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. 9,808,400

_____

Inter Partes Review No. IPR2019-00208

PETITION FOR *INTER PARTES* REVIEW

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

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Petitioner C. R. Bard, Inc. ("Petitioner" or "Bard") petitions for *inter partes* review of claims 13, 14, 16, and 17 of U.S. Patent No. 9,808,400 ("the '400 patent" (Ex.1001)) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq*.

I. INTRODUCTION

The '400 patent is directed to a kit for storing medical devices such as a catheter and related medical devices. (Ex.1001, 1:21-24.) The tray comprises multiple compartments that hold multiple syringes and a catheter assembly. The catheter assembly comprises an indwelling catheter (such as a Foley catheter), a fluid receptacle having an anti-reflux device, and a coiled tube coupled to the anti-reflux device and the catheter. Notably, illustrations or descriptions of this catheter assembly were added during examination, but only *after* Applicants *admitted* that all of these elements were well-known.

Indeed, the structure as well as the components of a catheter tray were well known by 2009, the earliest purported priority date of the '400 patent. For example, Solazzo (Ex.1005) discloses a tray with multiple compartments, such as compartments 3 and 27, as shown in annotated Figure 1 below.

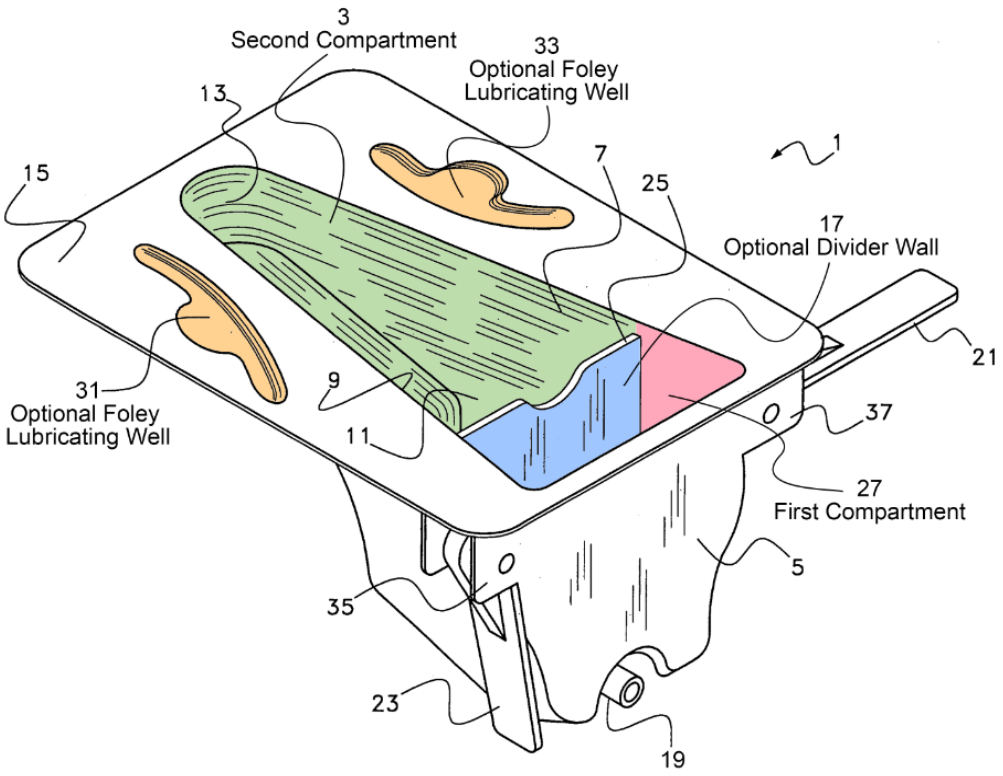


Fig. 1

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

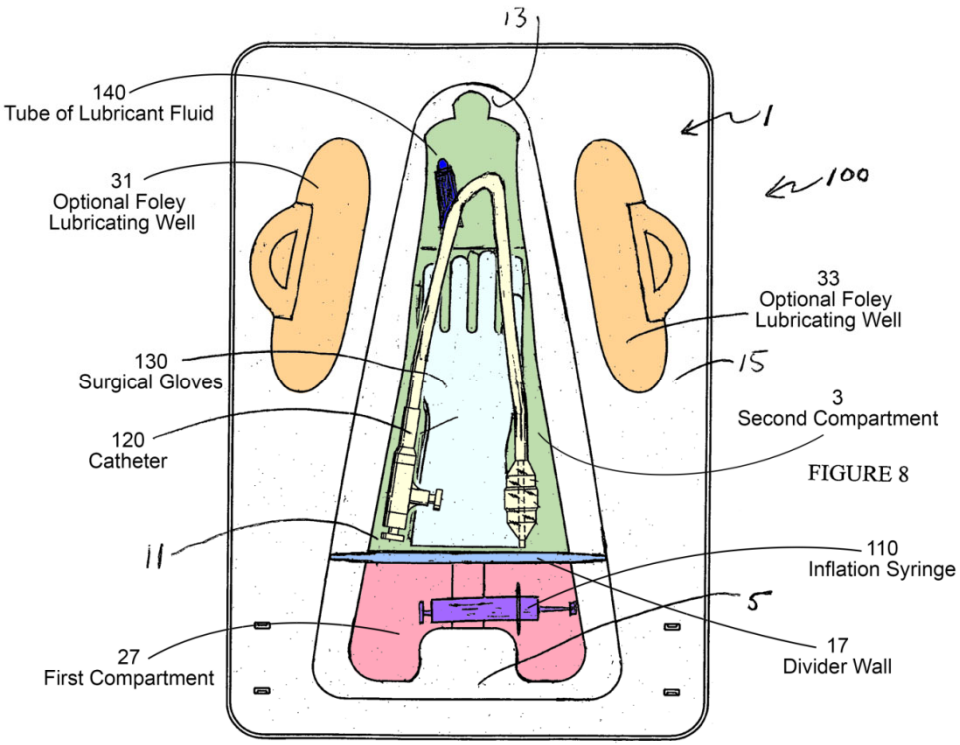


FIGURE 8

Solazzo does not explicitly disclose a coiled tube and a fluid receptacle with its Foley catheter. But catheters with these elements have been known, as Applicants admitted during examination. (Ex.1004, 259, ¶33 (Meyst).) Disston (Ex.1008), which issued in 1965 to Bard, is a good example of a closed-system Foley catheter with a coiled tube (drainage tubing 8) and a fluid receptacle (drainage bag 10):

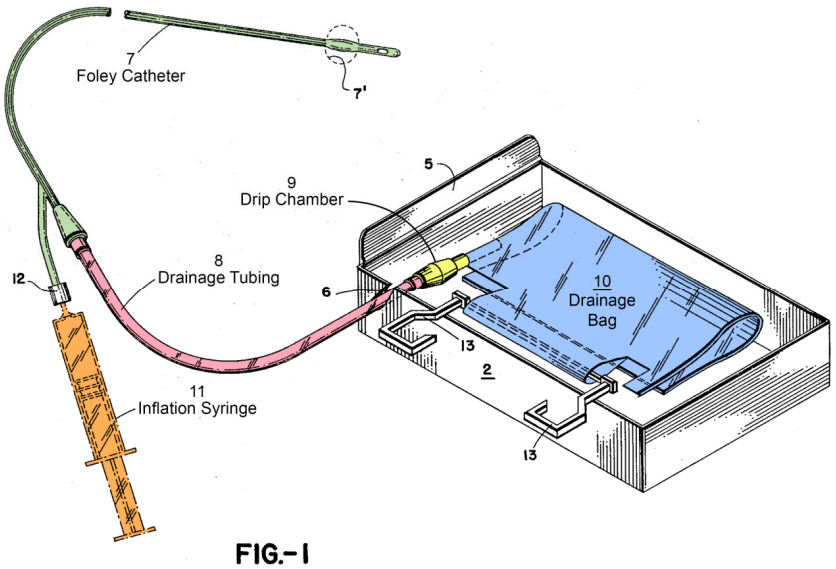


FIG.-1

As discussed in the Declarations of Michael Plishka (Ex.1002) and Dr. Edward Yun (Ex.1003), there are many reasons to utilize a closed-system Foley catheter in Solazzo. As Applicants also admitted during examination, "[h]ealthcare service providers familiar with administering catheters … knew in 2009 that CAUTI [Catheter-associated Urinary Tract Infections] is caused by Foley catheters." (Ex.1004, 239, ¶29 (Weintraub).) Utilizing a closed-system Foley catheter would reduce the risk of CAUTI and would be convenient ("ready for use" as Disston explains).

Furthermore, it would have also been obvious to include an anti-reflux device in the drainage bag of the closed-system Foley catheter. Anti-reflux devices were known since the 1970s and, by Applicants' admission, were associated with

Foley catheters. (*See*, *e.g.*, Ex.1034, 1:19-24; Ex.1004, 262, ¶41 (Meyst).) Because a drainage bag of a closed-system Foley catheter is typically flexible, an anti-reflux device in the bag would prevent urine reflux when pressure is applied to the side walls of the bag.

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

II. THE STATE OF THE ART

By 2009 (the earliest purported priority date of the ’400 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 ’400 patent in context, Bard presents a summary of the state of the art as of 2009 with respect to tray structure and components. 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 ’400 patent. (Ex.1002, ¶39.) 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, ¶¶39-43.)

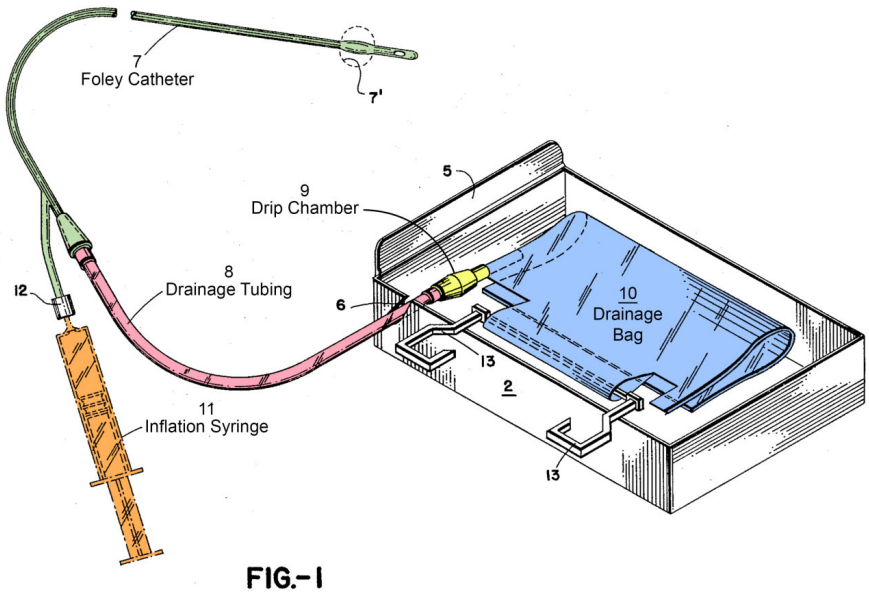


FIG.-1

U.S. Patent No. 3,329,261 to Serany (Ex.1006), filed on September 3, 1965 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 Figures 6 and 7 below. (Ex.1006, 2:39-40, 3:23-26; Ex.1002, ¶¶46-48.)

