chamber (e.g., for applying lubricant) cannot differentiate over the prior art. (*See* Section V below.)

As for the patient aid, that too was known years before 2009, but it should not be given patentable weight. The addition of a "patient aid" or "patient

instructions" cannot render the tray patentable under *In re Ngai, 367* F.3d 1336, 1339 (Fed. Cir. 2004). Nor is the content of those instructions entitled to patentable weight, as the PTAB found in rejecting claims of the '761 patent, as well as claims in a related patent. (*See* Section VI below.)

Even if given weight, Franks-Farah (Ex.1007) discloses the "patient aid" limitations at issue here, as it discloses a urinary cathether kit with "step-by-step" instructions that are designed to be used by a patient, caregiver, or healthcare provider.. (*See*, *e.g.*, Ex.1007, Figs. 2A and 2B.) Those instructions mirror the patient aid of the '761 patent by focusing on aseptic techniques (Ex.1007, 1:51-54), and the flow of urine (Ex.1007, Fig. 2A (Step 7); Fig. 2B (Step 10)).

Given that both Solazzo and Franks-Farah are directed to urinary catheters, there would be ample reasons to provide the patient aid of Franks-Farah with the tray of Solazzo. Doing so would ensure that the patient is, for example, aware of aseptic techniques (e.g., washing hands)—so as to minimize urinary tract infections. (Ex.1002, ¶¶209-213.)

Accordingly, Bard respectfully submits that the challenged claims are unpatentable for the reasons set forth in this Petition. This petition is supported by the accompanying declarations of Michael Plishka (Ex.1002) and Dr. Edward Yun (Ex.1003).

II. THE STATE OF THE ART

By 2009 (the earliest purported priority date of the '761 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 '761 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 '761 patent. (Ex.1002, ¶50.) 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 its related components, such as a water-filled syringe for inflating the balloon of the Foley catheter. (Ex.1008, 2:15-26; Figs. 1-2; Ex.1002, ¶¶50-54.)

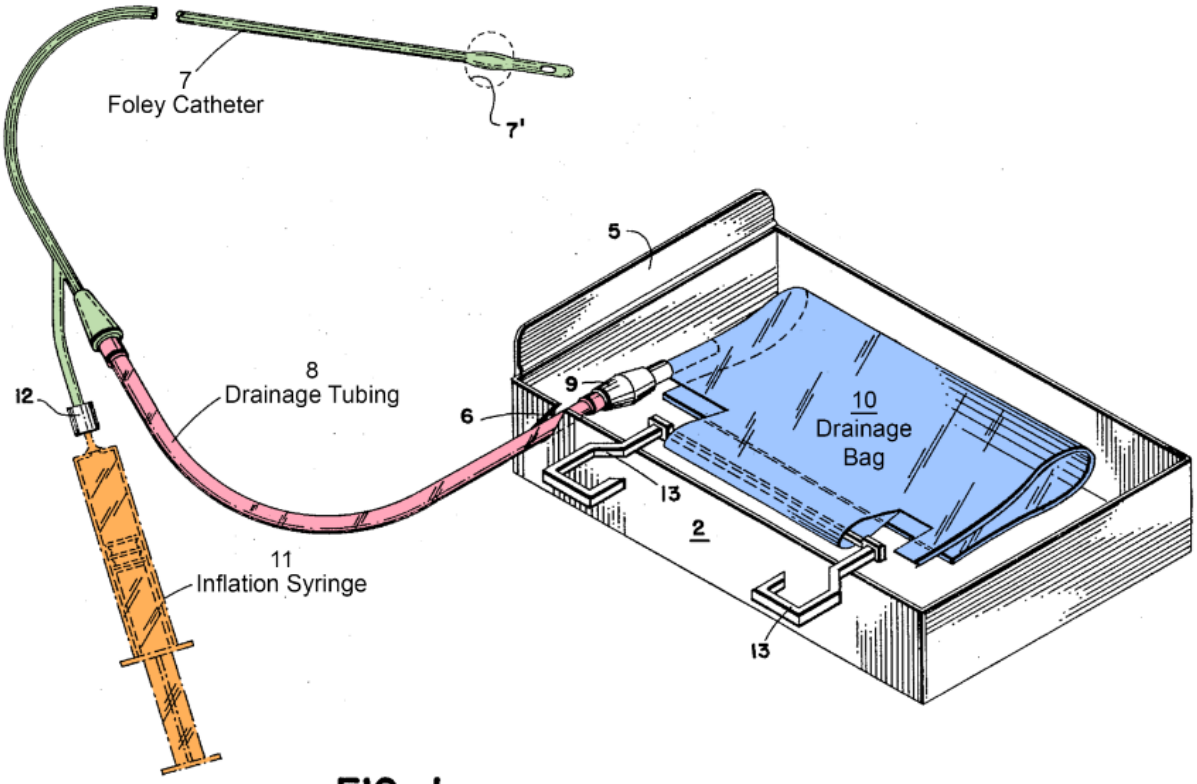


FIG.-1

U.S. Patent No. 3,329,261 to Serany (Ex.1006), filed on September 3, 1965 also by Bard, discloses a catheterization package including a Foley catheter, a bottom tray, and a top tray having multiple compartments contoured to fit components stored therein as shown in annotated Figs. 6 and 7 below. (Ex.1006, 2:39-40, 3:23-26.)

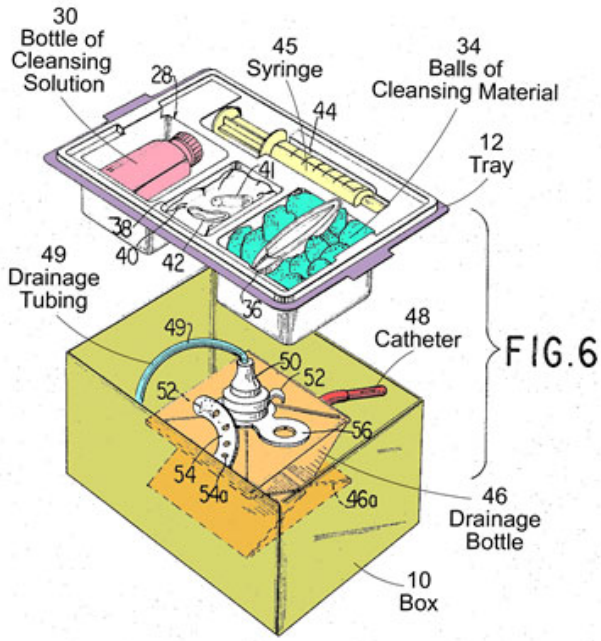


FIG.6

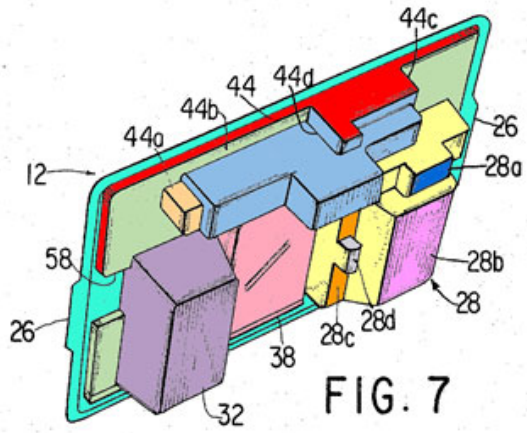
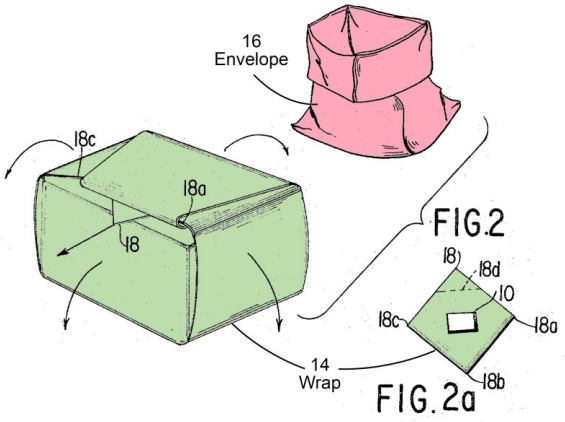


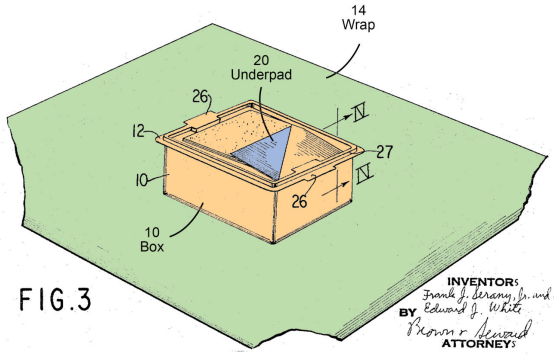
FIG. 7

Typically, a medical device tray is wrapped in a bag or outer wrap to allow shipment while holding components inside the tray. (Ex.1002, ¶61.) 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, ¶61.) Because Foley catheters must be sterile in order to be inserted into a patient's body, it was common practice to wrap a Foley catheter tray in a CSR wrap and enclose the wrapped tray with an outer packaging. (Ex.1002, ¶62.)

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, ¶63.) Serany's tray is "sterilized before or after

enclosure in the envelope," whereby the "envelope 16 seals the contents to maintain the sterility of the contents." (Ex.1006, 1:63-66; Ex.1002, ¶64.)





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, ¶¶66-89.)

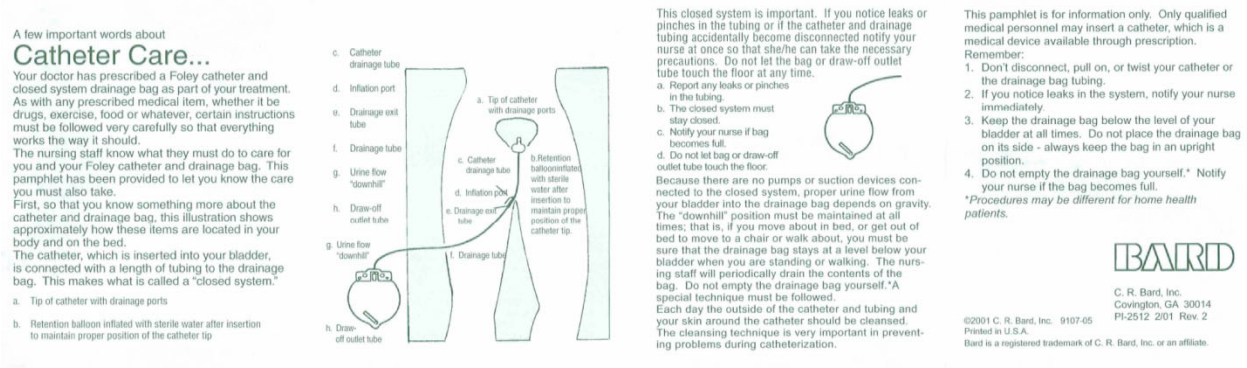
Foley catheter. Solazzo**,** Disston, and Serany all disclose trays with Foley catheters. (Ex.1002, ¶¶70-72, 127.) Foley catheter kits have long been available. (Ex.1003, ¶¶12-15.)

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, ¶73.)

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, ¶74.) Lubricant may also be provided in a syringe. (Ex.1010, 52; Ex.1002, ¶75; Ex.1003, ¶¶20-22.)

Instructions. The '761 patent acknowledges in its Background Art section that patient education materials were available before the purported invention. It states: "*While educational materials may be available*, it is *frequently* the case that the material fails to reach the intended target, i.e., the patient." (Ex.1001, 1:53-55 (emphasis added).) As discussed in more detail below, the Examiner during the examination of the '761 patent found that the "prior art also discloses an instructional patient aid." (Ex.1019, 11.).

Indeed, prior art Foley catheter trays have long included patient instructions. (Ex.1002, ¶¶79-84.) For example, Bard had a multipage pamphlet (with a copyright date of 2001) that provides patient instructions for a Foley catheter. (Ex.1032; *see also* Ex.1031.)



A few important words about
Catheter Care...

Your doctor has prescribed a Foley catheter and closed system drainage bag as part of your treatment. As with any prescribed medical item, whether it be drugs, exercise, food or whatever, certain instructions must be followed very carefully so that everything works the way it should.

The nursing staff know what they must do to care for you and your Foley catheter and drainage bag. This pamphlet has been provided to let you know the care you must also take.

First, so that you know something more about the catheter and drainage bag, this illustration shows approximately how these items are located in your body and on the bed.

The catheter, which is inserted into your bladder, is connected with a length of tubing to the drainage bag. This makes what is called a "closed system."

a. Tip of catheter with drainage ports

b. Retention balloon inflated with sterile water after insertion to maintain proper position of the catheter tip

c. Catheter drainage tube
d. Inflation port
e. Drainage exit tube
f. Drainage tube
g. Urine flow "downhill"
h. Draw-off outlet tube
a. Tip of catheter with drainage ports
b. Retention balloon inflated with sterile water after insertion to maintain proper position of the catheter tip
c. Catheter drainage tube
d. Inflation port
e. Drainage exit tube
f. Drainage tube
g. Urine flow "downhill"
h. Draw-off outlet tube

This closed system is important. If you notice leaks or pinches in the tubing or if the catheter and drainage tubing accidentally become disconnected notify your nurse at once so that she/he can take the necessary precautions. Do not let the bag or draw-off outlet tube touch the floor at any time.

a. Report any leaks or pinches in the tubing.
b. The closed system must stay closed.
c. Notify your nurse if bag becomes full.
d. Do not let bag or draw-off outlet tube touch the floor.

Because there are no pumps or suction devices connected to the closed system, proper urine flow from your bladder into the drainage bag depends on gravity. The "downhill" position must be maintained at all times; that is, if you move about in bed, or get out of bed to move to a chair or walk about, you must be sure that the drainage bag stays at a level below your bladder when you are standing or walking. The nursing staff will periodically drain the contents of the bag. Do not empty the drainage bag yourself.*A special technique must be followed.

Each day the outside of the catheter and tubing and your skin around the catheter should be cleansed. The cleansing technique is very important in preventing problems during catheterization.

This pamphlet is for information only. Only qualified medical personnel may insert a catheter, which is a medical device available through prescription.

Remember:

1. Don't disconnect, pull on, or twist your catheter or the drainage bag tubing.
2. If you notice leaks in the system, notify your nurse immediately.
3. Keep the drainage bag below the level of your bladder at all times. Do not place the drainage bag on its side - always keep the bag in an upright position.
4. Do not empty the drainage bag yourself.* Notify your nurse if the bag becomes full.

**Procedures may be different for home health patients.*

BARD

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PI-2512 2/01 Rev. 2

The instructions include post-procedural steps such as (1) "Don't disconnect, pull on, or twist your catheter or the drainage bag tubing"; (2) "If you notice leaks in the system, notify your nurse immediately"; (3) "Keep the drainage bag below the level of your bladder at all times. Do not place the drainage bag on its side – always keep the bag in an upright position"; and (4) "Do not empty the drainage bag yourself. Notify your nurse if the bag becomes full." (Ex.1032.) These were repeated in Figure 19 of the '761 patent. (Ex.1002, ¶¶83-84.)

Other examples abound. U.S. Patent No. 6,840,379 to Franks-Farah (Ex.1007), filed on September 11, 2003, teaches a urinary catheter kit with "detailed step-by-step" instructions as shown in Figures 2A and 2B below (Ex.1007, 2:33-37) (Fig. 4; Ex.1002, ¶86.) The instructions include procedural and

post-procedural information for a healthcare provider and patient. (Ex.1007, Fig. 2A-2B.) Franks-Farah also teaches "self-care documentation" that may be used by a practitioner to teach a patient how to perform a catheterization procedure. (Ex.1007, 2:33-37, Fig. 4.)