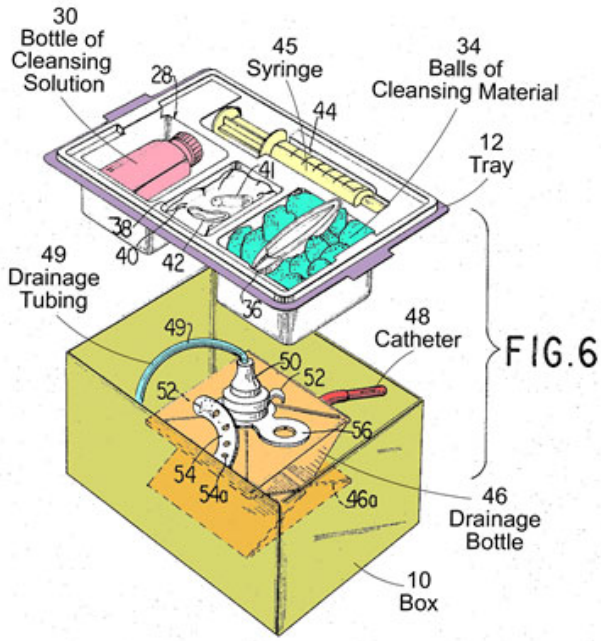


FIG.6

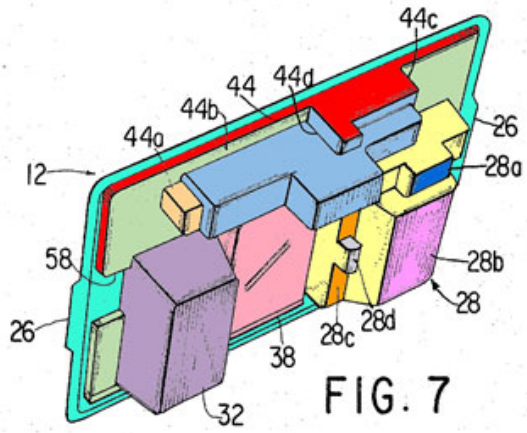
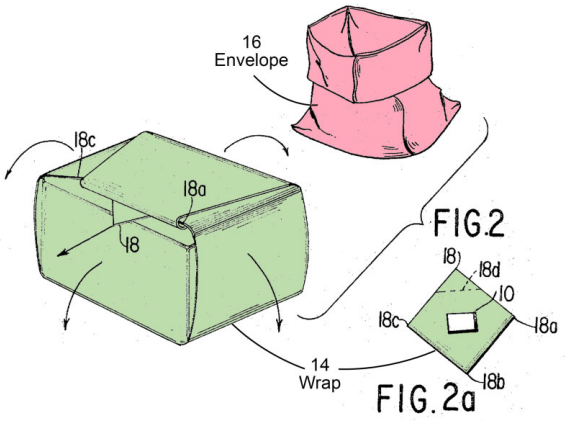
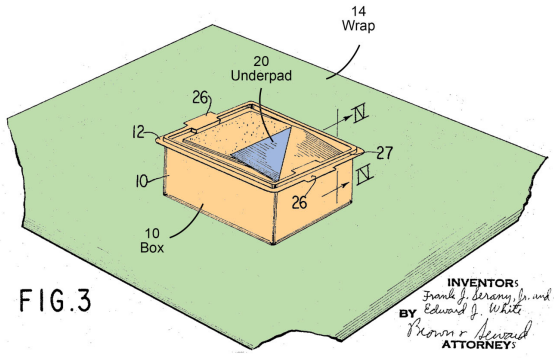


FIG. 7

Typically, a medical device tray is wrapped in a bag or outer wrap to allow shipment while holding components inside the tray. (Ex.1002, ¶49.) 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, ¶59.) 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, ¶50.)

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, ¶51.)





B. Tray Components

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, ¶¶54-77.)

Foley Catheter. Solazzo**,** Disston, and Serany all disclose trays with Foley catheters. (Ex.1002, ¶¶39, 45, 47.) Foley catheter kits have long been available. (Ex.1003, ¶¶12-15.)

Closed System Foley Catheter. "Reducing the risks associated with urinary catheters" is an article published in *Nursing Standard* on March 25, 2009 ("Nursing Standard"; Exs.1010, 1025). It describes a Foley tray including a "pre-

connected catheter and drainage bag," which creates a "closed system." (Ex.1010, 52; Ex.1002, ¶¶54-55.) According to Nursing Standard, using a "closed system" catheter reduces the risk of developing catheter-associated urinary tract infections ("CAUTIs") to between 8%-15%, as opposed to a 97% risk of infection with open systems. (Ex.1010, 61.) Disston, Serany, and Nursing Standard disclose closed-system Foley catheters. (Ex.1002, ¶¶57-61.)

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, ¶75.)

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], [and] inserting it in the patient[.]" (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, ¶76.) Lubricant may also be provided in a syringe. (Ex.1010, 52; Ex.1002, ¶77; Ex.1003, ¶¶20-22.)

Anti-reflux Device. Anti-reflux devices were introduced by the 1970s along with the rise of "flexible" urine collection bags. (Ex.1002, ¶¶62-67.)

"Pressure exerted against the side walls of the flexible bag may cause a reflux of urine from the bag into the drainage tube, and possibly the catheter and patient's bladder." (Ex.1034, 1:19-25; *see also* Ex.1036, 1:21-25.) To prevent urine reflux, collections bags may include a valve in the connector where the drainage tubing is coupled to the bag. Anti-reflux devices were ubiquitous with closed-system Foley catheters before the time of the invention. (Ex.1003, ¶¶46-47). For example, Nursing Standard notes that a majority of bags had anti-reflux devices. (Ex.1010, 51.) Applicants also admitted during prosecution that anti-reflux devices were associated with Foley catheters. (Ex.1004, 262, ¶41 (Meyst).)

Catheterization And Irrigation Procedures. A urethral (or urinary) catheter is placed to drain urine from the bladder. (Ex.1003, ¶11.) A Foley catheter is an indwelling catheter that is designed to remain in the patient for longer periods of time, and includes an inflatable balloon for this purpose. (Ex.1003, ¶11.)

A Foley catheterization procedure (as of 2009) using a Foley catheter kit involved a well-known series of steps. A practitioner (such as a nurse or urologist) opens the outside packaging and unfolds the CSR wrap to create a sterile field around the tray. (Ex.1003, ¶18; Ex.1010, 53.) The practitioner places an underpad beneath the patient. (Ex.1003, ¶18; Ex.1010, 53.)

The practitioner cleans the patient using cleansing balls or swab sticks, which have been soaked with an iodine solution. (Ex.1003, ¶19; Ex.1010, 53.) The practitioner lubricates the Foley catheter inside the tray using an included lubricant solution. (Ex.1003, ¶¶20-21.) Alternatively, the practitioner squirts lubricant directly into the patient's urethra using the tapered tip of a lubricant syringe. (Ex.1003, ¶22 Ex.1010, 53.) The catheter is then inserted by the practitioner, followed by inflation of the balloon. (Ex.1003, ¶23; Ex.1010, 53.)

An irrigation procedure is performed with a urethral catheter to remove blood clots, which reduce or inhibit the flow of urine. (Ex.1003, ¶26.) Irrigation procedures are often performed with patients that are already catheterized to improve the flow of urine. (Ex.1003, ¶27.) In that case, the Foley catheter must be disconnected from the drainage tubing that connects it to the drainage bag. (Ex.1003, ¶27.) Using an irrigation syringe, the practitioner draws up 60mL of saline solution and injects the catheter. (Ex.1003, ¶27.) The fluid is withdrawn and dispensed into a collection tray. (Ex.1003, ¶27.) The injection and withdrawal of the saline solution are performed repeatedly until the clots are removed and urine can flow again. (Ex.1003, ¶27.) The Foley catheter is then reconnected to the drainage bag via the drainage tubing. (Ex.1003, ¶27.)

III. THE '400 PATENT

A. Summary

The '400 patent is entitled "Catheter Tray, Packaging System, And Associated Methods." The '400 patent is directed to a kit for storing medical devices such as a catheter and related medical devices. (Ex.1001, 1:21-24.) The '400 patent focuses on tray structure and components therein. As discussed below, all these aspects were well-known in the art by 2009.

1. Tray structure

Figure 1 of the '400 patent shows a medical device tray with multiple compartments.

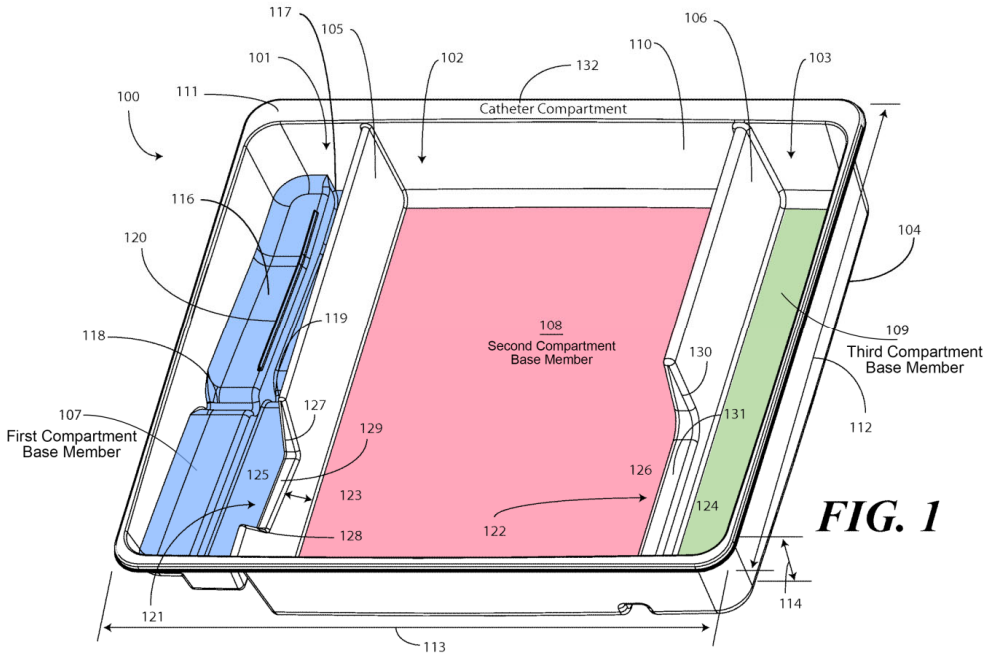


FIG. 1

The tray has a first compartment 101, a second compartment 102, and a third compartment 103. (Ex.1001, 4:21-23.)

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.)

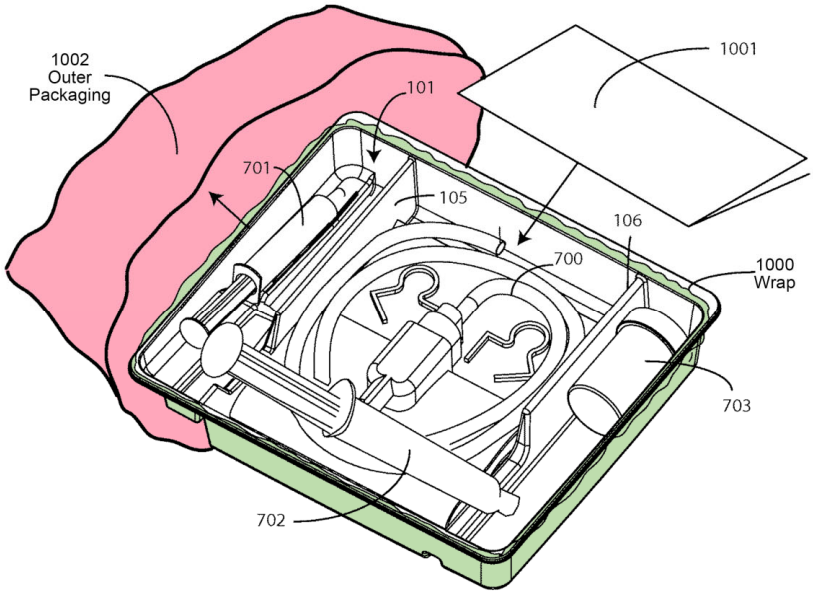


FIG. 10

2. Tray components

The '400 patent also describes common medical devices that may be provided in a catheter tray. The devices depicted in annotated Figure 7 (below) of the tray include a pair of syringes (shown in green and pink). (Ex.1001, 4:29-30;

8:21-25.) The second compartment of the tray includes a catheter assembly 700 (shown in blue in annotated Figure 4). (Ex.1001, 8:25-30.)

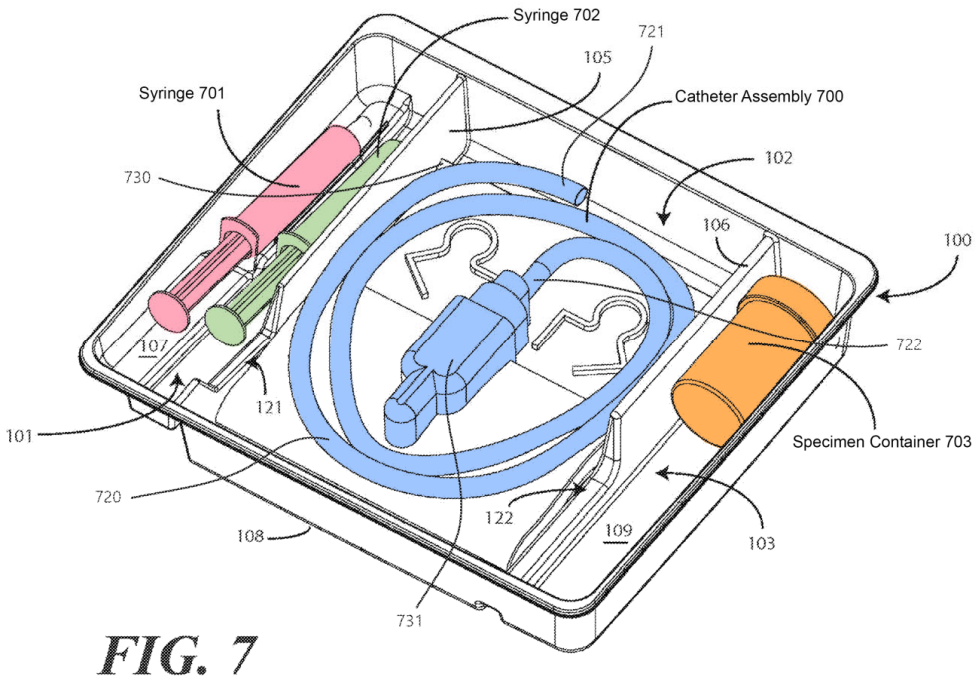


FIG. 7

As discussed in detail below, Applicants made numerous admissions of what was well-known in the art to amend the specification (and Figure 7) as follows:

> The catheter assembly 700 includes an indwelling (or Foley) catheter coupled to a fluid bag 730 by a tube 720. The first end portion 721 of the tube 720 is coupled to the indwelling catheter and the second end portion 722 of the tube 720 is coupled to the fluid bag 730 via an anti-reflux device 731.

(Ex.1001, 8:25-30.)

B. Effective Filing Date

Application no. 61/183, 629, filed on June 3, 2009, is the earliest-filed application listed on the face of the '400 patent. (*See also* Ex.1030, 3.) Bard assumes—for this Petition only—that the challenged claims are entitled to a priority date of June 3, 2009. Bard reserves the right to challenge this priority date.

C. Prosecution History

During examination, the Examiner questioned whether many of the claim elements were illustrated or described in the original application, e.g., an indwelling catheter, and a fluid receptacle coupled to the indwelling catheter via a coiled tube. Illustrations or descriptions of these elements were added during examination, but only after Applicants *admitted* that these elements were well-known.

Initial Filing. The '400 patent was filed on April 30, 2014, as application no. 14/265,909, with a single independent claim directed to a tray. (Ex.1004, 651.)

Series Of Office Actions/Amendments. Examiner Robert Poon subsequently rejected the claims in a series of Office Actions. He primarily relied on U.S. Patent No. 5,339,955 to Horan et al. ("Horan"; Ex.1037) and U.S. Published Application No. 2004/0004019 to Busch ("Busch"; Ex.1038). Applicants responded with a series of amendments, including adding "a catheter;

and a fluid bag attached to the catheter; the catheter and the fluid bag disposed within the tray." (Ex.1004, 413.)

Final Office Action. On January 10, 2017, Examiner Poon issued a final Office Action maintaining the rejections under §§ 102 and 103. The claims were also rejected under § 112 for lack of written description support. Specifically, Examiner Poon stated the claims were unsupported because there was "[n]o support in the original disclosure for a fluid bag attached to the catheter . . . ." (Ex.1004, 358.) Additionally, the drawings were objected to for not showing the claimed invention. (Ex.1004, 349-350.)

Interview. On May 30, 2017, Examiner Poon and Applicants' counsel conducted a telephonic interview. While Examiner Poon indicated that the applied prior art did not teach an indwelling catheter with certain other limitations, he also indicated that "[n]o agreement was reached on whether such a catheter was described in the original disclosure." (Ex.1004, 338.) Examiner Poon suggested submitting an affidavit for the claimed catheter. (Ex.1004, 338.)

RCE/Declarations. On July 10, 2017, Applicants submitted an RCE to amend claim 1 and add new claims, including claim 18, which became claim 13 at issue here. Claim 18 recited "an indwelling catheter" with "a coiled tube" coupling the indwelling catheter to "a fluid receptacle." Dependent claim 19 recited "wherein the fluid receptacle includes an anti-reflux device, an end of the

coiled tube coupled to the anti-reflux device." Claim 21 depended from claim 19 and further recited base members of the two tray compartments, with the coiled tube and the fluid receptacle disposed within the second compartment such that the fluid receptacle is between a second compartment base member and the coiled tube. No support in the application was provided for claims 19 and 21. (Ex.1004, 208.)

Applicants concurrently amended the specification and drawings. Specifically, Applicants submitted replacement drawings that added reference signs and lead lines pointing to a tube (720) and end portions thereof (721, 722), a fluid receptacle (730), and an anti-reflux device 731 in Figures 7 and 8. (Ex.1004, 212.) Original and replacement drawings of Figure 7 are shown below.