FIG. 2A

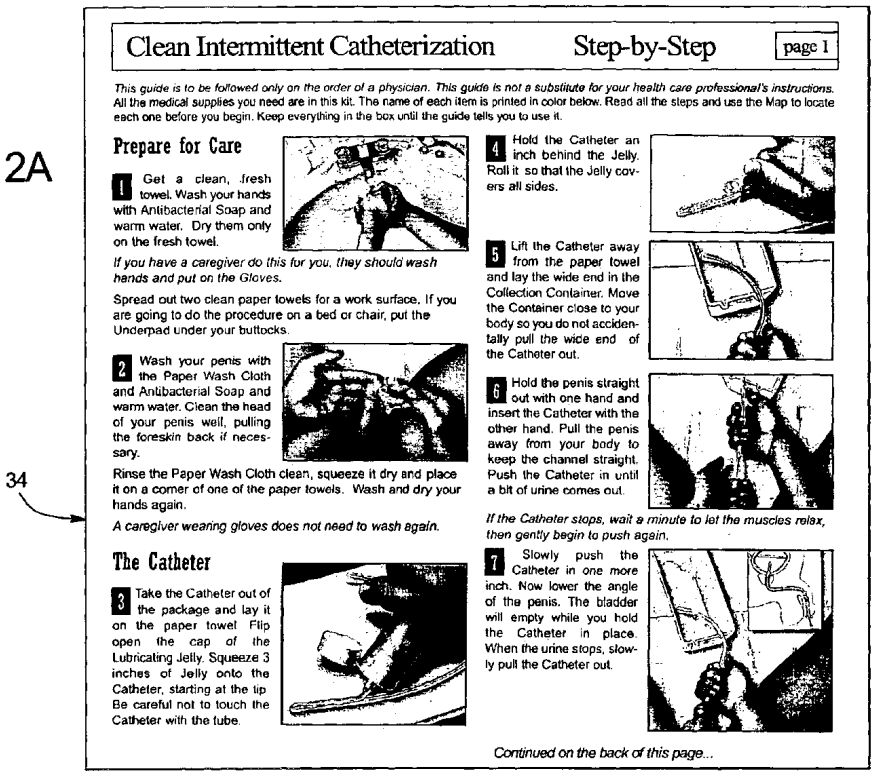
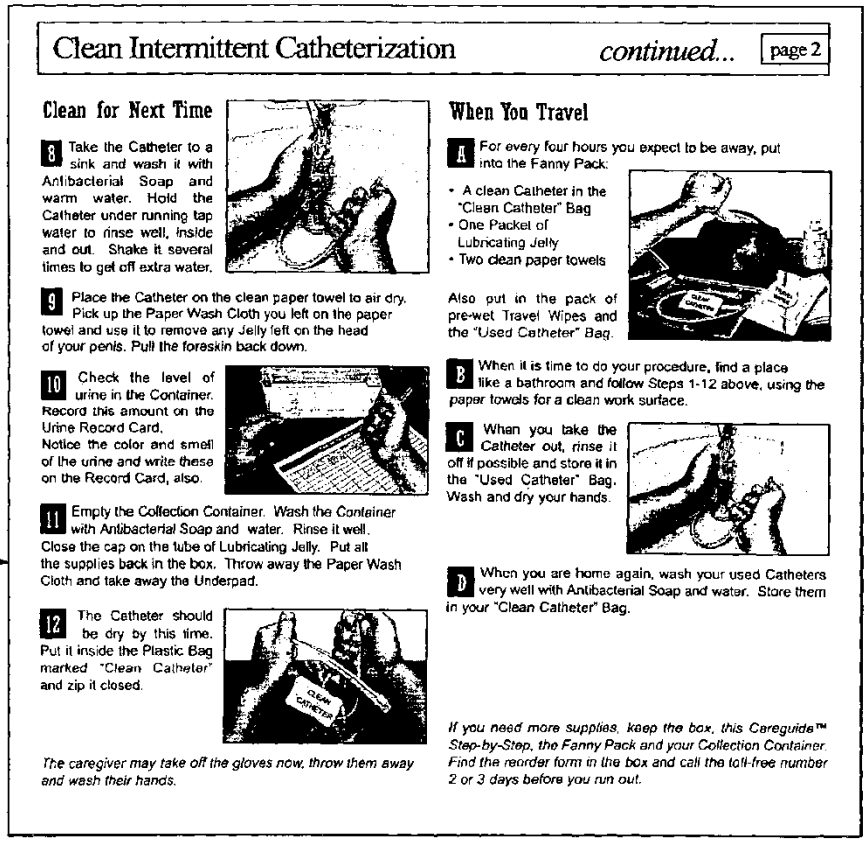


FIG. 2B



Dr. Yun also explains in his accompanying declaration (Ex.1003, ¶44) that it was well known to have patient educational materials with Foley catheter trays.

It was also standard practice at the time of the invention to include instructions on how to perform a catheterization procedure. (Ex.1002, ¶¶87-89. Franks-Farah, described above, provides one example of such instructions. (Ex.1007, Figs 2A and 2B; 3:34-38.)

Hand Sanitizers. Foley catheter trays have long included hand sanitizers to allow nurses to sterilize their hands before donning sterile gloves. (Ex.1002, ¶¶90-91; Ex.1013, ¶12.) The Nursing Standard article states: "Hands should be

decontaminated before carrying out the procedure and cleaned with alcohol gel before putting on sterile gloves." (Ex.1010, 52.) Solazzo discloses an "antiseptic solution" that would serve as a hand sanitizer. (Ex.1005, 3:24.) Similarly, Franks-Farah teaches an "alcohol gel (i.e., a waterless cleaner), an "antibacterial soap [] in liquid form" and a "pack of pre-wet travel wipes." (Ex.1007, 2:17-18; 3:41-42; 6:60-62; Fig. 1.)

C. Functional Aspects Of The Tray

Lubrication compartment. Compartments for lubricating catheters were well-known features of prior art trays. (Ex.1002, ¶¶92-100.) For example, a prior art YouTube video, uploaded on February 7, 2008, entitled "Nursing Lab: Take Two – *Male Catheter Insertion*" ("*Male Catheter Insertion*"; Exs. 1015A-B), shows a catheterization procedure performed using a 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 in the compartment. (Ex.1015B, 0:55-1:00.)

Arranging items consistent with order of use. Ordering components within a tray according to their use during a catheterization procedure was well-known in the art. For example, Disston's catheterization components are "arranged in such order as to be most conveniently available when the container is

opened…." (Ex.1008, 2:15-19.) In Serany's tray, "[e]verything is available in the proper order of use" and "in logical step-by-step order." (Ex.1006, 1:23-25; 1:31-35; *see also* Ex.1002, ¶¶101-106.)

Arranging Items to Prompt Certain User Behavior (i.e., Affordances). Prompting certain user behaviors through the design of things was well-known as "affordances," a term popularized by author Donald A. Norman in his book "*The Design of Everyday Things*," first published in 1988, which describes "affordances" as providing "clues as to the operation of things."

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

(Ex.1016, 9; Ex.1002, ¶¶107-109.)

Disston's tray presents items "arranged in such order as to be most conveniently available when the container is opened" and staggered so "that it can be opened without any part of either hand of the user coming in contact with the contents." (Ex.1008, 2:15-23, 2:63-72; *see also* Ex.1002, ¶¶110-112.)

III. THE '761 PATENT

A. Summary

The '761 patent is entitled "Medical Kit, Packaging System, Instruction Insert, and Associated Methods." (Ex.1001, 1:27-34.) The '761 patent is directed to a patient aid suitable for inclusion in a medical kit. (Ex.1001, 1:27-34.) Aside from the patient aid, the '761 patent focuses on tray structure, components in the tray and functional aspects of the tray. As discussed above, and in more detail below, all these aspects were well-known in the art by 2009.

1. Tray structure

Figure 2 of the '761 patent provides a depiction of a medical device tray with multiple compartments.

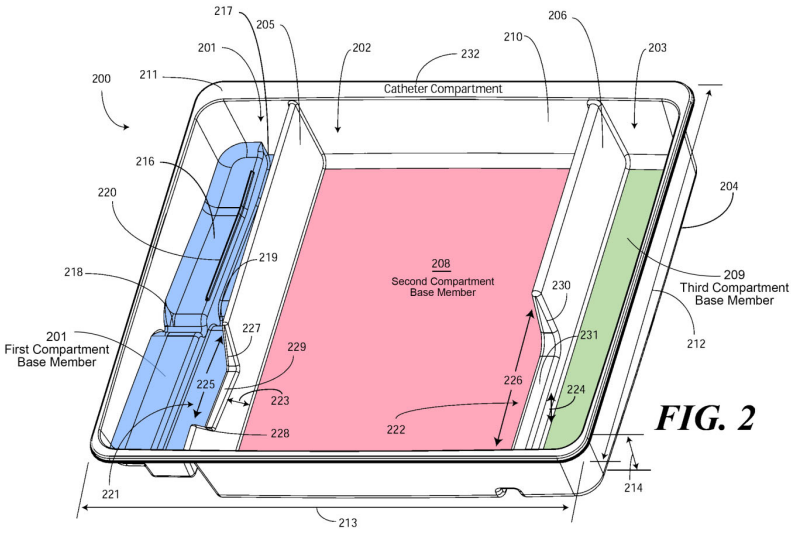


FIG. 2

Specifically, the tray has a first compartment 201, a second compartment 202, and a third compartment 203. (Ex.1001, 7:11-15.)

As shown in Figure 10 (annotated below), the tray when packaged is covered in a "CSR Wrap 1000" (shown in green) and "the assembly can be sealed in a packaging 1002 such as a thermally sealed bag" (shown in pink). (Ex.1001, 16:54-58; *see also* Ex.1001, 16:13-24.)

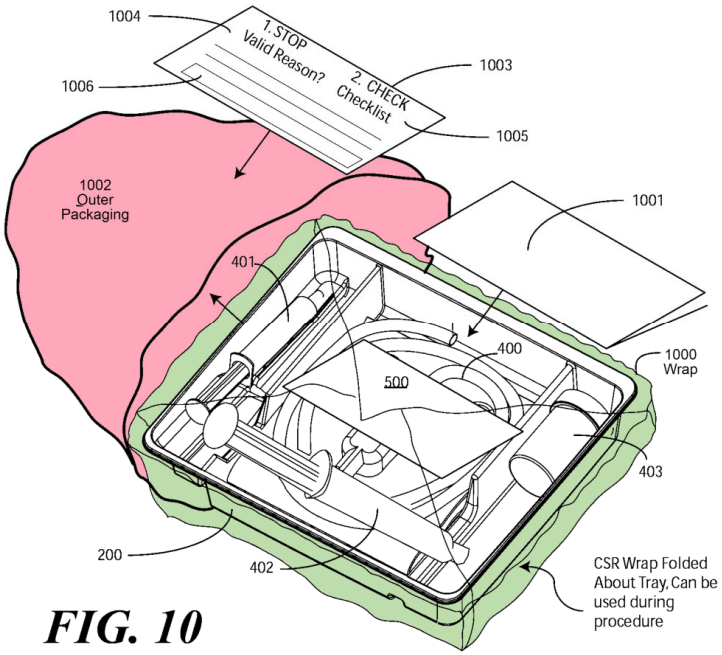


FIG. 10

2. Components of the tray

The '761 patent also describes various common medical devices that may be provided in a catheter tray. The devices depicted in annotated Figure 4 (below) of the tray include a pair of syringes (shown in green and pink). (Ex.1001, 4:60-61;

11:21-23.) The second compartment of the tray includes a catheter assembly 400 (shown in blue in annotated Figure 4). (Ex.1001, 11:20.)

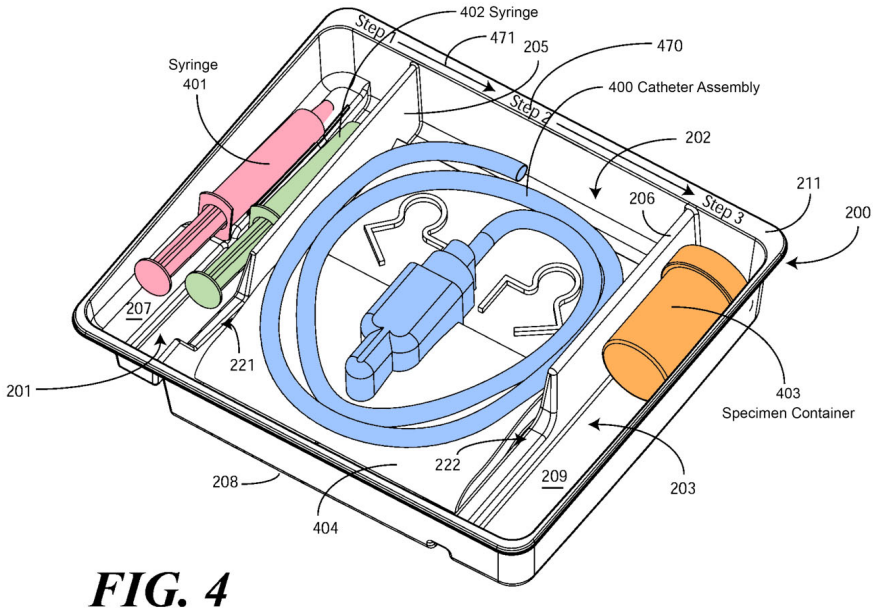


FIG. 4

The '761 patent also describes a medical tray that includes "a patient aid for ensuring proper dissemination of information relating to medical procedures, and in one or more embodiments, to a patient aid suitable for inclusion in a medical kit used for medical procedures that ensures the information is delivered to the patient undergoing the procedure." (Ex.1001, 1:27-34.) Figure 6 (below) provides an example of a "patient aid" with a "greeting card appearance." (*See also* Ex.1001, 3:28-3:34.)

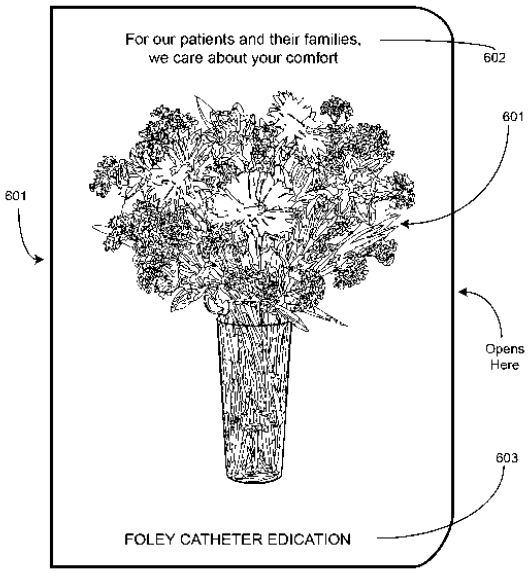


FIG. 6

The claims of the '761 patent refer to the patient aid comprising "post-procedure information." (*See*, *e.g.*, Ex.1001, 28:26-29.) All of the claims recite that the patient information is "for caring for the Foley catheter" when "applied to a patient." Figure 19 (below) illustrates patient information that refers to post-procedure information when the Foley catheter is applied to the patient. For example, at the bottom (1903) of Figure 19, it instructs the patient to be aware of urine flow: "Always keep the collection bag below the level of your belly button. Tell somebody whenever the bag is more than half full."

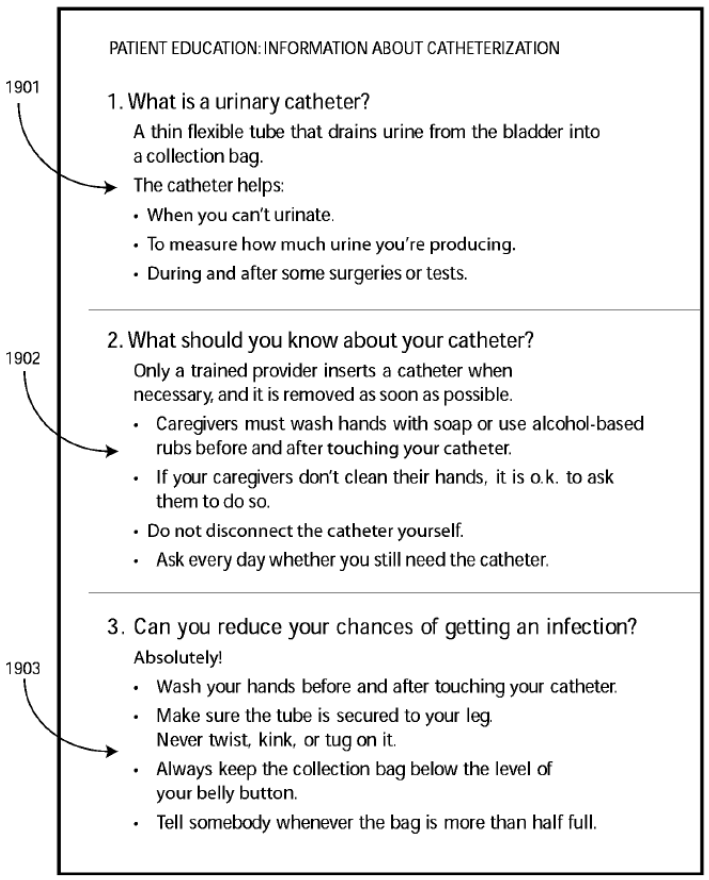


FIG. 19

Further, the patient aid of Figure 19 includes information (1902) on aseptic techniques such as cleansing hands before and after touching a catheter: "Caregivers must wash hands with soap or use alcohol-based rubs before and after touching your catheter. If your caregivers don't clean their hands, it is o.k. to ask them to do so." (Ex.1001, Fig 19.)

3. Functional aspects of the tray

The '761 patent asserts that the "compartments [of the tray] have multi-purpose functionality." (Ex.1001, 5:5-8.) One of the functional features described

by the ’761 patent is that a compartment of the tray may be used as a lubricating jelly application compartment, and that a syringe may be provided in the same compartment. (Ex.1001, 5:5-12.) The ’761 patent also describes the “first compartment” as being “a lubricant applicator for the catheter” when the first compartment is stair-stepped because lubricating jelly can be dispensed on the lower step portion. (Ex.1001, 9:31-47.)

The patent also notes that the items provided in the tray may be arranged within the tray “in accordance with their use during the procedure.” (Ex.1001, 7:53-62.) Similarly, the ’761 patent discloses that the tray may provide a “mnemonic device instructing [the medical services provider] in which order to use each device.” (Ex.1001, 4:63-5:4.) Specifically, the ’761 patent describes providing the syringes at different heights and locations to suggest an order of use of the syringes. When describing the “mnemonic device,” the ’761 patent states that “it may be intuitive” that a first syringe that is disposed to the left and higher than a second syringe is to be used first during a catheterization procedure. (Ex.1001, 8:10-19.)

B. Effective Filing Date

Application no. 12/495,148, filed on June 30, 2009, is the earliest-filed application listed on the face of the ’761 patent. But Medline has stated that the claims are only entitled to the filing date of later filed application—application no.

12/647,515—filed on December 27, 2009. (Ex.1030, 3.) Bard assumes—for this Petition only—that the challenged claims are entitled to a priority date of December 27, 2009. Bard reserves the right to challenge this priority date.