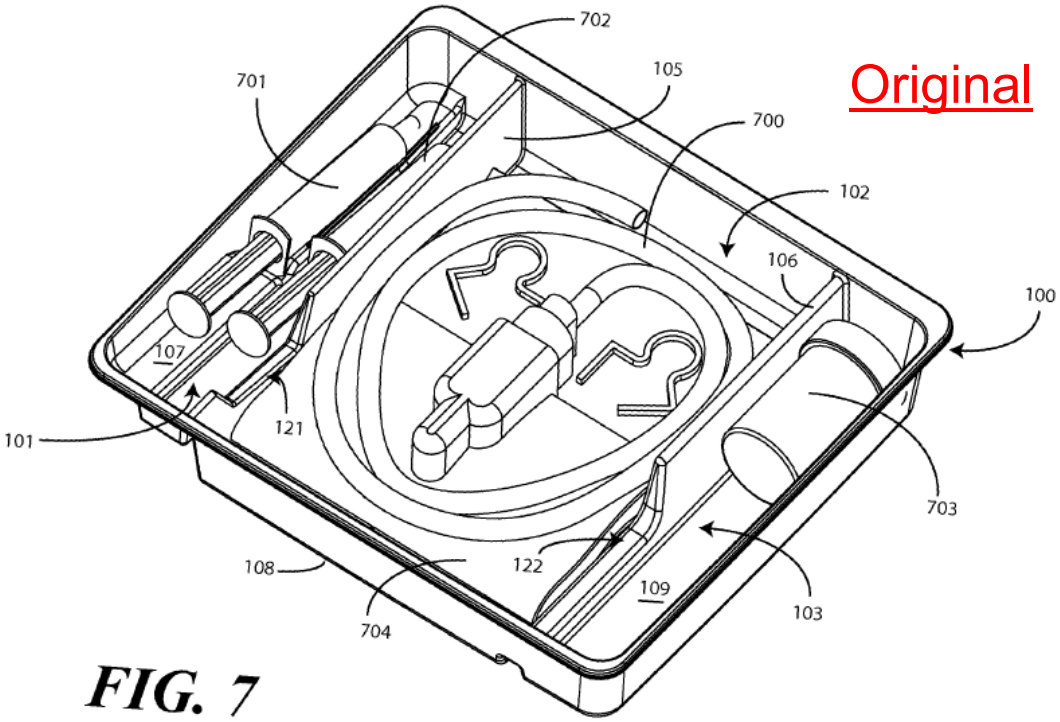


FIG. 7

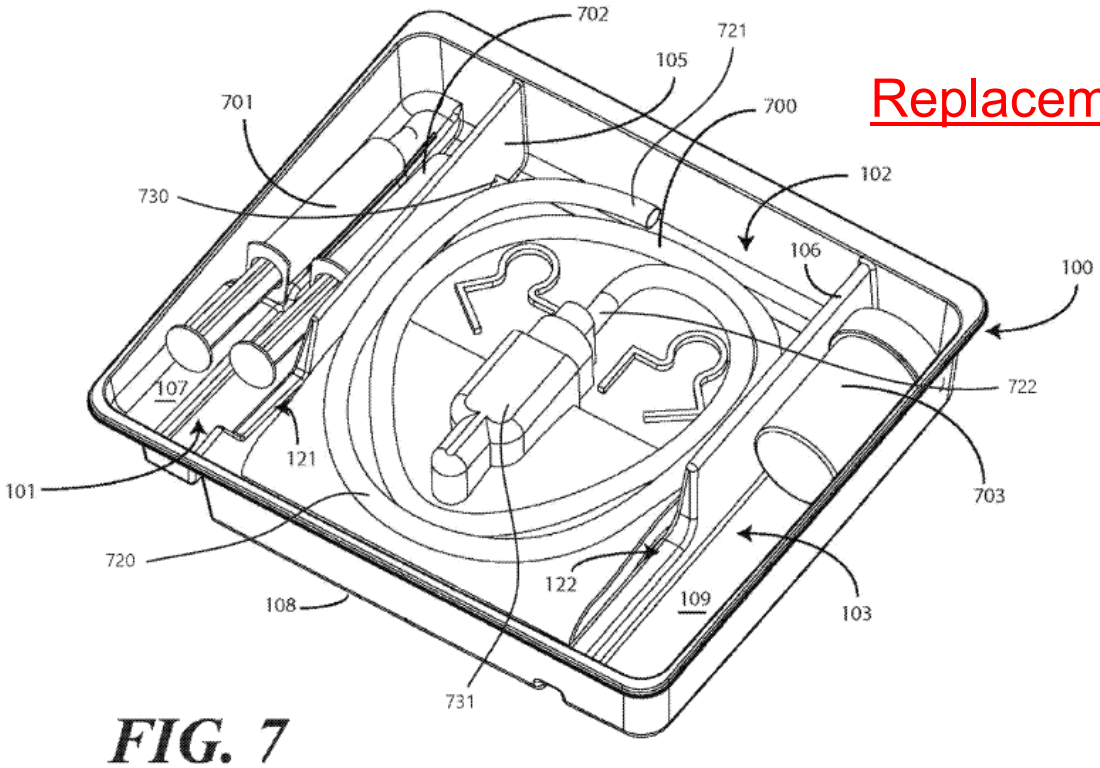


FIG. 7

Applicants also added text to the specification, including defining element 731 as an "anti-reflux device" for the first time:

> The catheter assembly 700 includes an indwelling (or Foley) catheter coupled to a fluid bag 730 by a tube 720. The first end portion 721 of the tube 720 is coupled to the indwelling catheter and the second end portion 722 of the tube 720 is coupled to the fluid bag 730 via an anti-reflux device 731.

(Ex.1004, 204.)

Because the application did not illustrate or describe an indwelling catheter coupled to a fluid receptacle via a coiled tube, or refer to element 731 as anti-reflux device, Applicants further submitted two declarations as "additional evidence to

show that a POSITA would understand that the applicant was in possession of the claimed subject matter." (Ex.1004, 213.) The declarations were by Barbara Weintraub (a nurse) and Richard Meyst and had been submitted in *Medline II* (discussed below). (Ex.1004, 212-213.) In submitting these declarations, Applicants endorsed admissions made by Ms. Weintraub and Mr. Meyst regarding what was known in the art:

- "Of urinary catheters, four types were known in 2009 and are still known today—Foley . . . ." (Ex.1004, 257, ¶20 (Meyst).)
- "Foley catheters are typically pre-connected to a drainage receptacle via a long coiled tubing." (Ex.1004, 259, ¶33 (Meyst).)
- "An anti-reflux chamber is a device that is designed to stop fluid from the bag from flowing back into the patient's bladder and is associated with a Foley catheter." (Ex.1004, 262, ¶41 (Meyst).)
- "Healthcare service providers familiar with administering catheters (including me) knew in 2009 that CAUTI is caused by Foley catheters." (Ex.1004, 239, ¶29 (Weintraub).)

Office Action. On August 24, 2017, Examiner Poon issued a non-final Office Action rejecting amended claim 1 and new independent claim 18 under § 103 as being unpatentable over a number of references (Exs. 1014, 1039-1041, 1048-1049). (Ex.1004, 102.)

With respect to dependent claim 19, which further recited the fluid receptacle having an anti-reflux device coupled to the coiled tube, Examiner Poon remarked that Applicants' affidavits admitted that this feature was known in the art:

> Regarding claim 19-20, the modified Misra teaches the kit of claim 18 except for the structure of the catheter having a anti-reflux device or fluid receptacle beneath coiled tube. However, applicant admits in the affidavit filed 7/10/2017 that such a catheter was known in the art, i.e., easily recognizable from the drawings, and one of ordinary skill in the art would have found it obvious to incorporate such features to the catheter of the modified Misra in order to facilitate catheterization.

(Ex.1004, 106.) Examiner Poon further noted that the feature of the fluid receptacle beneath the coiled tube was also admitted art. As discussed below, Applicants never challenged any of these findings of Examiner Poon.

Examiner Poon also remarked that Applicants' affidavits admitted that the recited indwelling catheter was "obvious to anyone in the field":

> Furthermore, the affidavit filed 7/10/2017 states that the figures disclosed in the drawings of the catheter clearly show a Foley catheter with the recited structure as claimed and would be obvious to anyone in the field that the drawings depict such features. If the catheter is obvious to anyone in the field, then it would be considered prior art without the need for its description in the specification. Otherwise, adding its description in the original disclosure would be considered new matter.

(Ex.1004, 107-108.)

Interview. On September 8, 2017, Applicants' counsel conducted another interview with Examiner Poon. Examiner Poon indicated that dependent claim 21 "may be allowable pending an update to the search." (Ex.1004, 54.)

Amendment. On September 12, 2017, Applicants filed an amendment. Applicants did not challenge Examiner Poon's findings of admitted art, including the recited indwelling catheter, the anti-reflux device, and the placement of the fluid receptacle beneath the coiled tube. Instead, Applicants responded by amending claim 18 to include the recitations of dependent claims 19 and 21, i.e. recitations of an anti-reflux device, base members, and arrangement of the catheter assembly. (Ex.1004, 67, 69-72.) Applicants provided no support in the application for the recitation relating to the placement of the receptacle between the second compartment base member and the coiled device.

Notice of Allowability. On October 2, 2017, Examiner Poon issued a Notice of Allowance. No reasons for allowance were provided. (Ex.1004, 10.)

D. Level Of Ordinary Skill

A person of ordinary skill in the art ("POSITA") in the field of the '400 patent in 2009 would have at least a Bachelor of Science degree in Packaging Science or Package Engineering, chemical engineering, mechanical engineering, or industrial design. Optionally, the POSITA would have a bachelor's degree in an

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

E. Litigation And Other Matters

Patent Owner has asserted the '400 patent against Bard in a co-pending litigation: *Medline Industries, Inc. v. C. R. Bard, Inc.*, 1:17-cv-07216 (N.D. Ill.) ("*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 '400 patent should be accorded their ordinary and customary meanings as understood by one of ordinary skill in the art and consistent with the '400 patent's disclosure. Accordingly, no term or phrase requires specific construction to find that the challenged claims are invalid.

Nevertheless, Bard notes that Patent Owner has proposed constructions in district court litigation. (Ex.1022.)

Claim Term	Patent Owner Construction
Barrier	structure that separates one compartment from another and prevents or blocks movement between the two
Catheter Assembly	a medical device that includes a Foley catheter connected via coiled tubing to a drainage receptacle
Reveal	to make visible or to make (something that was hidden) able to be seen

The application of the art in this Petition would meet the above claim language under Patent Owner's constructions. The application of art in this Petition would also meet Bard's constructions of these terms in district court. (Ex.1026, 22-25.)

V. PRECISE REASONS FOR RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.104(b), Bard requests cancellation of claims 13, 14, 16, and 17 of the '400 patent based on the following references:

Prior Art Reference	**Abbreviation**
U.S. Patent No. 7,278,987 to Solazzo	"Solazzo" (Ex.1005)
U.S. Patent No. 3,329,261 to Serany, Jr. et al.	"Serany" (Ex.1006)
U.S. Patent No. 3,166,189 to Disston	"Disston" (Ex.1008)
Madeo M. and Roodhouse, A.J., Reducing the risks associated with urinary catheters, *Nursing Standard*, Vol. 23, No. 29, 47-55 (2009)	"Nursing Standard" (Ex.1010)
U.S. Patent No. 3,965,900 to Boedecker	"Boedecker" (Ex.1034)
U.S. Patent No. 4,334,537 to Peterson	"Peterson" (Ex.1036)

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

Petition			
Ground	**35 U.S.C. §**	**Claim**	**References**
1	103(a)	13, 14, 16, 17	Solazzo, Serany, Boedecker
2	103(a)	13, 14, 16, 17	Solazzo, Serany, Peterson
3	103(a)	13, 14	Solazzo, Disston, Boedecker
4	103(a)	16, 17	Solazzo, Disston, Boedecker, Serany
5	103(a)	13, 14, 16, 17	Solazzo, Nursing Standard

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 13, 14, 16, 17) – Obvious Based on Solazzo, Serany, and Boedecker

1. Summary of Solazzo

Solazzo was filed on July 9, 2004, and issued on October 9, 2007. Solazzo is therefore prior art to the '400 patent under at least 35 U.S.C. § 102(b).

Solazzo is directed to a single layer catheterization/irrigation tray. The tray of Solazzo includes an "optional divider wall 17" creating "two separate compartments." (Ex.1005, 2:61-63; Fig.1; Ex.1002, ¶96.)

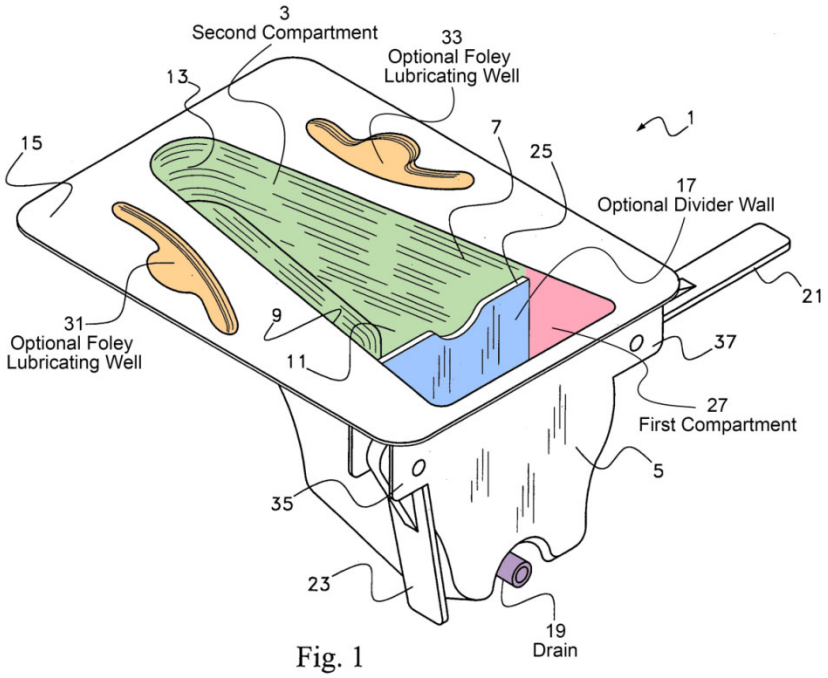


Fig. 1

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

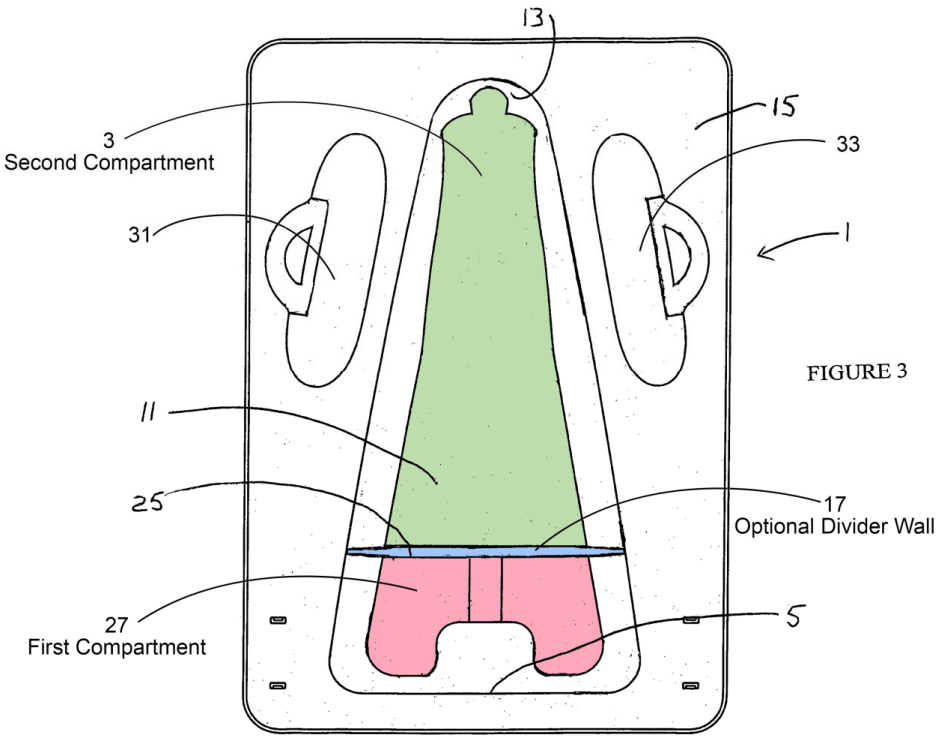


FIGURE 3

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

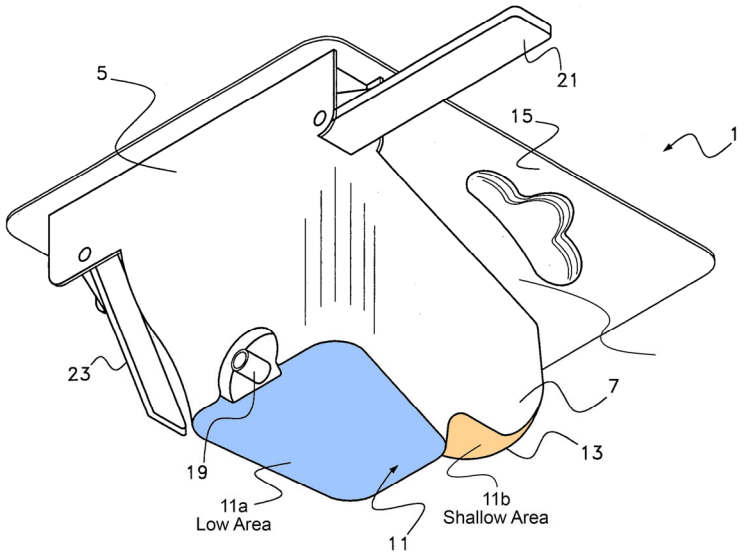


Fig. 2

Solazzo further discloses his invention in the context of a kit as shown in annotated Figure 8 below. The recessed area 3 and compartment 27 store medical devices included in tray kit 100, including a Foley catheter 120, urinary tract lubricant 140, surgical gloves 130, inflation syringe 110, irrigation syringe, and evacuation tubing. (Ex.1005, 3:14-24, 4:1-8; Fig. 8; Ex.1002, ¶¶101-03.)

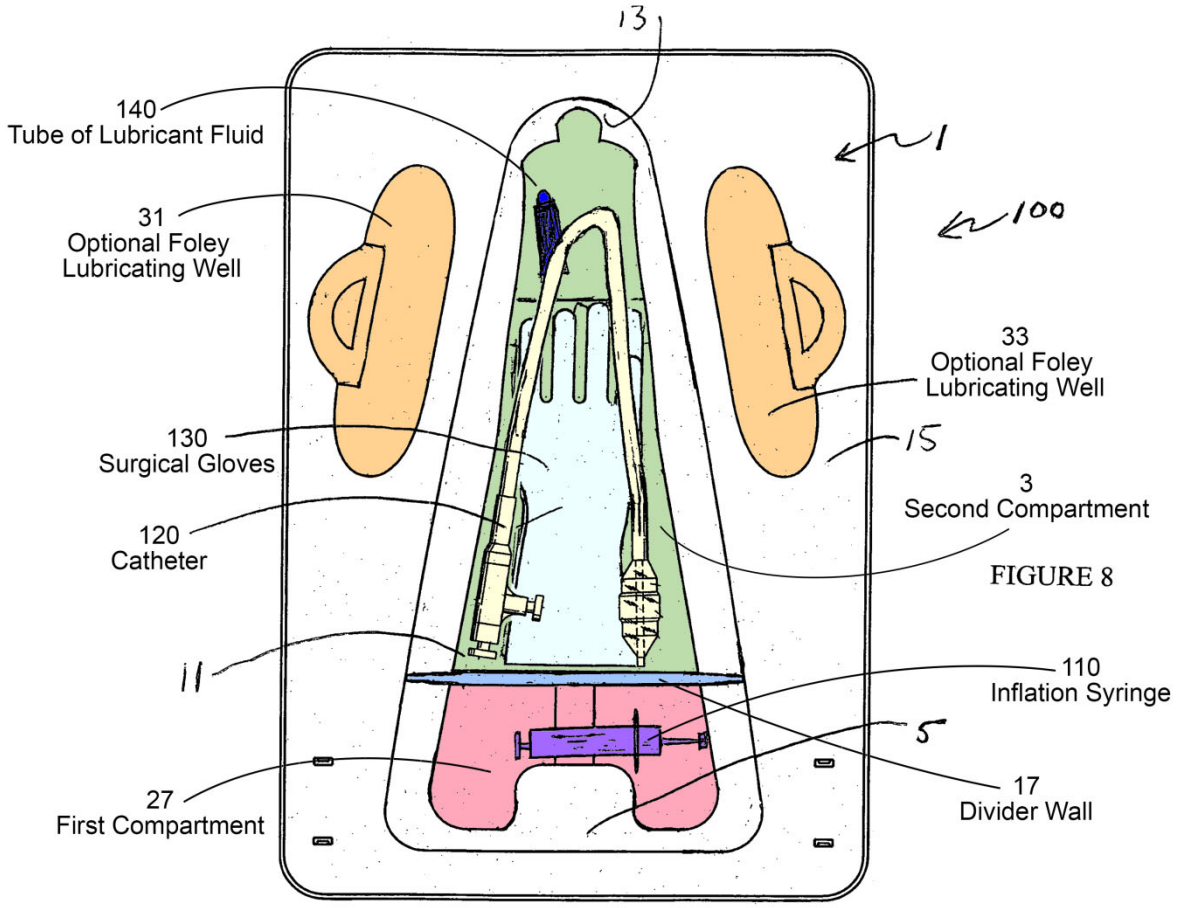


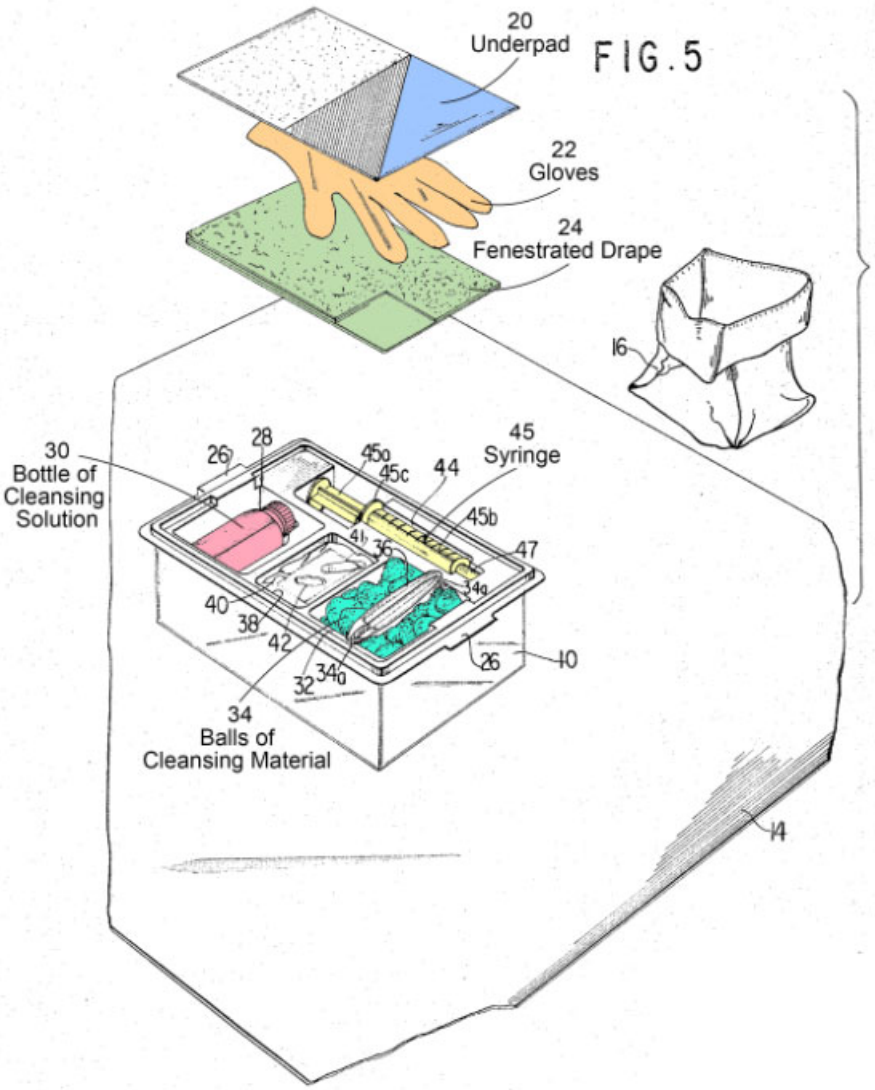
FIGURE 8

2. Summary of Serany

Serany issued on July 4, 1967. Serany is therefore prior art to the '400 patent under at least 35 U.S.C. § 102(b).