C. Prosecution History

Initial filing. The '761 patent was filed with 47 claims on June 3, 2011 as application no. 13/153,265. Claim 1 was directed to a pediatric patient aid:

> A pediatric patient aid, comprising:
>
> a set of patient information disposed on a first portion of the pediatric patient aid, the set of patient information comprising post-procedure information for caring for a medical device applied to a patient; and
>
> an activity card disposed on a second portion of the pediatric patient aid.

(Ex.1004, 516-521.)

Restriction/Election. Examiner Natalie Pass issued a restriction requirement, and Applicants elected claims 1-8 directed to "using printed matter" and cancelled the remaining claims 9-47. (Ex.1004, 395-396.)

Office Action/Amendment. On March 5, 2013, Examiner Pass rejected independent claim 1 based on U.S. Patent No. 6,004,136 to Ehrenpreis (Ex.1027). Applicants responded by amending claim 1 to include the limitation "the pediatric patient aid comprising a request that recipient be like a character depicted on the activity card." (Ex.1004, 349-354.)

Final Office Action. On July 12, 2013, Examiner Pass issued a final Office Action. She rejected claim 1 based on Ehrenpreis and U.S. Patent Application Pub. 2004/0161732 to Stump et al. (Ex.1028). (Ex.1004, 329-331.) Examiner Pass relied on Stump to address the newly added limitation. In Stump, a child selects character facial expressions from a card to indicate how he or she feels. (Ex.1028; Ex.1004, 330.)

Appeal. Applicants appealed the final rejection to the Patent Trial and Appeal Board ("PTAB"). Applicants argued that requesting a recipient to be like a character depicted on the card is different than Stump's requesting an indication of feelings based on character facial expressions. (Ex.1004, 281-287.) The PTAB disagreed. In a decision on October 6, 2016 (more than three years after the final Office Action), the PTAB noted that the "only difference between the claimed limitation and Stump lies in the type of request printed on the aid." (Ex.1004, 221.) Because the card would be the same regardless of what was printed on it, the Board held that "the specific type of request constitutes non-functional descriptive matter that may not be relied upon for patentability." (Ex.1004, 221-222.) The PTAB cited *In re Ngai*, 367 F.3d. 1336 (Fed. Cir. 2004) for support. (Ex.1004, 222.)

RCE. In response to the PTAB decision, Applicants filed an RCE with new claims on December 5, 2016. The independent claims, such as new claim 48, were

directed to a tray having multiple compartments and syringes for use in a Foley catheterization procedure. Dependent claims, such as claim 51, further added "a patient aid, the patient aid comprising a set of patient information disposed on a first portion of the patient aid, the set of patient information comprising post-procedure information for caring for the Foley catheter when applied to a patient." (Ex.1004, 109.)

Interview. A new Examiner (Examiner Gilligan) handled the RCE. On June 8, 2017, Examiner Gilligan and Applicants' counsel conducted a telephonic interview. Examiner Gilligan proposed adding subject matter of dependent claims—such as claim 51 directed to a patient aid—to the independent claims to place them in a condition for allowance. (Ex.1004, 68.) Applicants' counsel agreed.

Notice Of Allowability. Examiner Gilligan allowed the claims with the addition of patient aid limitations. He listed the closest prior art as Ehrenpreis, Stump, U.S. Patent Application Pub. 2006/0271019 to Stoller (Ex.1029) and the published application of Solazzo (Ex.1018; "Solazzo Publication"). (Ex.1019, 11-12.) Examiner Gilligan stated that these references disclose "a tray for a Foley catheter, syringes and lubricant." (Ex.1019, 11.) Examiner Gilligan also noted that the "prior art discloses an instructional patient aid." (Ex.1019, 11.) But, in his view, "the prior art does not teach or fairly suggest the particular combination and

arrangement of the claimed compartment with the particular compartments, barriers, and items in combination with the claimed patient aid." (Ex.1019, 11-12.)

Issuance. The '761 patent issued on October 24, 2017.

D. Level Of Ordinary Skill

A person of ordinary skill in the art ("POSITA") in the field of the '761 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 had a bachelor's degree in an alternative technical field and about two years' experience in the packaging of medical devices. This person would also have had an understanding of and experience with thermoforming and the design of thermoformed packages. One of ordinary skill in the art would not need to be a practitioner that would use the claimed methods or products (*i.e.*, catheterization trays), but would have learned about the procedures from those skilled in the procedures for which the claimed products and methods would be used (*e.g.*, a nurse). (Ex.1002, ¶14.)

E. Litigation And Other Matters

Patent Owner has asserted the '761 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 '761 patent should be accorded their ordinary and customary meanings as understood by one of ordinary skill in the art and consistent with the '761 patent's disclosure. Accordingly, no term or phrase requires specific construction to find that the challenged claims are invalid.

Nevertheless, Bard notes that Patent Owner has proposed constructions in district court litigation. The first two Patent Owner constructions below are from

Medline III, where the '761 patent is at issue, while the third Patent Owner construction is from *Medline II*. (Ex.1022; Ex.1023, 13.)

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

The application of the art in this Petition would meet the above claim language under Patent Owner's constructions. Indeed, the application of art in this Petition would also meet Bard's constructions of these terms in *Medline II* and *III*. (Ex.1023; Ex.1024; Ex.1026, 8, 11, 13, 18.)

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

Before addressing the individual Grounds, it is important to note that the claimed trays/container have a number of limitations directed to the manner in which the trays are used. For example:

- "the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter" (claims 1 and 19);

- "the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray" (claim 10); and
- "the first compartment defining a lubricating jelly application compartment to lubricate the Foley catheter with the lubricating jelly from the one of the first syringe or the second syringe when at least a portion of the Foley catheter is passed from the second compartment into the first compartment while remaining within a perimeter defined by the single-layer surface (claim 15).

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

Here, if the prior art discloses all the recited chambers (or compartments), as does Solazzo, a "lubricating jelly application chamber" or a chamber "to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray" does not differentiate the challenged claims from Solazzo because these claims are directed to how the chambers are used.

VI. "PATIENT AID" AND "PRINTED INSTRUCTIONS" DESERVE NO PATENTABLE WEIGHT

All the independent claims recite a tray or container comprising a "patient aid":

- "a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient" (claims 1 and 10);
- "information, disposed on a first portion of a patient aid, for caring for the Foley catheter when applied to a patient" (claim 15); and
- "post-procedure information for caring for the Foley catheter when applied to a patient, wherein the post procedure information is disposed on a first portion of a patient aid" (claim 19).

Dependent claims 4, 13, 17 and 22 recite that the tray or container further comprises "printed instructions for using the tray." Additional dependent claims (claims 5, 7-9, 14, 18 and 25) further define the content of the printed instructions.

None of these limitations deserves patentable weight.

First, if the claimed tray or container is known—which Bard will show below—then the addition of a "patient aid" or "printed instructions" does not render the tray or container patentable according to *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). There, the Court found that the applicants were not entitled "to patent a known product by simply attaching a set of instructions to that product." Medline is similarly not entitled to patent its trays/container by simply attaching a "patient aid" or "printed instructions" to them. Importantly, *In re Ngai* was cited by the PTAB in affirming the rejections of the original '761 patent claims.

Second, even if the PTAB were to give weight to a "patient aid" or "printed instructions," the content of the aid or instructions is certainly not entitled to patentable weight. In other words, no weight should be given to the fact that the patient aid "comprises post-procedure information" or the printed instructions have certain "suggestions," "illustrations" or "instructions" on how to dispense lubricating jelly and apply it to the catheter. Once again, the PTAB decision in the original examination is instructive. The PTAB affirmed the rejection of the claims precisely because it did not give weight to the content (a "request") of the claimed pediatric aid. Because the substrate (*e.g.*, a card) would be the same regardless of what was printed on it, the Board held that "the specific type of request constitutes non-functional descriptive matter that may not be relied upon for patentability."

(Ex.1004, 221-222.) Medline never appealed the PTAB's analysis. The result should be the same here as to the content of the patient aid or printed instructions.

There is more. The '761 patent is part of a complex patent portfolio. (Ex.1017.) In another application (13/153,300), Medline claimed a "patient aid" comprising a greeting card appearance. The Examiner rejected the claims, and Medline once again appealed. And, once again, the PTAB did not give weight to the content, i.e., the "greeting card appearance," on a patient aid. (Ex.1033, 5-7.) The PTAB noted that the "function of the aid of educating and encouraging patients (*see* Spec. ¶108) would be the same regardless of the color, phrasing, or images on the aid are healing, inspirational, or aesthetically pleasing." (Ex.1033, 6.) Medline did not appeal the PTAB decision, and the application went abandoned.

Both of these PTAB decisions thus direct the PTAB here to give no weight to the content of the "patient aid" or "printed instructions" in the challenged claims.

Finally, even if the limitations are given weight, Bard herein presents the reference Franks-Farah (Ex.1007) that discloses the limitations at issue.

VII. PRECISE REASONS FOR RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.104(b), Bard respectfully requests cancellation of claims 1-19 and 22-25 of the '761 patent based on the following references:

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

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

Ground	35 U.S.C. §	Claim	Prior Art Reference(s)
1	103(a)	1-9, 10-19, 23-25	Solazzo, Serany, Franks-Farah
2	103(a)	3, 12, 22, 24	Solazzo, Serany, Franks-Farah, Disston

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 1-9, 10-19, 23-25) – Obvious Based on Solazzo, Serany, and Franks-Farah

1. Summary of Solazzo

Solazzo was filed on July 9, 2004, and issued on October 9, 2007. Solazzo is therefore prior art to the '761 patent under at least 35 U.S.C. § 102(b).

Solazzo is directed to an ergonomic, 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, ¶¶120-21.)

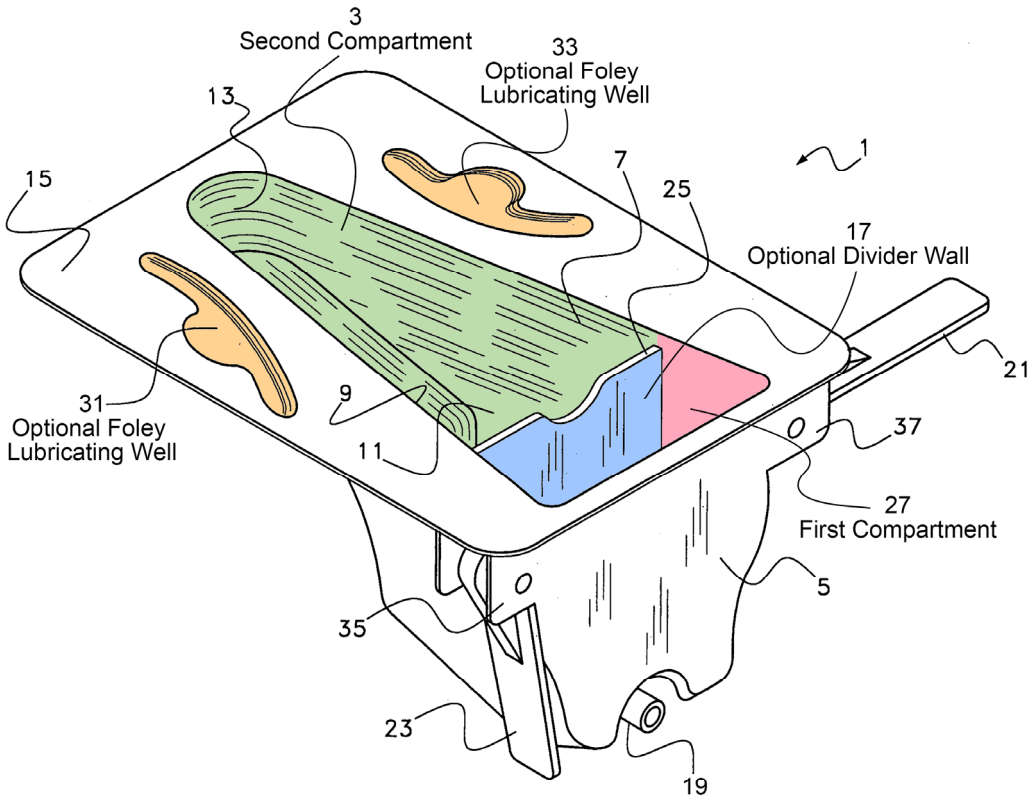


Fig. 1

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.) The tray also includes two additional compartments: "optional Foley catheter lubricating wells 31 and 33." (Ex.1005, 4:21-25.).

Figure 3 (also annotated) provides a top down view of the tray:

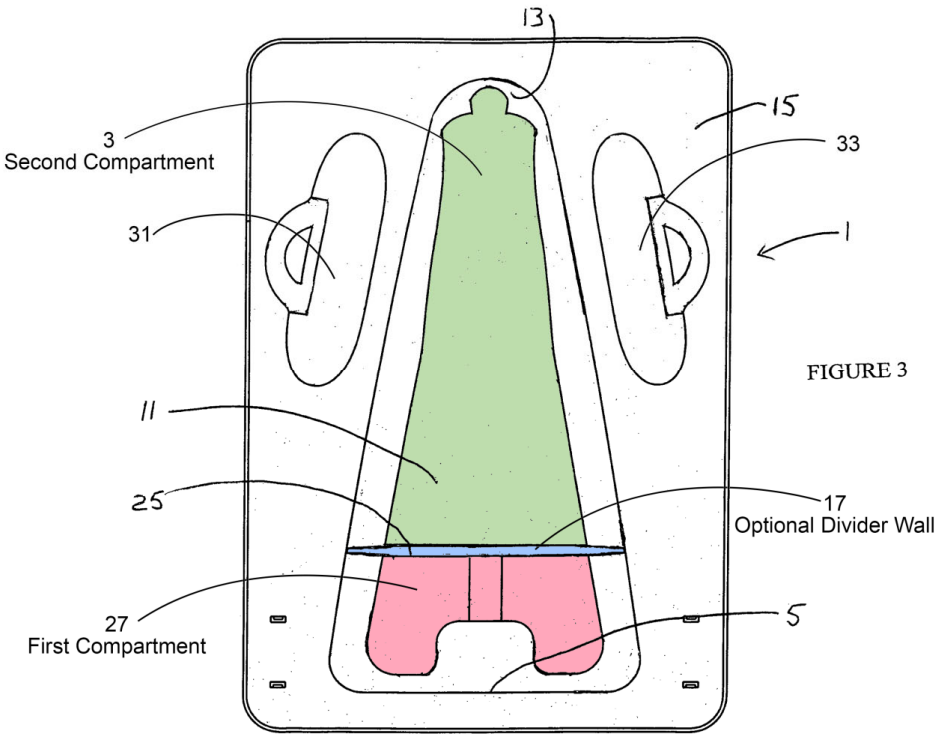


FIGURE 3

The bottom (11) of the tray is inclined, i.e., it "has non-flat topography." (Ex.1005, 3:12-13.) Solazzo further explains that the bottom has a "non constant depth." (Ex.1005, 3:63-66.) Bottom area 11a – a "low area" – and bottom area 11b – a "shallow area" – are shown in Figure 2 (annotated).

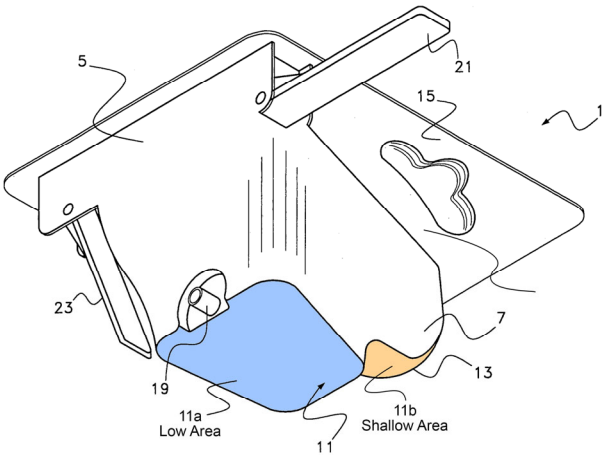


Fig. 2

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, urinary tract lubricant, surgical gloves, inflation syringe, irrigation syringe, evacuation tubing, and antiseptic solutions. (Ex.1005, 3:14-24, 4:1-8; Fig. 8; Ex.1002, ¶¶127-29.)