Serany is directed to a double-wrapped, sterile package providing catheterization components, including a Foley catheter 48, "ready for use" and in the order needed. (Ex.1006, 1:8-16, 1:60-63, 3:23-26; 63-4:2; Figs. 1-3, 5-6; Ex.1002, ¶¶112-14.) As shown in annotated Figures 5 and 6 below, the package includes a multi-compartment tray 12 mounted on a box 10 and enclosed with an

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



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

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

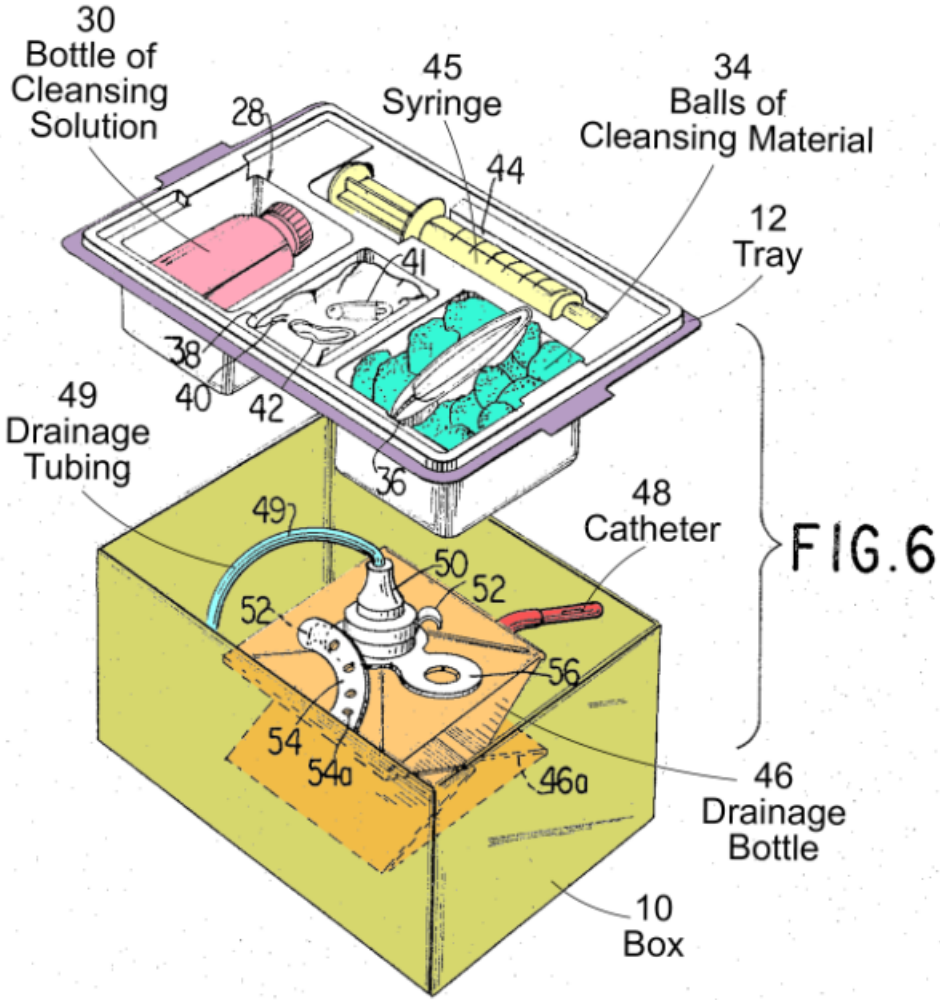
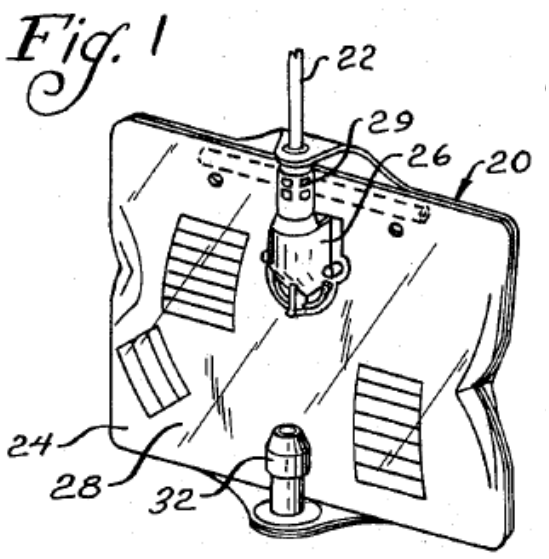


FIG.6

3. Summary of Boedecker

Boedecker issued on June 29, 1976. Boedecker is therefore prior art to the '400 patent under at least 35 U.S.C. § 102(b).

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



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

To prevent urine reflux, Boedecker's collection bag 24 provides an anti-reflux device at its inlet opening. The anti-reflux device includes a flexible valve element 34 covering the inlet opening such that when urine flows into the bag (e.g., from the patient's bladder through a catheter, drainage tube 22, and a connector or drip chamber 26 coupling the tube 22 to the bag 24), the valve element 34 flexes open to permit passage of urine into the bag. (Ex.1034, 2:54-3:3, 3:20-23; Figs. 1-2, 5; Ex.1002, ¶125.)

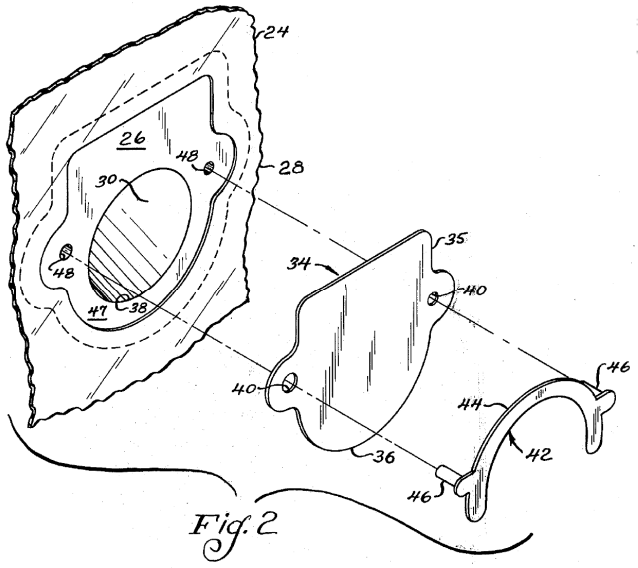


Fig. 2

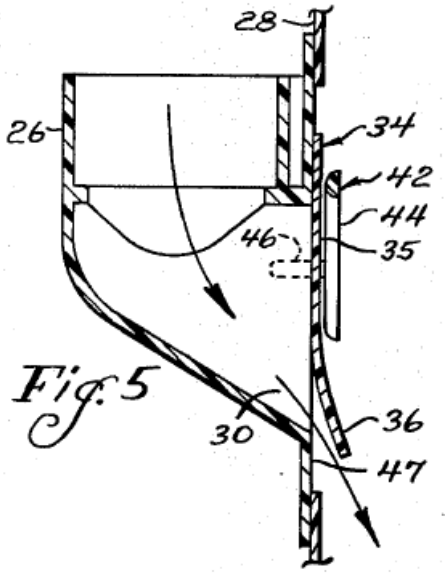


Fig. 5

When pressure is exerted onto the flexible valve element 34 from inside the bag 24 (e.g., by inadvertent squeezing, bumping, tilting of the bag), the flexible valve element 34 seals the inlet opening shut to prevent reflux. (Ex.1034, 3:23-33; Ex.1002, ¶125.)

4. The Combination

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

1) Claim 13

a. Preamble and 13[a]: *"A kit, comprising: a single level tray including a first compartment base member…"*

Solazzo discloses "*a kit, comprising: a single level tray including a first compartment base member and a second compartment base member, the single level tray defining a first compartment and a second compartment, the first compartment base member forming a portion of a boundary of the first*

compartment, the second compartment base member forming a portion of a boundary of the second compartment, the single level tray including a barrier separating the first compartment from the second compartment."

(i) "*a single level tray…*"

Solazzo discloses "*a kit comprising: a single level tray including a first compartment base member and a second compartment base member*."

As shown in Figure 1, Solazzo discloses a *single level tray*:

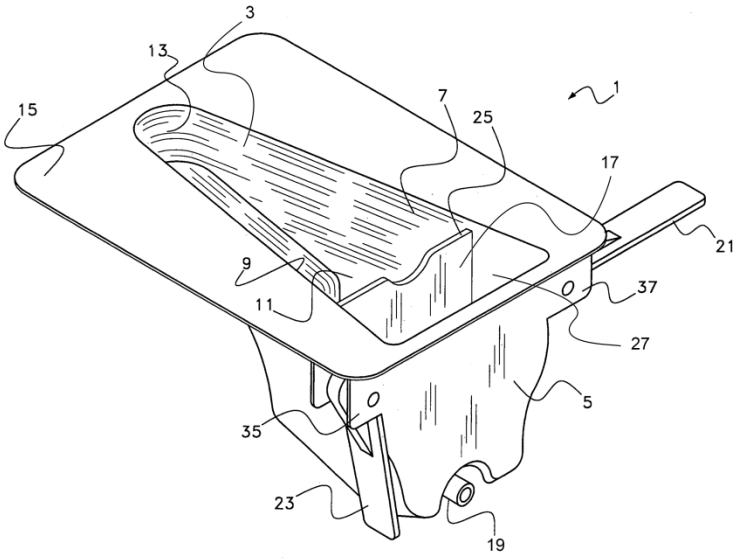


Fig. 1

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

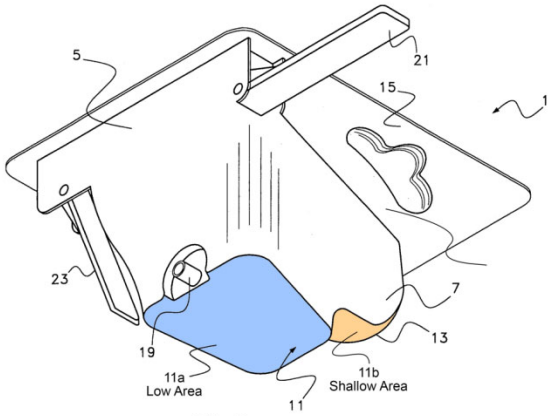


Fig. 2

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

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

Solazzo discloses "*the single level tray defining a first compartment and a second compartment*."