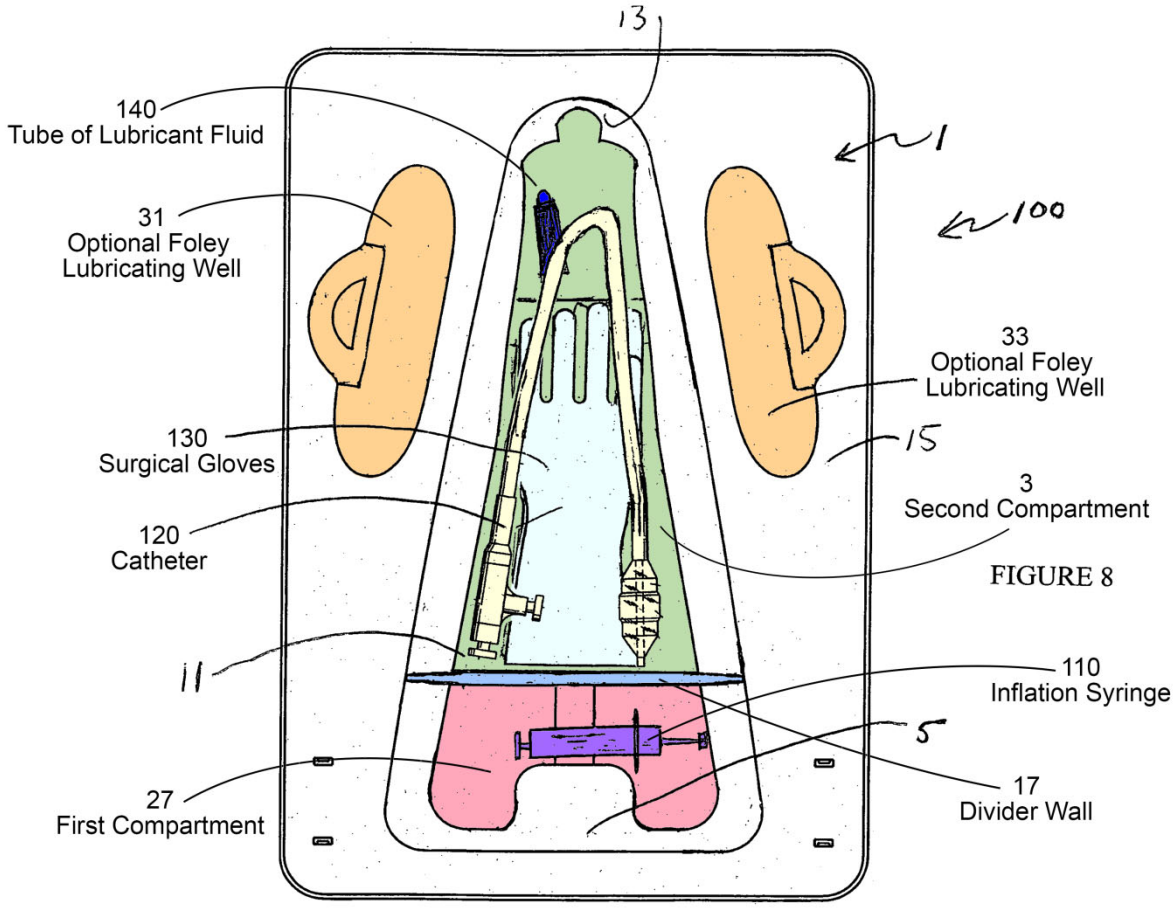


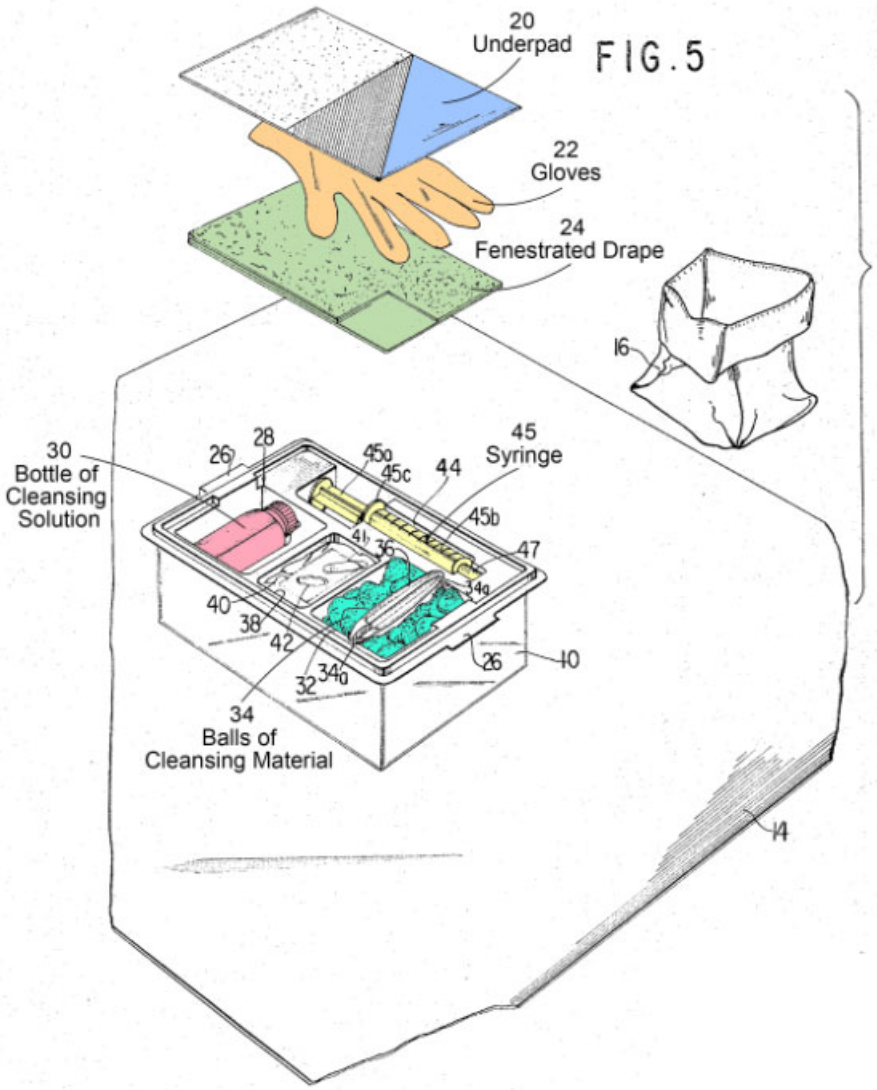
FIGURE 8

2. Summary of Serany

Serany issued on July 4, 1967. Serany is therefore prior art to the '761 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 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, ¶¶137-40.) The package includes a multi-compartment single-layer tray 12 mounted on a box 10 and enclosed with a sealed outer envelope 16 and an inner wrap 14 that unfolds to provide a sterile field work area (as shown in the figures in

Section II of this Petition and Figure 5 below). (Ex.1006, 1:60-72, 2:17-20; Figs. 1-5.)



3. Summary of Franks-Farah

Franks-Farah was issued on January 11, 2005. Franks-Farah is therefore prior art to the '761 patent under at least 35 U.S.C. § 102(b).

Franks-Farah teaches a urinary catheter kit that includes common devices for performing a catheterization procedure: "The system contains apparatus for at

least one intermittent male catheterization and includes at least one male catheter, antibacterial soap, a lubricant, step-by step-instructions, and a container, where the above named items are positioned inside the container." (Ex.1007, Abstract.)

Franks-Farah teaches a urinary catheter kit with printed aids and instructions for a catheterization procedure. (Ex.1002, ¶¶145-52.) Specifically, the tray "includes extremely detailed and specific step-by-step instructions 34 as illustrated in FIGS. 2A and 2B that the user uses with the intermittent catheterization system 1." (Ex.1007, 4:12-16.) Franks-Farah explains that "the user may be the patient himself, the patient's caregiver, an in-home care provider or a healthcare provider which, for brevity, are referred herein as the 'user.'" (Ex.1007, 3:34-38.)

The step-by-step instructions address procedures before and after insertion of the catheter. For example, Franks-Farah teaches cleansing hands in Step 1 of Figures 2A. Step 7 in Figure 2A relates to urine flow: "The bladder will empty while you hold the Catheter in place." Step 10 in Figure 2B relates to the amount of flowed urine: "Check the level of urine in the Container."

Franks-Farah also describes a tray that includes a "patient education system" including "a set of black and white step-by-step instructions without illustrations (referred to herein as self-care documentation)." (Ex.1007, 7:23-33; Fig. 4.) The self-care documentation may be used by a practitioner to teach a patient how to perform a catheterization procedure. (Ex.1007, 2:48-55.)

4. The Combination

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

1) Claim 1

a. *Preamble and 1[a]:* *"A tray configured to accommodate a Foley catheter…"*

Solazzo discloses "*a tray configured to accommodate a Foley catheter, the tray comprising: a surface defining a single layer tray comprising at least two compartments separated by a barrier*."

Solazzo discloses a tray with "two separate compartments" with a barrier in between (divider wall 17) as shown in Figure 1 below. (Ex.1005, 2:61-63.)

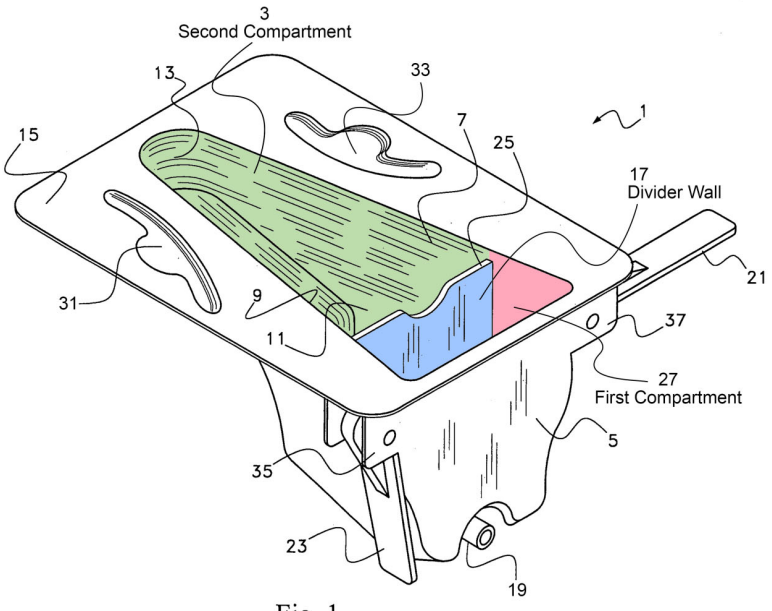
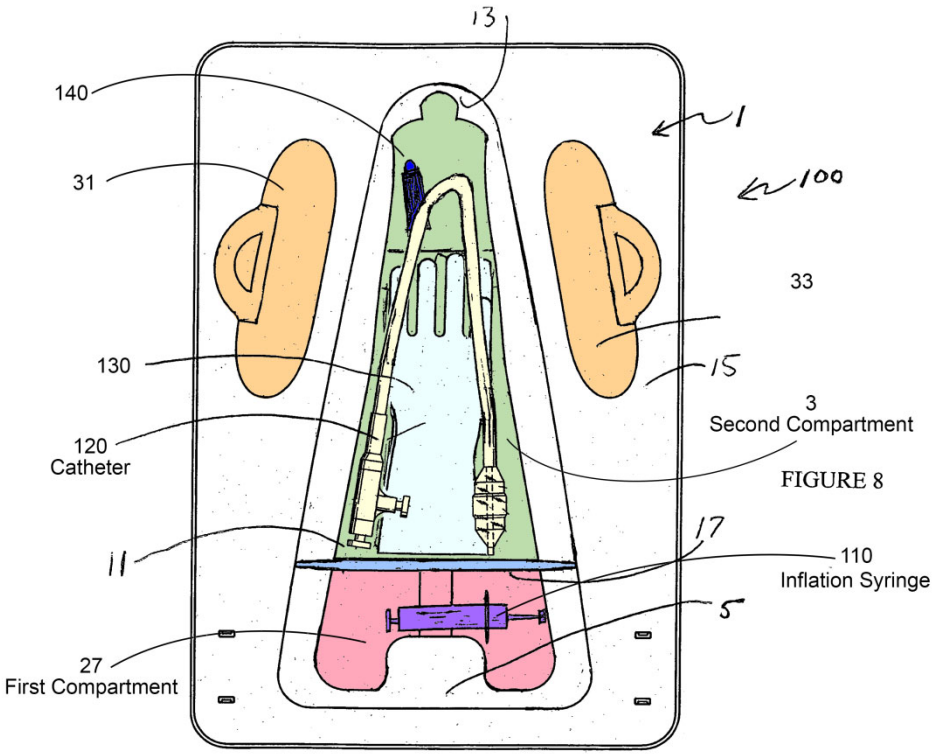


Fig. 1

The second compartment (compartment 3) holds a Foley catheter (catheter 120), as shown in annotated Figure 8 below. Thus, the tray is configured to accommodate a Foley catheter.



Accordingly, Solazzo discloses this claim element. (Ex.1002, ¶¶156-60.)

b. *1[b]:* *"a first compartment supporting a first syringe and a second syringe at different heights…"*

Claim 1[b] requires "*a first compartment supporting a first syringe and a second syringe at different heights based upon order of use in a Foley catheterization procedure*."

(i) ***"…a first syringe and second syringe"***

Solazzo discloses a kit with two syringes: an "inflation syringe" and an "irrigation syringe." (Ex.1005, 3:15-24.) Solazzo thus expressly discloses a kit that includes two syringes. Solazzo's kit also includes "a tube of lubricant fluid 140" disposed in the tray" shown in Figure 8 below. (Ex.1005, 4:41-46.)

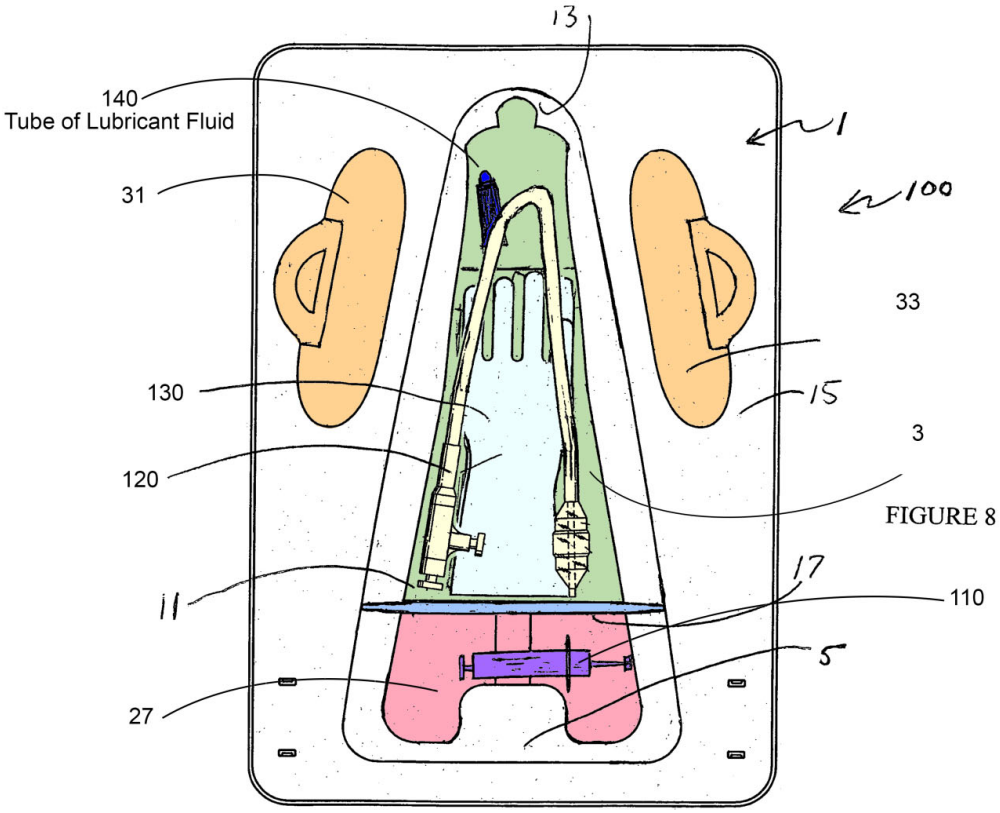


FIGURE 8

It would have further been obvious to a person of ordinary skill in the art 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, ¶¶165-

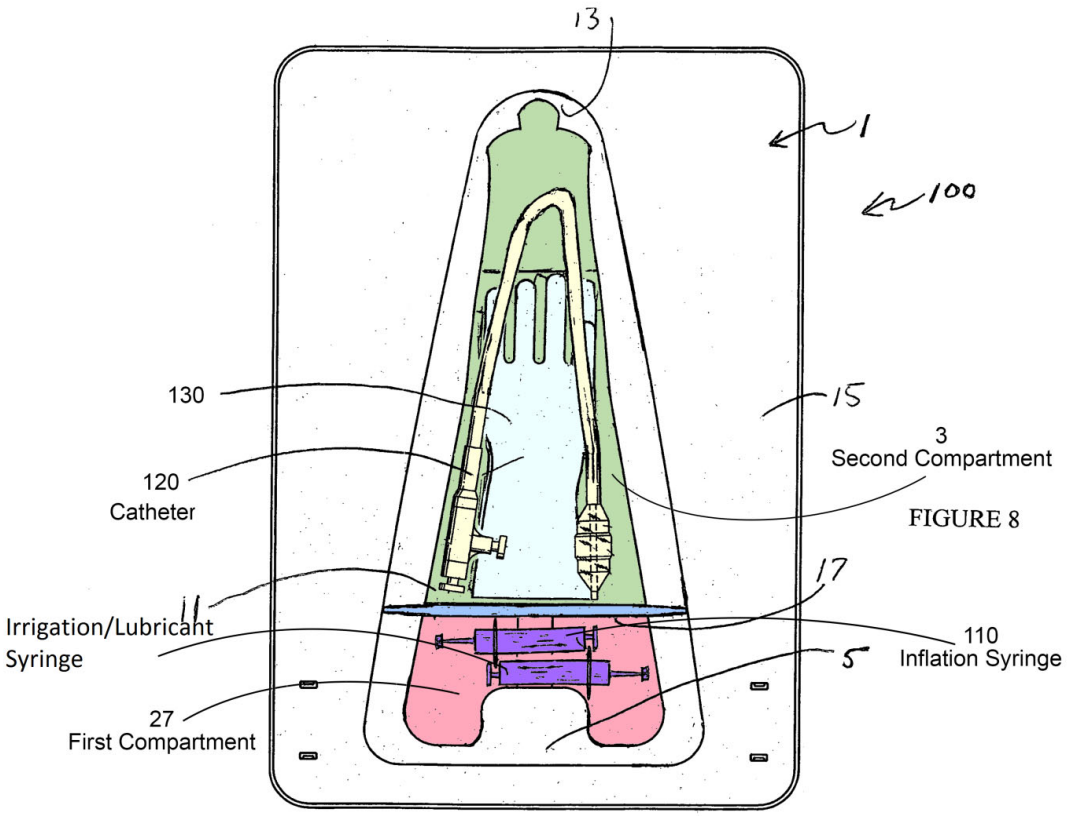
66.) Indeed, the Board has found such a substitution to be obvious. (See IPR2015-00513, 13 ("On the current record, we agree with Petitioner that "[s]ubstituting one container for another type of container (e.g., substituting a lubricant in a 'packet' with a lubricant in a syringe) would have been an obvious substitution of components known to be suitable to yield predictable results.").)

Further, a lubricant syringe (unlike a tube) has a tapered tip that allows for injection of lubricant directly into a male patient's urethra (a favored approach of urologists to avoid wasting lubricant). (Ex.1003, ¶22.) Thus, a known technique (injecting lubricant directly into a patient's urethra using a lubricant syringe) is applied to improve a known device (a Foley catheter tray) to yield predictable results. (Ex.1002, ¶166-67.)

(ii) ***"a first compartment supporting a first syringe and a second syringe…"***

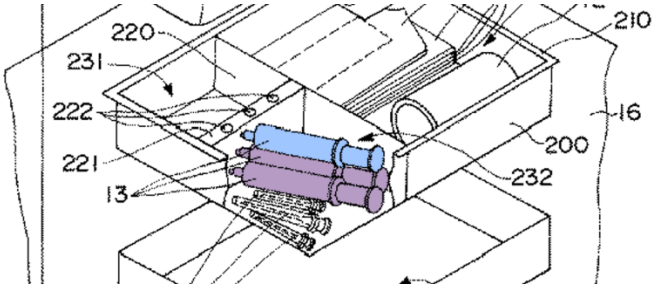
Compartment 27 of Solazzo holds at least inflation syringe 110. (Ex.1005, Fig. 8.) The location of the "irrigation syringe" (Ex.1005, 3:22) within the tray of Solazzo is not expressly provided. But there are very limited locations where it would likely be held, e.g., compartment 3 or compartment 27. Compartment 27 is a natural place to store the irrigation 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. (Ex.1002, ¶168.)

Modified Figure 8 below shows the first compartment accommodating two syringes: an inflation syringe 110 and an irrigation or lubrication syringe. (It also shows removal of the optional lubricating wells.)



It was well-known in the art to group like items in the same compartment of a tray as shown in modified Figure 8 above. 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.)

Additionally, Imai discloses grouping syringes in the same compartment of a catheter tray, as shown in Figure 1 below:



Accordingly, a POSITA would have been motivated to group at least two syringes in the first compartment of Solazzo, so as 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 (removing the lubricant and/or irrigation syringe from the second 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, ¶¶173-74.)

Thus, Solazzo in view of Serany discloses *a first compartment supporting a first and a second syringe.*

(iii) ***"…a first syringe and a second syringe at different heights based upon order of use in a Foley catheterization procedure…"***

When the first compartment holds multiple syringes, Solazzo further discloses the syringes are supported "*at different heights based upon order of use in a Foley catheterization procedure*."

A lubricant syringe is generally used in a Foley catheterization procedure before an inflation syringe because a catheter must be lubricated before insertion and the catheter must be inserted before the balloon is inflated. (Ex.1003, ¶28.) This order of procedure with respect to these syringes is taught by Solazzo: "The gloves being worn by the surgeon, the catheter being lubricated, inserted and then inflated with fluid using the syringe." (Ex.1005, 4:46-48.)

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:

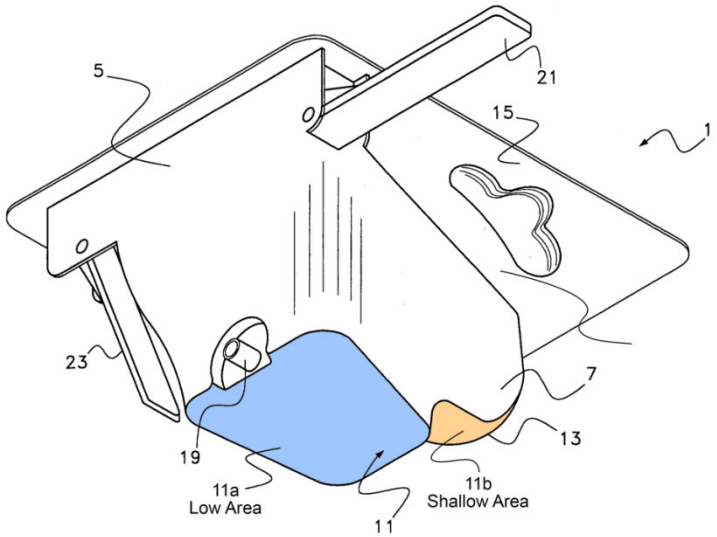
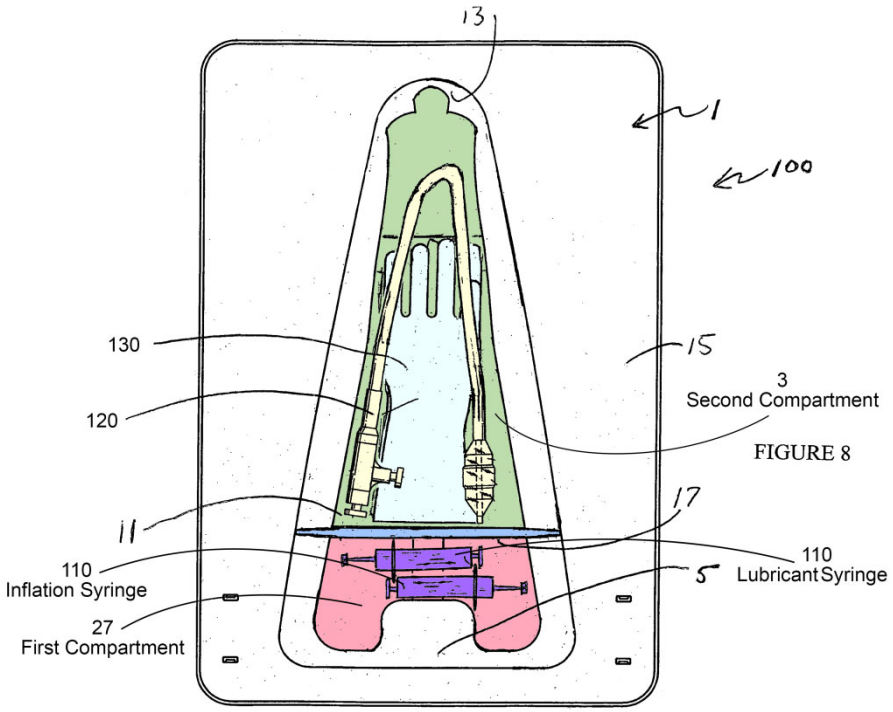


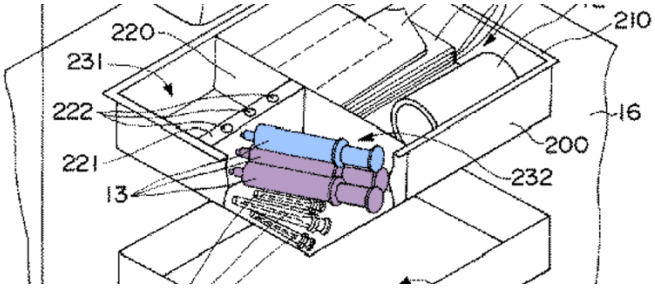
Fig. 2

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, ¶¶178-79.)

A POSITA would be motivated to maintain this same arrangement 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, ¶¶180-83.) For example, modified Figure 8 shows such an arrangement:



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).

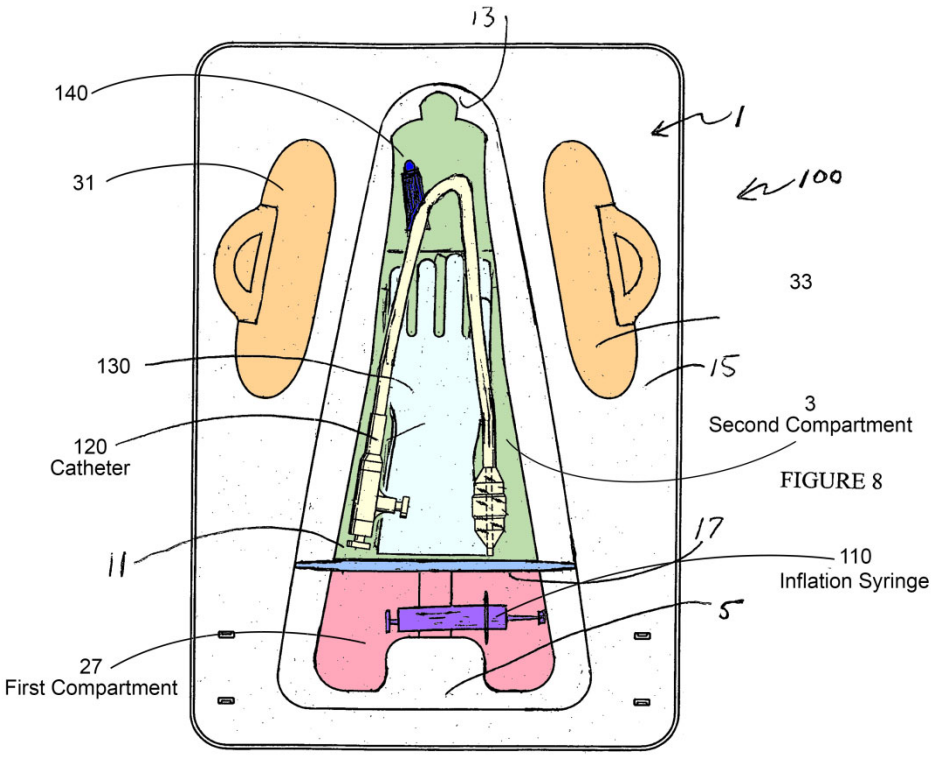


In either configuration, the syringes are supported "*at different heights based upon order of use in a Foley catheterization procedure*" because a lubricant syringe may be used first in a Foley catheterization procedure. (Ex.1002, ¶¶185-87; Ex.1003, ¶28.)

Accordingly, the combination of Solazzo in view of Serany discloses this claim element. (Ex.1002, ¶¶168-88.)

c. ***1[c]****: a second compartment to accommodate the Foley catheter…"*

Solazzo discloses "*a second compartment to accommodate the Foley catheter*." Specifically, compartment 3 accommodates a Foley catheter 120 as annotated shown in Figure 8 below:



Accordingly, Solazzo discloses this claim element. (Ex.1002, ¶¶189-90.)

d. ***1[d]:*** *"the barrier separating the first compartment from the second compartment …"*

Solazzo discloses "*the barrier separating the first compartment from the second compartment*." Specifically, Solazzo discloses a barrier (divider wall 17) that separates compartment 27 from compartment 3, as shown in annotated Figure 8 below:

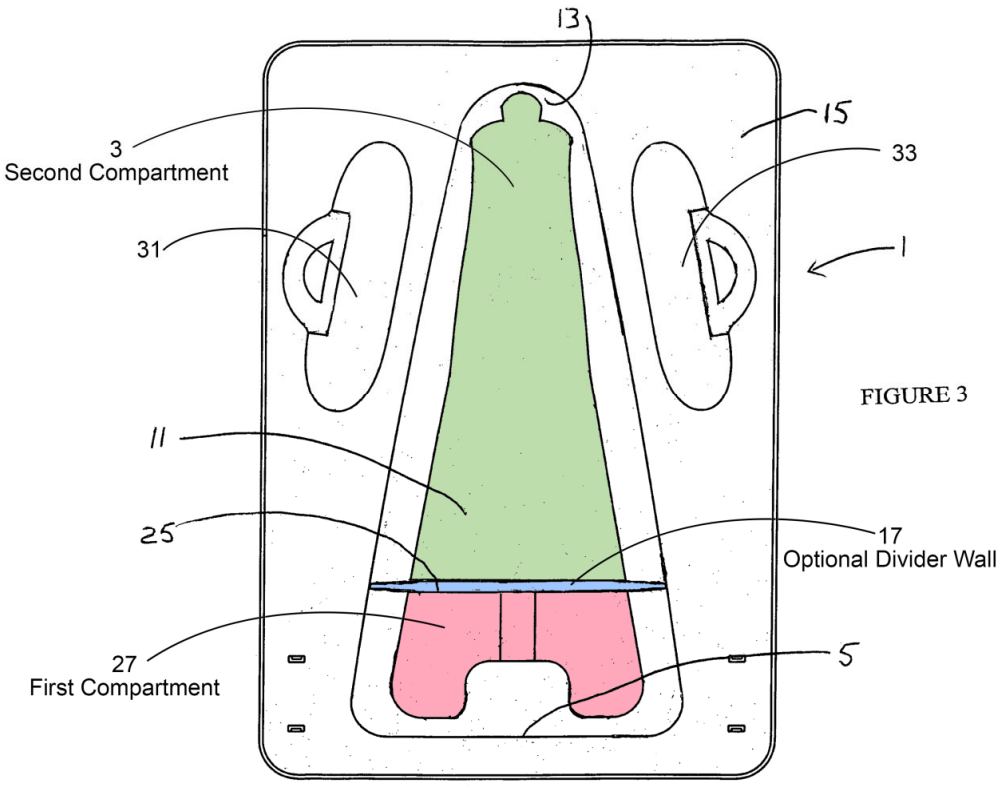


FIGURE 3

Accordingly, Solazzo discloses this claim element. (Ex.1002, ¶¶191-92.)

e. *1[e]:* *"the first compartment defining a lubricating jelly application chamber ..."*

Solazzo in view of Serany discloses "*the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter*." As discussed in Section V, the manner of using the claimed tray (e.g., a lubricating jelly application chamber) does not differentiate the tray over the prior art. In any event, the limitation is met by the combination.

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. (Ex.1003, ¶¶21-22.)

The '761 patent describes the "first compartment" as being "a lubricant applicator for the catheter" when the first compartment is *stair-stepped*. (Ex.1001, 7:38-59.) Specifically, lubricating jelly may be "spread" along the "second step portion 117," which forms a "channel" as it is lower in the tray than the "first step portion 116." (Ex.1001, 9:31-35.)

Solazzo discloses essentially the same structure as the '761 patent in this respect. 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.)

The "terraced arrangement" of the bottom member of Solazzo would necessarily function as a "*lubricating jelly application chamber*" to lubricate the catheter for the same reason a "stair-stepped" base member functions as a lubricating jelly application chamber. Specifically, the "low area 11A," which includes the bottom of 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. (Ex.1002, ¶¶197.)

Also, the Foley catheter lubricating wells are "optional." (Ex.1005, 4:21-25.) The absence of the optional lubricating wells would have provided further motivation to lubricate within compartment 27. (Ex.1002, ¶¶198-199.)

Furthermore, Serany teaches a multi-purpose compartment that "conveniently houses and stores the accessories to provide protection against damage during shipment and make such accessories readily available while at the same time facilitating their use." (Ex.1006, 4:2-8.) A person of ordinary skill in the art would have been motivated by Serany to use compartment 27 of Solazzo to

have a multi-purpose functionality: both as place to *store* the lubricant 140 and as a location to *lubricate* the catheter within the tray. (Ex.1002, ¶¶200-202.)

Accordingly, the combination of Solazzo in view of Serany discloses this claim element. (Ex.1002, ¶¶193-203.)

f. *1[f]:* *"...a patient aid ..."*

Claim 1[f] requires "*a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter when applied to a patient*."

The *patient aid* element should not be given patentable weight for the reasons described above at Section VI. Even if patient aid is given patentable weight, claim limitations directed to the *content* of the printed matter are certainly not a patentable distinction over the prior art. Regardless, the printed instructions found in the prior art includes the same content that Medline purports to claim.

Franks-Farah teaches a urinary catheter kit with printed instructions for performing a urinary catheterization procedure that are designed to be used by a patient, caregiver, or healthcare provider and that further include post-procedure information. (Ex.1007, 2:5-7.) Franks-Farah is analogous art to Solazzo because both references are directed to urinary catheterization kits. Franks-Farah discloses two forms of printed instructions designed to aid a patient: (1) "extremely detailed and specific step-by-step instructions;" and (2) "self-care documentation." Both

can be viewed as patient aids.

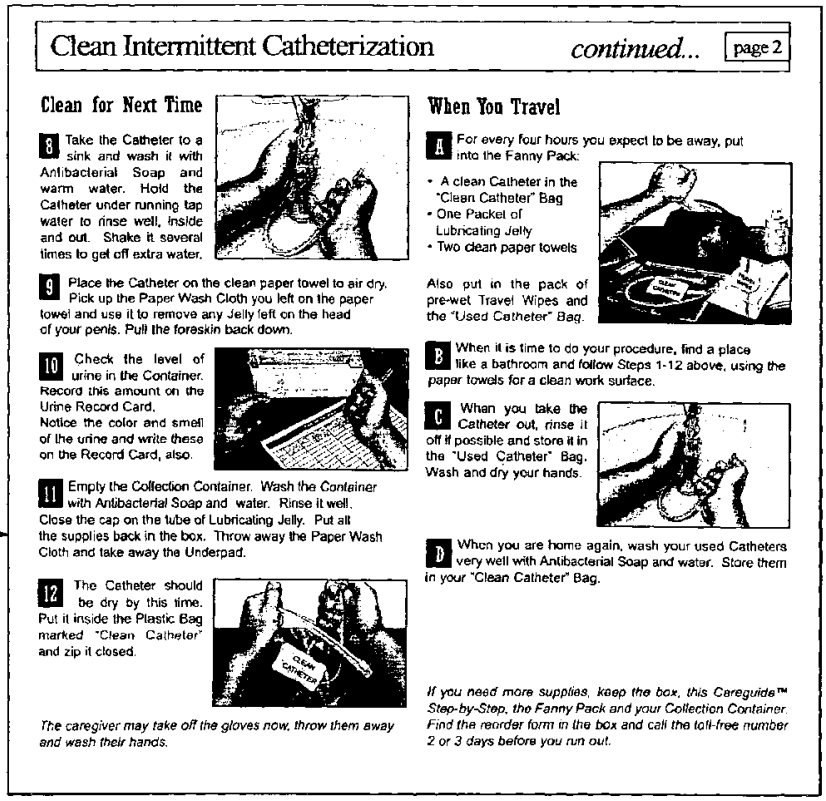
The "specific step-by-step instructions" are a patient aid, because they instruct a user (including a patient) how to perform catheterization using the kit of Franks-Farah. (Ex.1007, Fig. 2A; Ex.1002, ¶¶207-08.) Figure 2A includes step-by-step procedural information for performing an intermittent catheterization procedure. (Ex.1002, ¶209.) Step 1 refers to washing hands which is consistent with Franks-Farah's emphasis on "strict aseptic techniques." (Ex.1007, 1:51-53.) Figure 19 of the '761 patent also emphasizes washing hands.

FIG. 2A

Figure 2B shows page 2 of the step-by-step instructions with further post-procedural information. (Ex.1002, ¶¶210.) Step 10 – how to check the level of

urine in the container – is similar to the "Tell somebody whenever the bag is more than half full" in Figure 19 of the '761 patent as they both relate to the amount of flowed urine. Solazzo also reflects a concern for the amount of flowed urine. (Ex.1004, 4:17-20.)

FIG. 2B



In view of Franks-Farah, a POSITA would have been motivated to include a patient aid (such as the step-by-step instructions) in the catheter tray of Solazzo.

First, Franks-Farah's step-by-step instructions ensure that Solazzo's urinary catheterization is performed with "strict aseptic techniques," which is critical to reducing catheter related infections. (Ex.1007, 1:51-53; 4:13-17.) For example,

informing the patient about the importance of cleansing his and any practitioner's hands is an "aseptic technique" that is taught by the instructions of Franks-Farah and also highlighted in Figure 19 of the '761 patent. (Ex.1002, ¶¶212-13.)

Second, a signature block (provided on the self-care documentation) ensures that important procedural and post-procedural information is delivered by the healthcare provider to the patient to aid him or her. (Ex.1007, 7:15-23; Fig. 4.) This feature provides additional motivation to include a patient aid in the tray of Solazzo. (Ex.1002, ¶¶215-223.)

Third, a POSITA would have been motivated to include patient instructions in the tray of Solazzo that describe post-procedural information such as the importance of monitoring urine flow. Urine flow is a prominent feature of the procedures described by both the Solazzo and Franks-Farah trays. Awareness of flowed urine is a technique that is also highlighted in Figure 19 of the '761 patent. (Ex.1002, ¶214.)

Accordingly, the combination of Solazzo in view of Franks-Farah discloses this claim element. (Ex.1002, ¶¶204-224.) Thus, the combination of Solazzo in view of Serany and Franks-Farah renders this claim obvious.

2) Claim 2

For the reasons set forth at claim 1[b], Solazzo in view of Serany discloses "*wherein a higher of the first syringe or the second syringe is for use in the Foley*

catheterization procedure before a lower of the first syringe or the second syringe."

3) Claims 4, 13, 17

a. *4[a], 13[a], 17[a]:* *"a wrap disposed about the tray"*

Claims 4[a], 13[a], and 17[a] require "*a wrap disposed about the tray*."

Solazzo discloses an "ergonomic urological catheterization/irrigation tray kit," but does not explicitly 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 Foley catheter tray that is "enclosed within a wrap 14." (Ex.1006, 1:60-63.) Annotated Figure 2 shows the tray enclosed within one or more folds of the at least one layer of wrap material 14 in green:

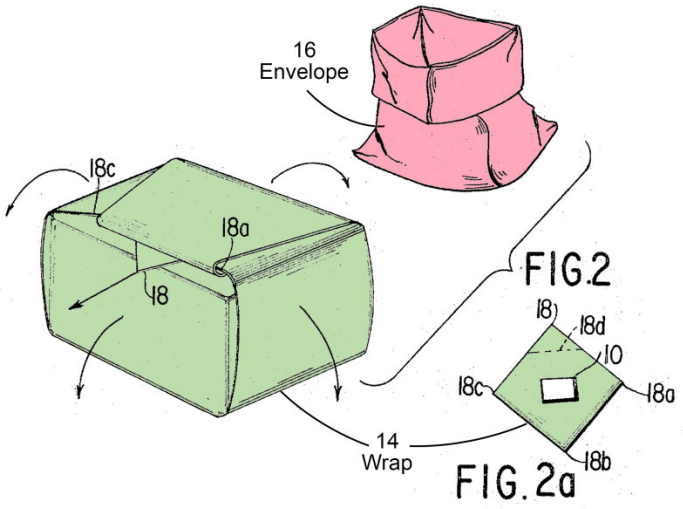


Figure 3 (annotated) of Serany shows the wrap 14 when unfolded:

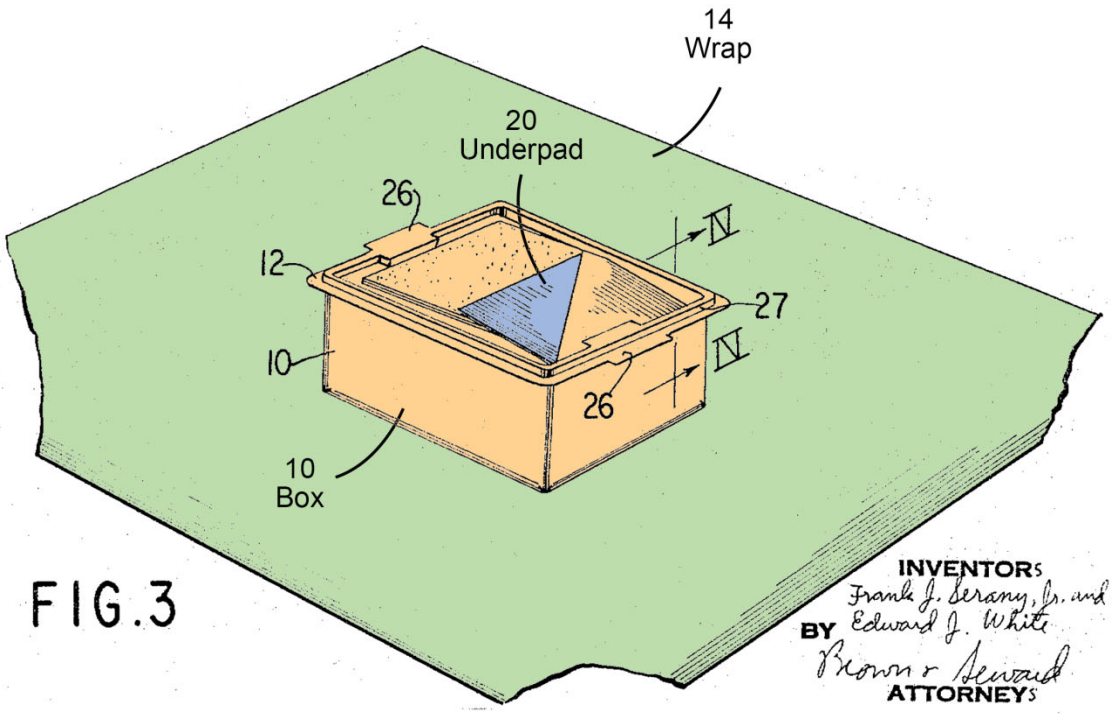


FIG.3

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

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, ¶233.)

Furthermore, a POSITA would have been motivated to enclose the tray of Solazzo in a wrap in view of Serany. Solazzo teaches sterile components such as "a Foley catheter" and "surgical gloves." (Ex.1005, 3:15-24.) Serany teachings 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, ¶234-35.) Thus, wrapping the tray of Solazzo in Serany's wrap would preserve the sterility of Solazzo's components provided inside the tray (not to mention maintain the components within the tray in their respective compartments and prevent damage to the components).

Accordingly, the combination of Solazzo in view of Serany discloses these claim elements. (Ex.1002, ¶¶227-36.)

b. ***4[b], 13[b], 17[b]:*** *"printed instructions for using the tray"*

Claims 4[b], 13[b], 17[b] requires "*printed instructions for using the tray*."

The *printed instructions* element should not be given patentable weight for the reasons described above at Section VI. Even if printed instructions are given patentable weight, claim limitations directed to the *content* of the printed matter certainly are not a patentable distinction over the prior art. Regardless, the printed

instructions found in the prior art includes the same content that Medline purports to claim.

Franks-Farah discloses "*printed instructions for using the tray*." As explained at claim 1[f], Franks-Farah, discloses two forms of printed instructions for using the tray: (1) "specific step-by-step instructions;" and (2) "self-care documentation."

The step-by-step instructions are used by a healthcare provider, caregiver, or patient to perform a catheterization procedure. (Ex.1007, 3:32-37; Figs. 2A and 2B.) The self-care documentation includes "a set of black and white step-by-step instructions without illustrations (referred to herein as self-care documentation)." (Ex.1007, 2:46-48; Fig. 4)

In view of Franks-Farah, a POSITA would have been motivated to include printed instructions (such as the self-care documentation) in the tray of Solazzo. (Ex.1002, ¶242.) Franks-Farah provides motivation by teaching self-care documentation to allow a medical care professional to instruct the patient regarding the catheterization procedure. (Ex.1007, 7:15-23; Fig. 4.) Further, the signature block on the self-care documentation ensures that the patient receives and understands the instructions. (Ex.1007, 7:15-23; Fig. 4; Ex.1002, ¶243-45.)

Accordingly, the combination of Solazzo in view of Franks-Farah discloses this claim element. (Ex.1002, ¶237-46.)

c. ***4[c], 13[c], 17[c]:*** *"a sealed bag disposed about the wrap"*

Claim 4[c], 13[c], and 17[c] require "*a sealed bag disposed about the wrap*."

Solazzo discloses an "ergonomic urological catheterization/irrigation tray kit," but does not explicitly describe how the tray is packaged for shipping.

Serany discloses "a sealed bag disclosed about the wrap." Specifically, Serany discloses a Foley catheter tray that is "encased within an envelope 16, which has a "heat seal 17." (Ex.1006, 1:60-72.)

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

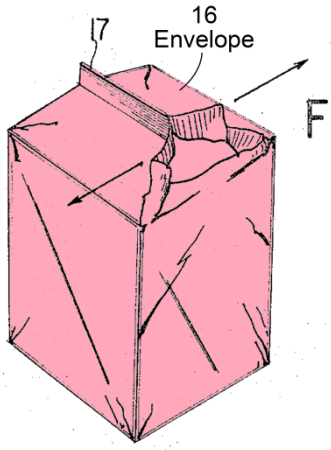


FIG. 1

Serany teaches a packaging solution wherein "components are maintained sterile until the package is opened." (Ex.1006, 1:13-16.) The sealed bag (envelope 16) of Serany maintains the sterility of components within the tray: "The envelope 16 seals the contents to maintain the sterility of the contents, the latter, of course, having been sterilized before or after enclosure in the envelope." (Ex.1006, 1:63-72.)

It would have been obvious to a POSITA at the time of the invention to combine the sealed bag 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 sealed bag 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, ¶¶253-56.)

Accordingly, the combination of Solazzo in view of Serany discloses these claim elements. Thus, the combination of Solazzo in view of Serany and Franks-Farah renders these claims obvious. (Ex.1002, ¶¶253-56.)

4) Claims 5, 9, 14, 18, and 25

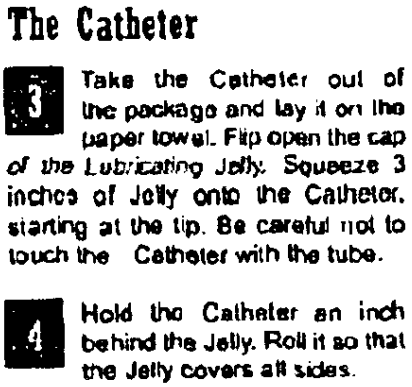
Claims 5, 9, 14, 18, and 25 all recite printed instructions related to lubrication of the catheter. Specifically, claim 5 requires "*the printed instructions to instruct application of the lubricating jelly disposed in one of the first syringe or the second syringe to the Foley catheter using the lubricating jelly application compartment*." Claim 9 requires "*printed instructions instructing passage of a tip of the Foley catheter into lubricating jelly dispensed from one of the first syringe or the second syringe into the first compartment, thereby lubricating the tip of the Foley catheter*."

Claims 14 and 18 require "*the printed instructions instructing dispensation*

of lubricating jelly from [the] one of the first syringe or the second syringe into the first compartment and application of the lubricating jelly to [the at least a portion of] the Foley catheter using the lubricating jelly application compartment." Claim 25 requires "*printed instructions instructing application of lubricating jelly dispensed from the first syringe into the first compartment to at least a portion of the Foley catheter using the lubricating jelly application compartment*."

The *printed instructions* element should not be given patentable weight for the reasons described above at Section VI. Nor should content of the instructions be given patentable weight as the PTAB has repeatedly found. Regardless, such content was known in prior art instructions.

Steps 3 and 4 of the self-care documentation included in the Franks-Farah catheter kit include instructions related to lubricating the catheter:



The Catheter

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

4 Hold the Catheter an inch behind the Jelly. Roll it so that the Jelly covers all sides.

In view of Franks-Farah, a POSITA would have been motivated to include printed instructions in the tray of Solazzo that includes instructions, such as for the healthcare provider, regarding how to lubricate the catheter using the tray of

Solazzo. A POSITA would have specifically been motivated to instruct the use of compartments of the tray, including the first compartment 27, to lubricate the catheter because Solazzo teaches lubricating the Foley catheter in the tray. (Ex.1005, 4:46-48; Ex.1002, ¶264-65.)

Accordingly, Solazzo in view of Serany and Franks-Farah discloses this claim element. (Ex.1002, ¶258-66.) Solazzo in view of Serany and Franks-Farah therefore renders claims 5, 9, 14, 18, and 25 obvious.

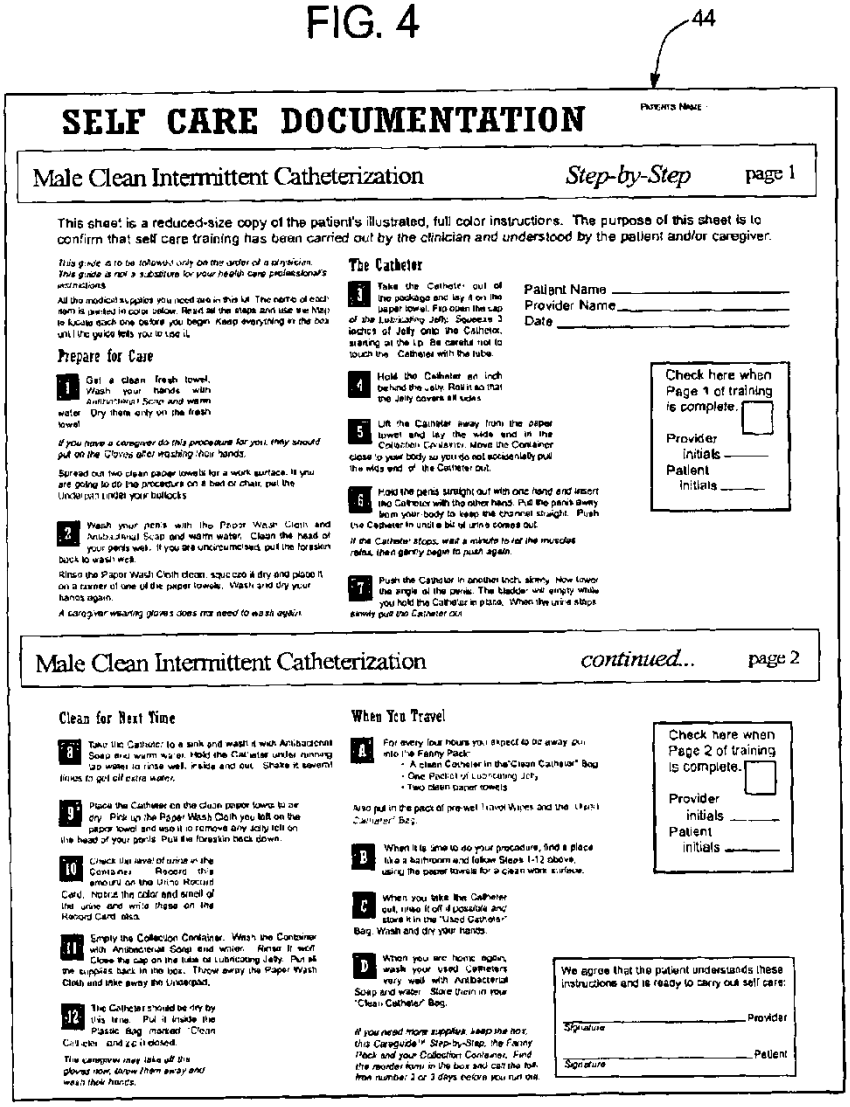
5) Claim 6

Claim 6 requires "*the printed instructions comprising one or more panels separated by one or more folds*."

The *printed instructions* element should not be given patentable weight for the reasons described above at Section VI. Further, the simple act of folding printed instruction does not transform them into a patentable invention. Solazzo in view of Franks-Farah also discloses "*the printed instructions comprising one or more panels separated by one or more folds*."

The self-care documentation includes multiple pages with multiple panels as shown in Fig. 4 below:

FIG. 4



As shown in Fig. 4, the top half labeled "page 1" ensures delivery of a first page of the step-by-step instructions, while the bottom half labeled "page 2" ensures delivery of the second page of the step-by-step instructions. It would have been obvious to a POSITA that the self-care documentation could be folded in half to create at least two panels separated by a fold that is consistent with the top and bottom layout of the printed instructions to reduce the amount of space the

instructions occupy in the tray. (Ex.1002, ¶¶270-75.)

Thus, the combination of Solazzo in view of Serany and Franks-Farah renders this claim obvious.

6) Claim 7

Claim 7 requires "*the printed instructions comprising illustrations showing how to use the Foley catheter and corresponding medical devices on a patient*."

The *printed instructions* element should not be given patentable weight for the reasons described above at Section VI. Nor should content of the instructions be given patentable weight as also discussed in Section VI. Regardless, such content was known in prior art instructions.

Franks-Farah teaches self-care documentation with step-by-step instructions for performing a catheterization procedure using a catheter and related medical devices, and incorporates the illustrations in the step-by-step instructions by stating that "[t]his sheet is a reduced-size copy of the patient's illustrated, full color instructions." (Ex.1007, Fig. 4.) The "step-by-step instructions" of Franks-Farah include color illustrations showing how to use the catheter and related medical devices (e.g., a tube of lubrication). (Ex.1007, Figs. 2A and 2B.)

Accordingly, Solazzo in view of Franks-Farah discloses this claim element. (Ex.1002, ¶¶279-82.)

Thus, Solazzo in view of Serany and Franks-Farah renders this claim

obvious.

7) Claim 8

Claim 8 requires "*the printed instructions comprising suggestions for preventing catheter associated urinary tract infections*."

The *printed instructions* element should not be given patentable weight for the reasons described above at Section VI. Nor should content of the instructions be given patentable weight. Regardless, such content was known in prior art instructions.

Franks-Farah notes that the risk of "catheter-related nosocomial infections can be reduced using strict aseptic techniques":

> The most common nosocomial infections are related to or arise from indwelling urinary bladder catheters (i.e., catheters that remain in the urinary tract for a relatively long length of time). The risk of such catheter-related nosocomial infections can be reduced using strict aseptic techniques (i.e., using gloves, disinfectants, antibacterial soaps, etc.) when handling the catheter.

(Ex.1007, 1:48-54.)

Franks-Farah further teaches instructions that instruct the user to adhere to "strict aseptic techniques." For example, both the step-by-step instructions and self-care documentation instruct a patient to use antibacterial soaps and/or gloves. (Ex.1007, Figs. 2A, 2B, and 4.)

Accordingly, Solazzo in view of Franks-Farah discloses this claim element.

Thus, Solazzo in view of Serany and Franks-Farah renders this claim obvious.

8) Claim 10

a. ***Preamble and 10[a]:*** *A Foley catheter container…"*

For the reasons as set forth at claim 1[a], Solazzo discloses "*a Foley catheter container, comprising: a single layer tray comprising a surface defining at least two compartments separated by a barrier*."

b. ***10[b]:*** *"a first compartment comprising a first compartment base member…"*

Claim 10[b] requires "*a first compartment comprising a first compartment base member, the first compartment to accommodate a first syringe and a second syringe*."

For the reasons set forth at claim 1[b], the combination of Solazzo in view of Serany discloses "*the first compartment to accommodate a first syringe and a second syringe*."

Solazzo further discloses "*a first compartment comprising a first compartment base member.*" Specifically, Solazzo discloses a "terraced" base member (bottom 11) that comprises a first compartment base member ("low area 11A") and a second compartment base member ("shallow area 11B")." (Ex.1005, 3:63-66.) Figure 2 shows the "terraced" bottom of the tray with a first and second base member:

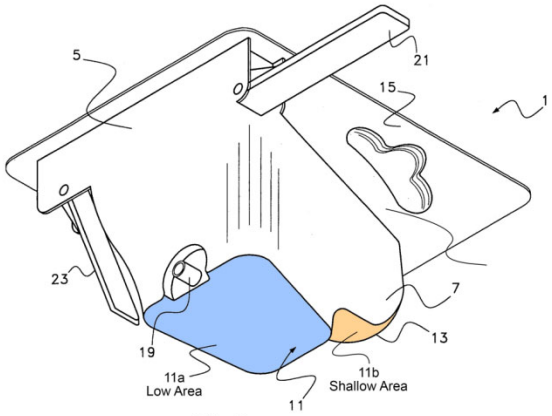


Fig. 2

Thus, Solazzo in view of Serany discloses this claim element. (Ex.1002, ¶¶294-98.)

c. ***10[c]:*** *"a second compartment comprising a second compartment base member"*

For the reasons set forth at claim 10[b], Solazzo discloses "*a second compartment comprising a second compartment base member*."

d. ***10[d]:*** *"the Foley catheter, situated in the second compartment"*

For the reasons set forth at claim 1[c], Solazzo discloses "*the Foley catheter, situated in the second compartment*."

e. ***10[e]:*** *"the barrier separating the first compartment from the second compartment*"

For the reasons set forth at claim 1[d], Solazzo discloses "*the barrier separating the first compartment from the second compartment*."

f. ***10[f]:*** *"the first compartment base member situated at a different height within the tray than the second compartment base member"*

Solazzo discloses "*the first compartment base member situated at a different height within the tray than the second compartment base member*."

Specifically, Solazzo discloses that the "bottom 11 has *terraced* arrangement with low area 11A and shallow area 11B (FIG. 2)." (Ex.1005, 3:63-66.) As shown in Figure 2 below, the first compartment base member 11A is situated at a different height within the tray than the second compartment base member 11B:

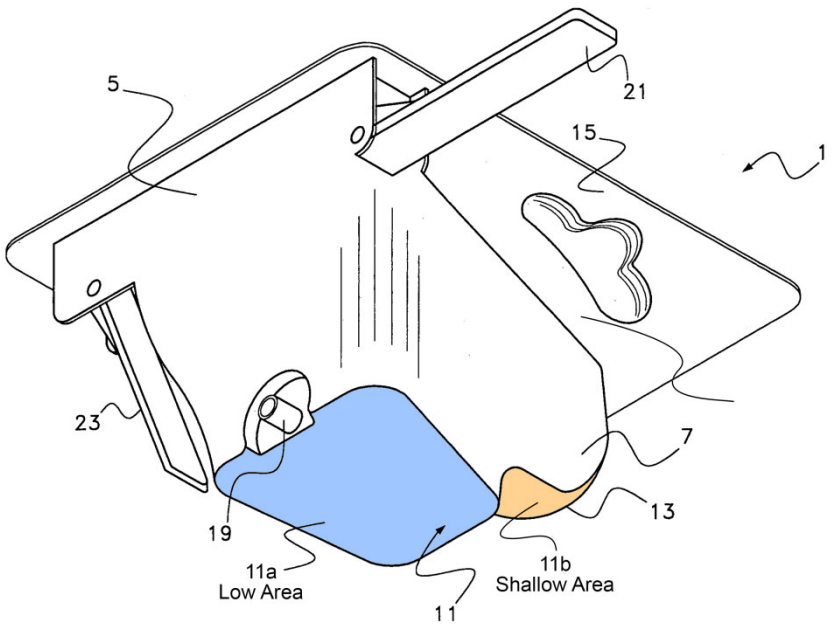


Fig. 2

Thus, Solazzo discloses this claim element. (Ex.1002, ¶304-07.)

g. ***10[g]:*** *"the first compartment defining a lubricating jelly*

> *application chamber to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray"*

Solazzo discloses "*the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter when passed from the second compartment into the first compartment of the single layer tray*." As discussed in Section V, the manner of using the claimed tray (e.g., a lubricating jelly application chamber) does not differentiate the tray over the prior art.

Regardless, for the reasons set forth at claim 1[e], Solazzo discloses "*the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter*."

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:

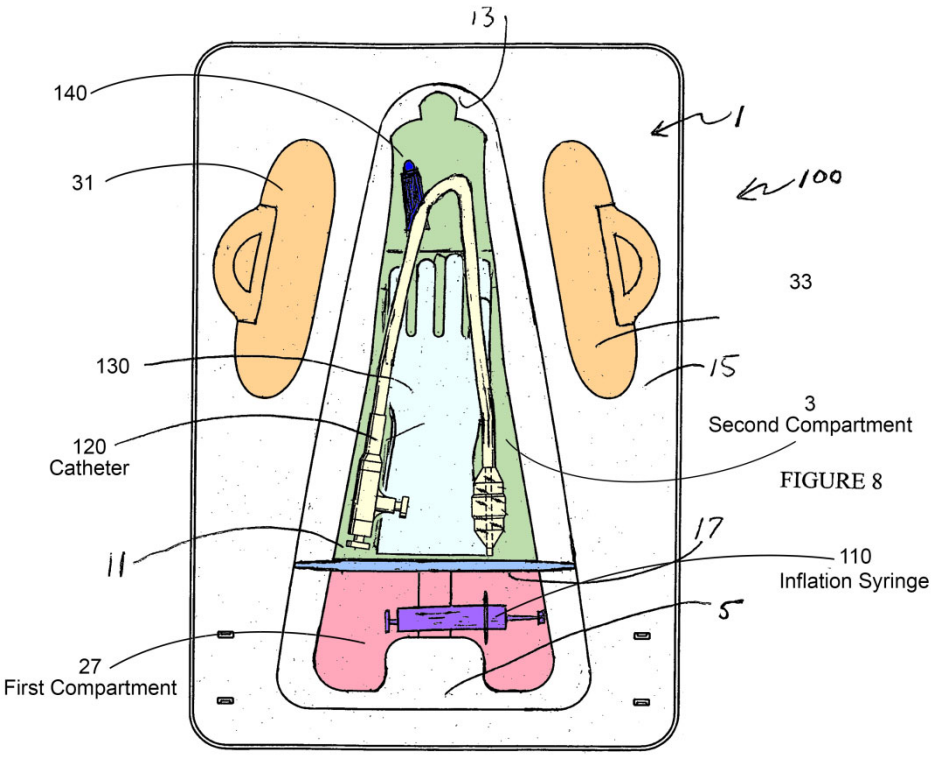


FIGURE 8

The Foley catheter may be passed from the second compartment into the first compartment without removing the catheter from the tray 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.) As such, the catheter may be lubricated while remaining within the perimeter defined by the single-level tray.

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.

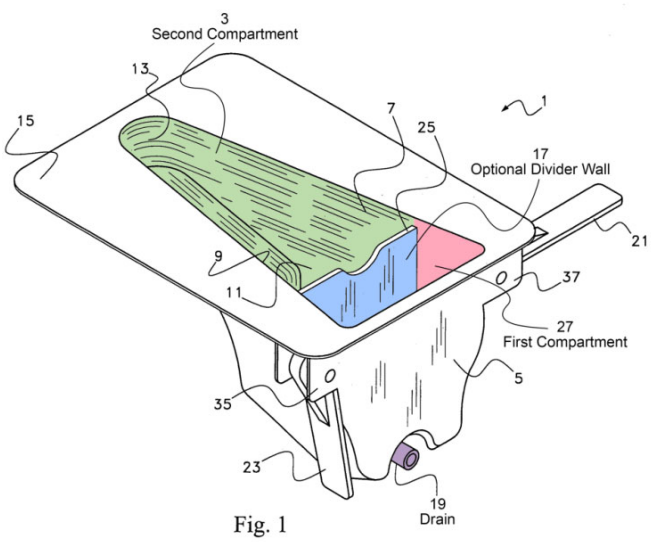


Fig. 1

Thus, Solazzo discloses this claim element. (Ex.1002, ¶308-14.)

h. ***10[h]****: … "a patient aid"*

For the reasons as set forth at claim 1[f], Solazzo in view of Frank-Farah discloses "*a patient aid comprising post-procedure information, disposed on a first portion of the patient aid, for caring for the Foley catheter applied to a patient.*"

9) Claims 11, 16, 23

a. 11[a], 16[a], 23[a]: *"a wrap disposed about the tray."*

For the reasons as set forth at claims 4[a], 13[a], and 17[a], Solazzo in view of Serany discloses "*a wrap disposed about the tray*."

b. ***11[b], 16[b], 23[b]:*** *"a sealed bag disposed about the wrap."*

For the reasons as set forth at claims 4[c], 13[c], and 17[c], Solazzo in view of Serany discloses "*a sealed bag disposed about the tray.*

Thus, Solazzo in view of Serany and Franks-Farah renders these claim

obvious.

10) Claim 15

a. Preamble and 15[a]: *"A tray for a Foley catheter…"*

For the reasons set forth at claim 1[a], Solazzo discloses "*a tray for a Foley catheter, comprising: a single-layer surface defining at least two compartments separated by a barrier*."

b. ***15[b]:*** *a first compartment comprising a base member, the first compartment accommodating a first syringe and a second syringe…"*

For the reasons set forth at claim 10[b], Solazzo in view of Serany discloses "*a first compartment comprising a base member, the first compartment accommodating a first syringe and a second syringe*."

c. ***15[c]:*** *"a second compartment accommodating the Foley catheter*."

For the reasons set forth at claim 1[c], Solazzo discloses "*a second compartment accommodating the Foley catheter*."

d. 15[d]: *the barrier separating the first compartment from the second compartment;*

For the reasons set forth at claim 1[d], Solazzo discloses "*the barrier separating the first compartment from the second compartment*."

e. 15[e]: *"the base member defining a mnemonic device…"*

Claim 15[e] requires "*the base member defining a mnemonic device*

indicating which of the first syringe or the second syringe should be used to dispense lubricating jelly disposed in one of the first syringe or the second syringe into the first compartment."

For the reasons set forth in claim 1[b], it would have been obvious to substitute the *tube* of lubricant 140 with a *syringe* of lubricant 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,¶¶335-38.)

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 a higher height than a *second* syringe, as a design affordance. (Ex.1002, ¶338.)

Accordingly, Solazzo in view of Serany discloses this claim element. (Ex.1002, ¶¶332-39.)

f. ***15[f]:*** *"the first compartment defining a lubricating jelly application compartment…"*

As discussed in Section V, the manner of using the claimed tray (e.g., a lubricating jelly application compartment) does not differentiate the tray over the

prior art.

Regardless, for the reasons set forth at claim 1[e] and 10[g], Solazzo discloses "*the first compartment defining a lubricating jelly application compartment to lubricate the Foley catheter with the lubricating jelly from the one of the first syringe or the second syringe when at least a portion of the Foley catheter is passed from the second compartment into the first compartment while remaining within a perimeter defined by the single-layer surface*." (Ex.1002, ¶¶340-45.)

g. *15[g]:* *"… a patient aid…"*

For the reasons set forth at claim 1[f], Solazzo in view of Franks-Farah discloses "*further comprising information, disposed on a first portion of a patient aid, for caring for the Foley catheter when applied to a patient*."

11) Claim 19

a. *Preamble and 19[a]:* *"A single-layer tray…"*

For the reasons set forth at claim 1[a], Solazzo discloses "*a single-layer tray, comprising: a surface defining at least two compartments separated by a barrier*."

b. *19[b]:* *" a first compartment to support a first syringe and a second syringe…"*

Solazzo in combination with Serany discloses: "*a first compartment to support a first syringe and a second syringe, the first compartment comprising one or more recesses for accommodating flanges of one or more of the first syringe or*

the second syringe."

For the reasons as set forth at claim 1[c], Solazzo in combination with Serany discloses "*a first compartment to support a first syringe and a second syringe*."

Solazzo further discloses "*the first compartment comprising one or more recesses for accommodating flanges of one or more of the first syringe or the second syringe.*"

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

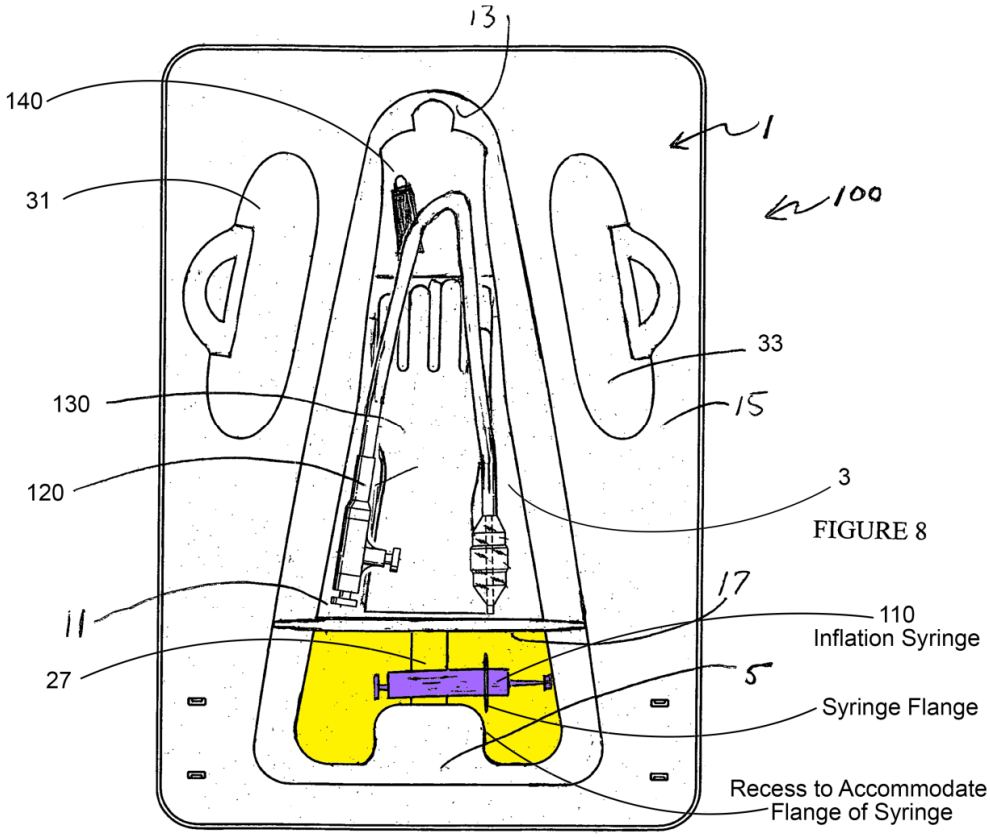


FIGURE 8

Serany also 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; 3:6-22.) In view of Serany, a POSITA would have been motivated to contour the compartments of Solazzo to have recesses 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, ¶357.)

Accordingly, Solazzo discloses this element. To the extent Patent Owner might argue that Solazzo does not disclose this claim element, the combination of Solazzo in view of Serany discloses this claim element. (Ex.1002, ¶¶353-58.)

c. ***19[c]:*** *"a second compartment to accommodate a Foley catheter."*

For the reasons set forth at claim 1[c], Solazzo discloses "*a second compartment to accommodate a Foley catheter*."

d. ***19[d]:*** *"the first syringe and the second syringe, situated in the first compartment."*

For the reasons set forth at claim 1[b], Solazzo in combination with Sernay discloses "*the first syringe and the second syringe, situated in the first compartment.*"

e. ***19[e]:*** *"the Foley catheter, situated in the second compartment"*

For the reasons set forth at claim 1[c], Solazzo discloses "*the Foley catheter, situated in the second compartment*."

f. ***19[f]:*** *"the barrier separating the first compartment from the second compartment"*

For the reasons set forth at claim 1[d], Solazzo discloses "*the barrier separating the first compartment from the second compartment*."

g. ***19[g]: "****the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter."*

For the reasons set forth at claim 1[e], Solazzo discloses "*the first compartment defining a lubricating jelly application chamber to lubricate the Foley catheter*.

h. ***19[h]: "*** *... a patient aid"*

For the reasons set forth at claim 1[f], Solazzo in view of Franks-Farah discloses "*further comprising post-procedure information for caring for the Foley catheter when applied to a patient, wherein the post procedure information is disposed on a first portion of a patient aid.*"

Thus, Solazzo in view of Serany and Franks-Farah renders this claim obvious.

B. Ground 2 (Claims 3, 12, 22, 24) – Obvious Based on Solazzo, Serany, Franks-Farah, and Disston

1. Summary of Disston

Disston issued on January 19, 1965. Disston is therefore prior art to the '761 patent under at least 35 U.S.C. § 102(b).

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

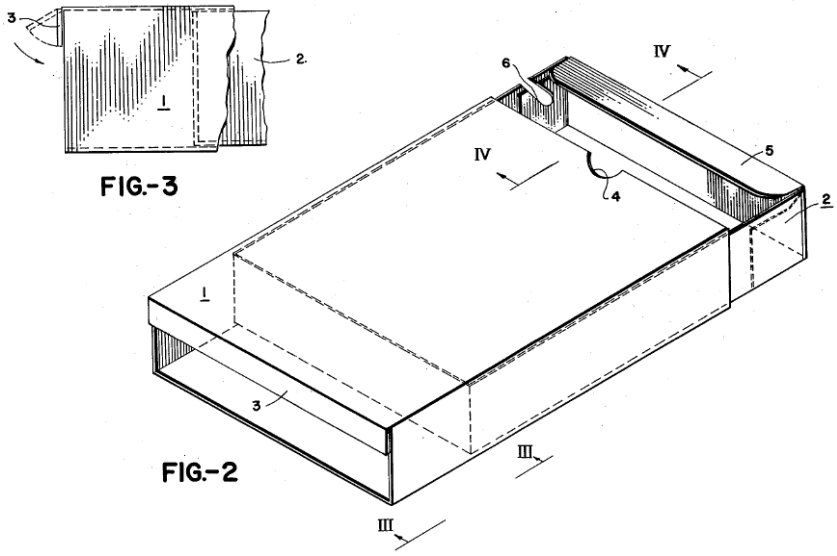


FIG.-3

FIG.-2

When opened, the tray presents contents including gloves, cleansing solution, protective pad or sheet, lubricant, sterile water packet, syringe, "and most importantly, a pre-assembled catheter-drainage tube-drip chamber-drainage bag and hanger, assembly, sterile and ready for use immediately." (Ex.1008, 1:26-35, 2:41-52; Fig. 1.)

2. The Combination

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

1) Claim 3

a. ***Preamble and 3[a]:*** *"...a wrap disposed about the tray..."*

For the reasons set forth at claim 4[a], 13[a], and 17[a], Solazzo in view of Serany discloses "*a wrap disposed about the tray*."

b. ***3[b]:*** *"liquid hand sanitizer"*

Solazzo discloses "liquid hand sanitizer."

Solazzo discloses a Foley catheter "kit [that] includes … .. (h.) antiseptic solutions." (Ex.1005, 3:15-24) A hand sanitizer is a type of antiseptic solution. (Ex.1002, ¶381.)

Solazzo's disclosure is consistent with the state of the art. It was well-known to provide a hand sanitizer in a catheterization tray to allow nurses to

sterilize their hands before donning sterile gloves. The Nursing Standard article states: "Hands should be decontaminated before carrying out the procedure and cleaned with alcohol gel before putting on sterile gloves." (Ex.1010, 52.) Similarly, Franks-Farah teaches an "antibacterial soap [] in liquid form" and an "alcohol gel (i.e., a waterless cleaner cleaner)." (Ex.1007, 2:17-18; 3:38-42; Fig. 1).

Thus, Solazzo discloses this claim element. (Ex.1002, ¶¶380-94.)

c. ***3[c]:*** *"a sealed bag disposed about the wrap"*

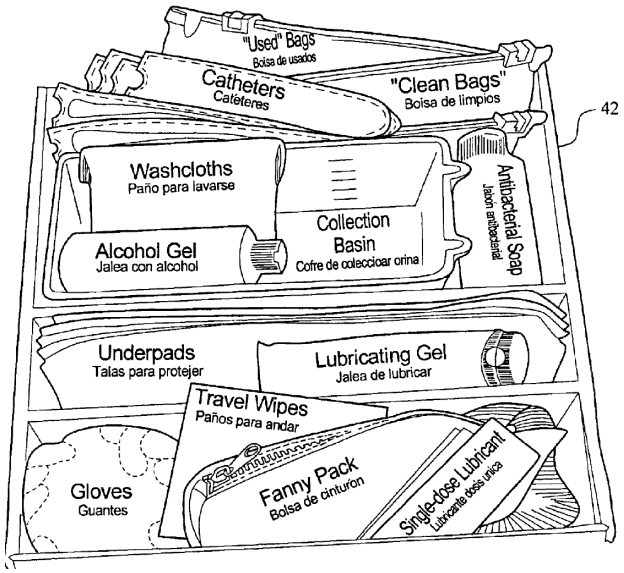
For the reasons set forth at claim 4[c], 13[c], and 17[c], Solazzo in view of Serany discloses "*a sealed bag disposed about the wrap*."

a. ***3[d]:*** *"the liquid hand sanitizer disposed between at least a portion of the wrap and the sealed bag"*

Claim 3[d] requires "*the liquid hand sanitizer disposed between at least a portion of the wrap and the sealed bag*."

As described at claim 3[b], Solazzo discloses a liquid hand sanitizer. Solazzo does not specify the location of the liquid hand sanitizer within the tray.

Figure 1 of Franks-Farrah shows the arrangement of the hand sanitizers (such as alcohol gel and antibacterial soap) within a catheter tray:



As shown in step of Figure 2A (step-by-step) instructions, Franks-Farah teaches "Wash your hands with Antibacterial Soap" during the first step of a catheterization procedure before the placement of an "underpad."

Prepare for Care

1 Get a clean, fresh towel. Wash your hands with Antibacterial Soap and warm water. Dry them only on the fresh towel.

If you have a caregiver do this for you, they should wash hands and put on the Gloves.

Spread out two clean paper towels for a work surface. If you are going to do the procedure on a bed or chair, put the Underpad under your buttocks.

It was well-known in the art to (1) provide liquid hand sanitizer in a catheter tray and (2) for liquid hand sanitizer to be used first in a catheterization procedure.

Further, 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. Storing hand sanitizer between the wrap and the bag is one such design affordance. It presents the user first with hand sanitizer because hand sanitizer is used first during a catheterization procedure. (Ex.1002, ¶¶399.)

Further, the prior art includes explicit teachings regarding such design affordances. Specifically, Disston describes a tray with the items "arranged in such order as to be most conveniently available when the container is opened." (Ex.1008, 2:15-19.) In particular, Disston teaches arrangement of items in a tray to avoid a user coming into contact with its contents before sterile gloves are donned:

> The container is so constructed that it can be opened without any part of either hand of the user coming in contact with the contents. When opened, the container presents the user first with a sheet or underpad, which is placed under the patient, and then with a pair of sterile disposable gloves, designed to be put on without need for touching the outside of either one, and after that all further manipulations are effected by the sterile gloved hands working with sterile pieces of equipment.

(Ex.1008, 2:63-72.)

In view of Disston, a POSITA would have been motivated to dispose the liquid hand sanitizer of Solazzo "between at least a portion of the wrap and the sealed bag" to ensure that all further manipulations of the tray are effected by

sterilized hands working with the sterile equipment in the Solazzo tray. (Ex.1002, ¶¶401-02.)

Disposing hand sanitizer between the wrap and the bag works in tandem with the procedural steps described by Disston and Franks-Farah. Disston teaches providing an underpad that is placed *before* the user dons gloves, but does not teach means provided in the tray for the user to cleanse his or her hands in preparation of placing the underpad. Franks-Farah instructs the user to wash his hands with the included liquid antibacterial soap *before* placing the underpad. Thus, it would have been obvious in view of Disston and Franks-Farah to order the components of the tray of Solazzo including the liquid hand sanitizer (i.e., antiseptic solutions) such that the user cleanses his or her hands with a liquid hand sanitizer before donning the included gloves. (Ex.1002, ¶¶402-04.)

Accordingly, Solazzo in view of Franks-Farah, Serany, and Disston discloses this claim element. (Ex.1002, ¶¶395-406.)

Thus, Solazzo in view of Serany, Franks-Farah, and Disston renders this claim obvious.

2) Claims 12 and 24

For the reasons as set forth at claim 3[b] and 3[d], Solazzo in view of Franks-Farah, Serany, and Disston discloses "*liquid hand sanitizer disposed outside the at least a portion of the wrap and inside the sealed bag*."

3) Claim 22

i. ***Preamble and 22[a]:*** *"…a wrap disposed about the tray."*

For the reasons as set forth at claims 4[a], 13[a], and 17[a], Serany discloses "*a wrap disposed about the tray*."

j. ***22[b]:*** *"printed instructions for using the tray."*

For the reasons as set forth at claims 4[b], 13[b], and 17[b], Serany discloses "*printed instructions for using the tray.*"

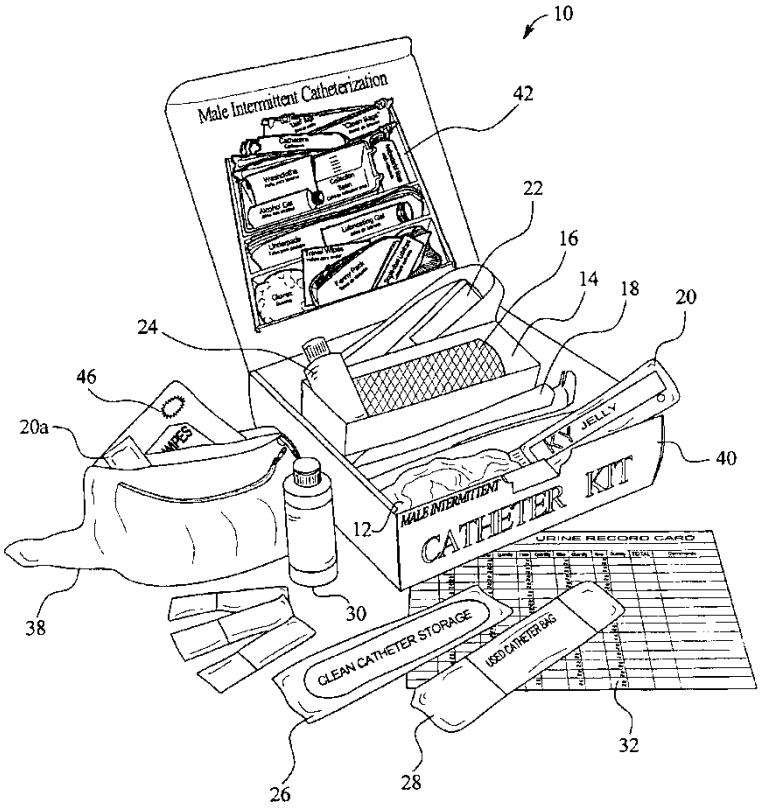
k. ***22[c]****: "a sealed bag disposed about the wrap."*

For the reasons as set forth at claims 4[c], 13[c], and 17[c], Serany discloses "*a sealed bag disposed about the tray.*"

l. ***22[d]:*** *the printed instructions disposed between the wrap and the sealed bag.*

Claim 22 requires "*the printed instructions disposed between the wrap and the sealed bag*."

Franks-Farah discloses a "container or box 40" for storing the items of the kit as shown in Figure 1 below:



As shown in Figure 1, the container of Frank-Farah includes a "contents map 42" on the inner flap of the lid of the box 40. (Ex.1007, 3:56-58.) Franks-Farah teaches use of the step-by-step instructions and contents map 42 together such that "users can easily identify when each item is required in the method and readily find it in the container 40." (Ex.1007, 4:55-61.) Similarly, Disston describes a tray with the items "arranged in such order as to be most conveniently available when the container is opened." (Ex.1008, 2:15-19.)

Thus, it was known in the art in view of Franks-Farah and Disston to includes items (including instructions) in an immediately apparently location within a catheter kit to assist the user in using the device.

It would have been obvious to a POSITA in view of Franks-Farah and Disston to provide instructions in a location where they are immediately apparent upon opening the tray of Solazzo (such as with the contents map of Franks-Farah). Specifically, it would have been obvious to place the instructions between the outer sealed bag and the wrap. (Ex.1002, ¶¶417-18.) With such a placement, the user, e.g., a healthcare provider, can use the instructions to "readily find" items in the tray.

Accordingly, Solazzo in view of Franks-Farah, Serany, and Disston discloses this claim element. (Ex.1002, ¶¶412-19.) Thus, Solazzo in view of Serany, Franks-Farah, and Disston renders this claim obvious.

VIII. SECONDARY CONSIDERATIONS

While secondary considerations of non-obviousness must be taken into account when present, Patent Owner offered no such evidence during the prosecution of the '761 patent. To the extent Medline raises alleged evidence of non-obviousness in response to Bard's Petition, Bard should be afforded the opportunity to respond.

IX. SECTION 325(d) IS INAPPLICABLE

Neither the original examination of the '761 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

As discussed above, Examiner Gilligan identified the closest prior art as Ehrenpreis, Stump, Stoller, and the Solazzo Publication. (Ex.1019, 11.) While he recognized that these references disclose a Foley catheter, syringes and lubricant, it was the combination of these features with the claimed patient aid that appears to have moved him to allow the claims. (Ex.1019, 11-12.) Franks-Farah teaches the claimed patient aid as discussed above.

Moreover, Franks-Farah is materially different and not cumulative of the art discussed in the Examiner's Notice of Allowability. None of them discloses instructions directed to a urinary catheter like Franks-Farah, and none of them discloses instructions directed to aseptic techniques, urine flow and the amount of flowed urine from a urinary catheter as disclosed by Franks-Farah. These disclosures, as discussed above, provide compelling reasons to combine Solazzo and Franks-Farah, unlike the prior art of record. While Franks-Farah was considered along with the hundreds of other references during the examination, the Examiner never mentioned Franks-Farah in the entire examination, including in the Notice of Allowability.

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 syringes, in contrast to the art raised in the IPRs.

X. NOTICES AND STATEMENTS

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

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following related matters: (i) *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:17-cv-07216 (N.D. Ill.) and (ii) *inter partes* review petitions (IPR2019-00035 and -00036) for U.S. Patent No. 9,745,088.

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 '761 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

XI. CONCLUSION

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

The USPTO is authorized to charge any required fees, including the fee as set forth in 37 C.F.R. § 42.15(a) and any excess claim fees, to Deposit Account No. **03-1952** referencing Docket No. **480100000021**.

Dated: October 24, 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 13,508 words (as counted by the "Word Count" feature of the Microsoft Word™ word-processing system), exclusive of "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

Dated: October 24, 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. 9,795,761.

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Dated: October 24, 2018

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