Solazzo discloses the single level tray defining a first compartment (compartment 27) and second compartment (compartment 3) separated by a barrier as shown below in annotated Figure 1. (Ex.1005, 2:61-63.)

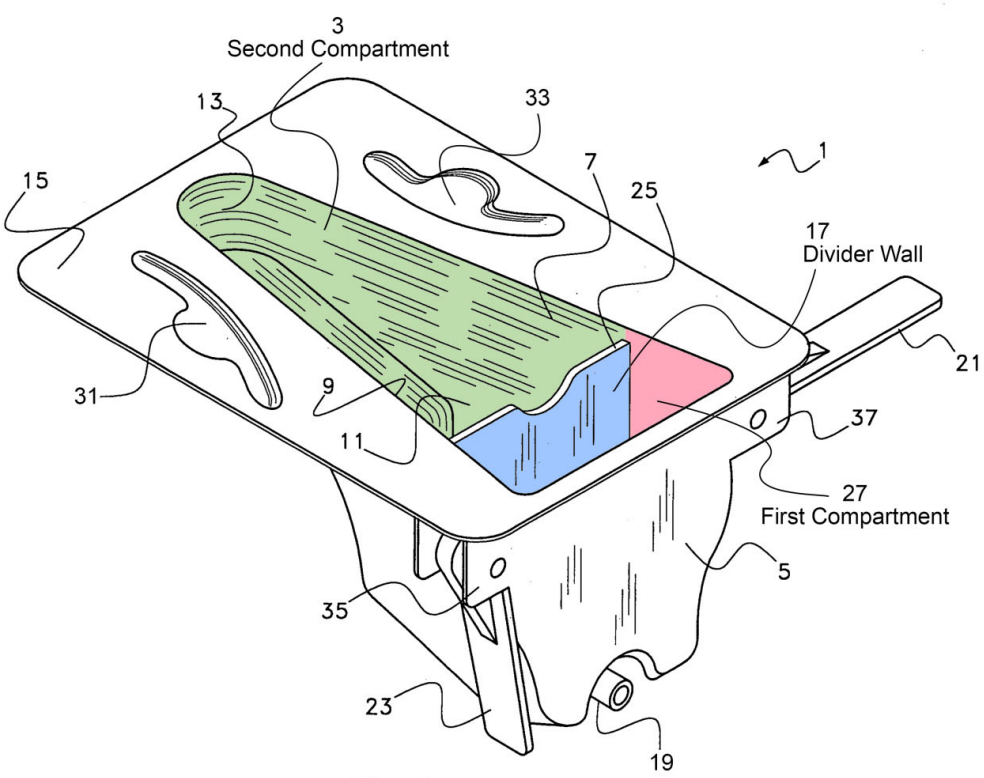


Fig. 1

(iii) ***"… [a first and second] base member forming a portion of a boundary …"***

Solazzo discloses "*the first compartment base member forming a portion of a boundary of the first compartment*, *the second compartment base member forming a portion of a boundary of the second compartment*."

As described at claim 13[a][i] above, low area 11A is a *first compartment base member* and shallow area 11B is a *second compartment base member*. The base members form a boundary (i.e., the bottom surface) of their respective compartments as shown in Figures 1 and 2 below:

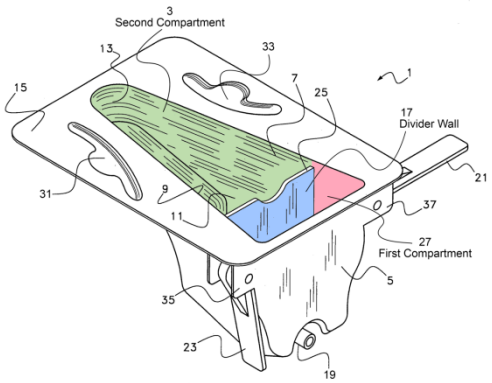


Fig. 1

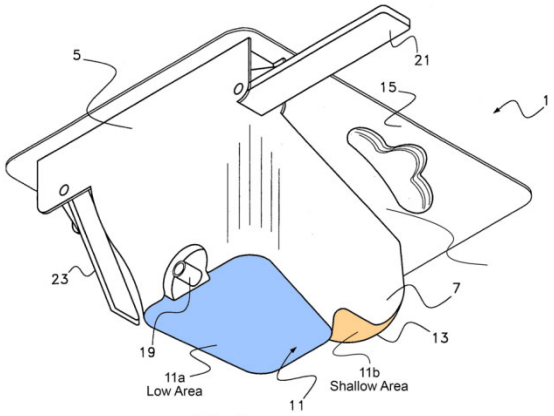


Fig. 2

(iv) ***"…a barrier separating the first compartment from the second compartment"***

Solazzo discloses "*the single level tray including a barrier separating the first compartment from the second compartment*."

Specifically, Solazzo discloses a barrier ("divider wall 17") separating a first compartment 27 and a second compartment 3.

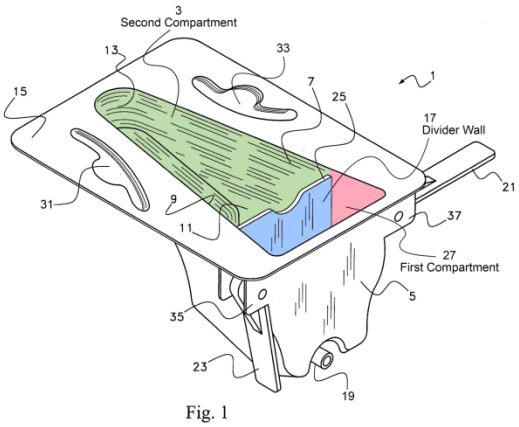


Fig. 1

Accordingly, Solazzo discloses claim 13[a]. (Ex.1002, ¶¶139-54.)

b. ***13[b]:*** *"a first syringe …"*

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

Solazzo discloses: "The kit includes … an inflation syringe for inflation of a catheter with fluid." (Ex.1005, 3:15-24.) The inflation syringe is stored in first compartment (compartment 27) as shown in annotated Figure 8 below:

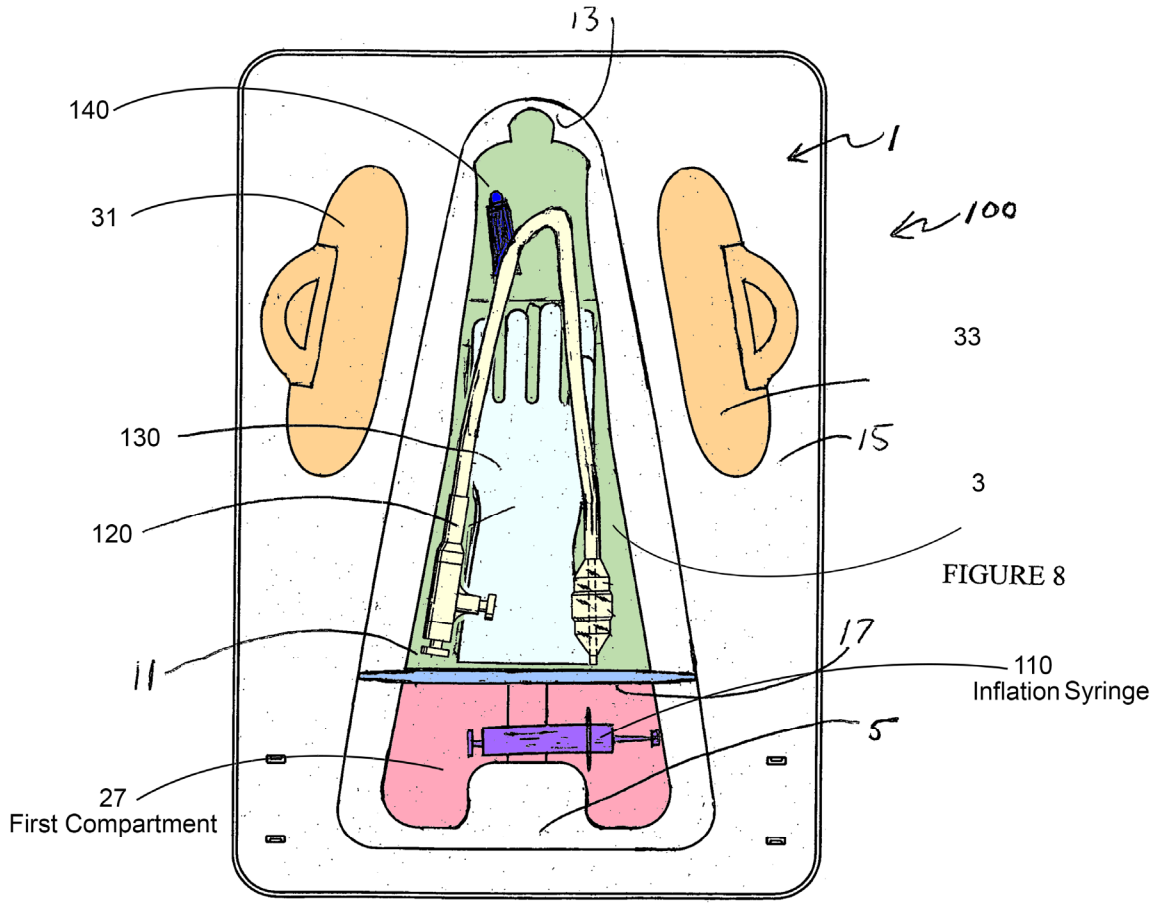


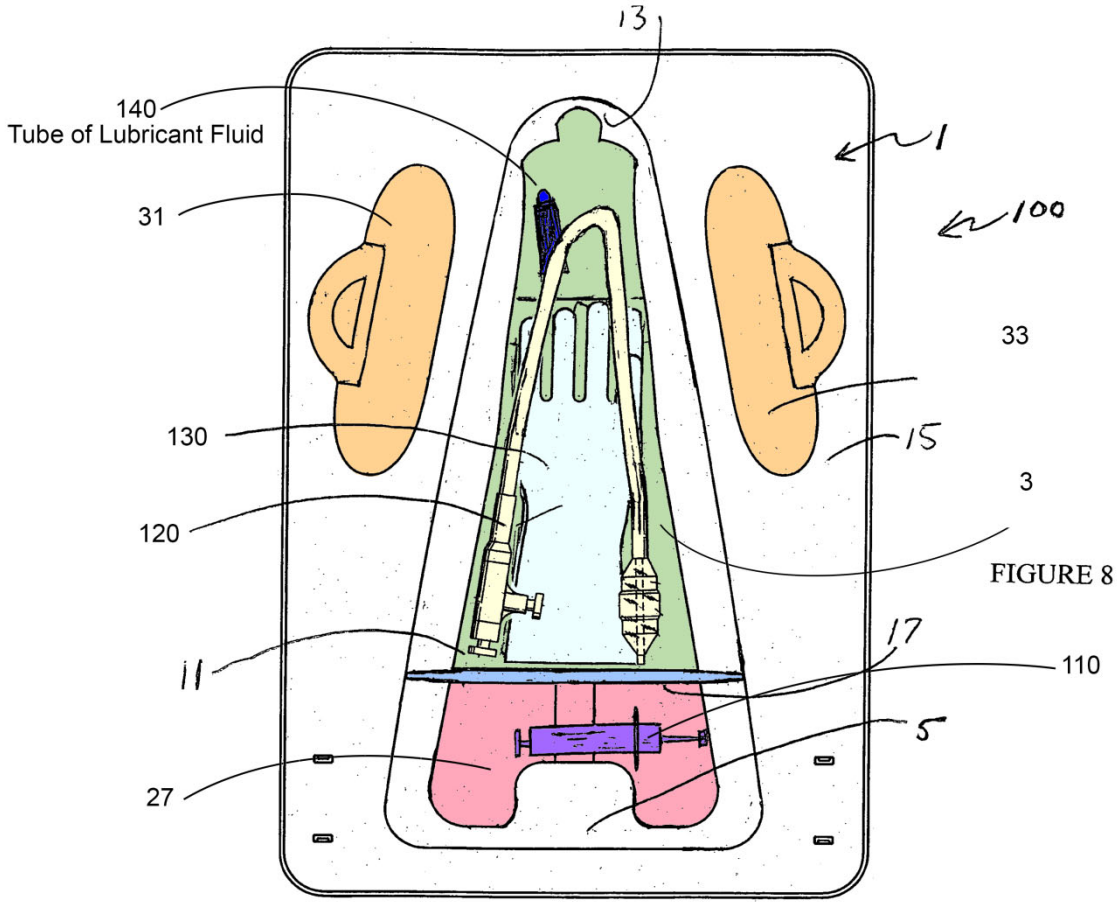
FIGURE 8

Accordingly, Solazzo discloses claim 13[b]. (Ex.1002, ¶¶155-57.)

c. *13[c]*: *"a second syringe… "*

Claim 13[c] requires "*a second syringe disposed within the single level tray, the second syringe containing a lubricant*."

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



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

It would have been obvious to a POSITA at the time of the invention to provide a *syringe* of lubricant fluid in place of the *tube* of lubricant fluid. Doing so would merely involve a simple substitution of one container (a tube as taught by

Solazzo) for another known type of container (a syringe as also taught by Solazzo) to produce predictable results. (Ex.1002, ¶¶160-162.) Indeed, the Board has found such a substitution to be obvious in one of the *Medline I* IPRs. (*See* IPR2015-00513, Institution Decision (Paper 9), 13 ("On the current record, we agree with Petitioner that '[s]ubstituting one container for another type of container (e.g., substituting a lubricant in a 'packet' with a lubricant in a syringe) would have been an obvious substitution of components known to be suitable to yield predictable results.'").)

Accordingly, Solazzo discloses claim 13[c]. (Ex.1002, ¶¶155-163.)

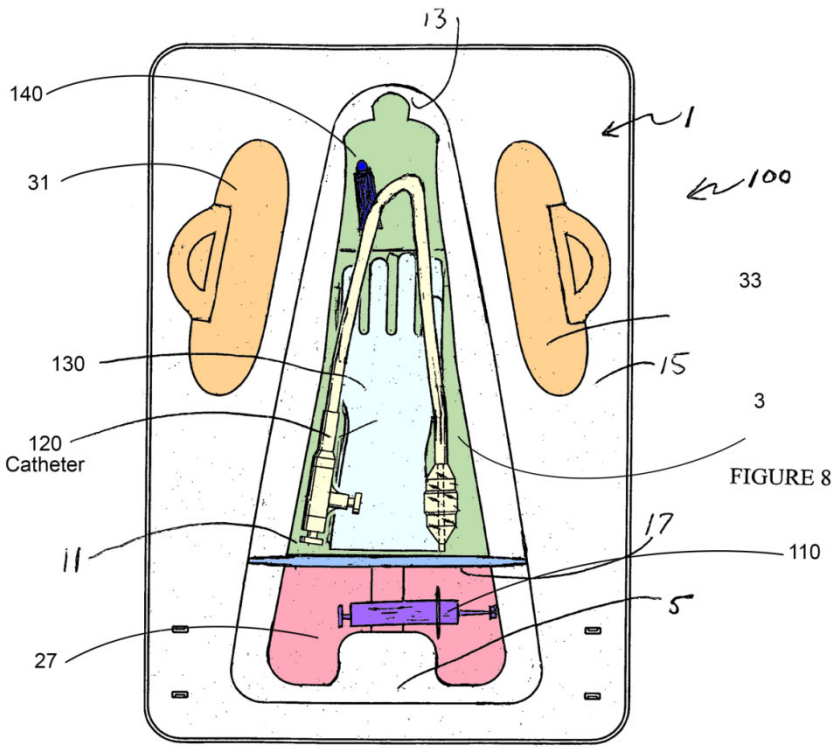
d. *13[d]:* *"a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle ..."*

Claim 13[d] requires "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient, the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device, the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*."

(i) "*…a catheter assembly…*"

Claim 13[d][i] requires "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.*"

Solazzo discloses a catheter (i.e., Foley catheter 120) disposed in the second compartment (compartment 3). (Ex.1005, 3:17; Fig. 8.) A Foley catheter is an *indwelling* catheter. (Ex.1003, ¶11.) The Foley catheter of Solazzo is also an "*indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.*" Solazzo discloses "an inflation syringe [110] for inflation of a catheter with fluid." (Ex.1005, 3:15-24.) Figure 8 depicts a Foley catheter with an inflated balloon:



Solazzo does not expressly mention a Foley catheter that is *pre-connected* to a drainage bag via coiled tubing. But Applicants admitted during the examination of the '400 patent that such an arrangement was well-known. (Ex.1004, 259, ¶33 (Meyst) ("Foley catheters are typically pre-connected to a drainage receptacle via a long coiled tubing.").) Indeed, this arrangement has been known for over 50 years, as evidenced by Serany.

Specifically, Serany discloses a coiled tubing 49 coupling an indwelling catheter ("Foley catheter 48") and a fluid receptacle ("drainage bottle 46"):

"Included in the box 10 beneath the tray 12 are a collapsible drainage bottle 46 and

a Foley catheter 48 (partly shown) connected thereto by the drainage tube 49 and ready for use." (Ex.1006, 3:23-26.)

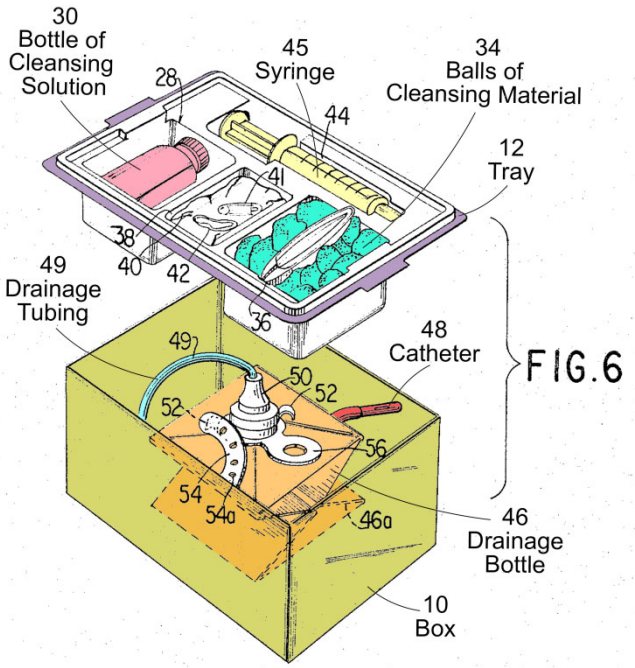


FIG.6

Serany expressly states the tubing 49 is "coiled": "The catheter 48 and drainage tubing 49 connecting it to the bottle 46 are coiled in the box about the bottle." (Ex.1006, 3:33-35.) Serany thus discloses "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle*."

In view of Serany, a POSITA would have been motivated to include a closed-system Foley catheter (including "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle*") in the tray of Solazzo for multiple reasons. (Ex.1002, ¶173.)

First, Serany teaches pre-connected systems that are "ready for use." (Ex.1006, 3:26.) Including a pre-connected Foley system that is "ready for use" in the tray of Solazzo reduces the steps in a Foley catheterization procedure because a fluid/drainage bag does not need to be fetched and connected to the Foley catheter. (Ex.1003, ¶35, Ex. 1006, 1:20-23.)

Second, as Applicants admitted, it was known by 2009 that Foley catheters (such as shown by Solazzo) caused CAUTI. (Ex.1004, 239, ¶29 (Weintraub).) It was further known in the art that closed-system Foley catheters (i.e., Foley catheters that are pre-connected to a drainage bag via tubing) reduce the risk of infection. The Nursing Standard article, which was published in March 2009, notes that providing a "closed system" catheter in a catheterization tray kit, such as in Serany, was a standard practice: "Catheters should be connected to a sterile catheter bag or valve, creating a closed system." (Ex.1010, 52; Ex.1002, ¶390.) According to Nursing Standard, "[t]he risk of infection with an open system is 97% but this falls to between 8% and 15% when a sterile closed system is adopted." (Ex.1010, 51.) Serany describes that "an object of this invention is to provide a catheterization package which reduces the rate of infection." (Ex.1006, 1:31-32; 3:23-36). Thus, reducing the risk of infection would have motivated a POSITA to utilize Serany's closed-system Foley catheter in Solazzo's tray. (Ex.1002, ¶¶171-73.)

Furthermore, placing the closed-system Foley catheter in Solazzo's tray does not eliminate the catheterization and irrigation features of the tray. (Ex.1002, ¶174.) As explained by Dr. Yun, the tray can be best utilized for both purposes when a closed-system Foley catheter is provided in the tray of Solazzo. (Ex.1003, ¶¶41-42.) For example, a practitioner may use the tray to catheterize a patient. The tray can be later used to perform an irrigation procedure if the patient is unable to urinate due to the formation of clots. (Ex.1003, ¶¶41-42.)

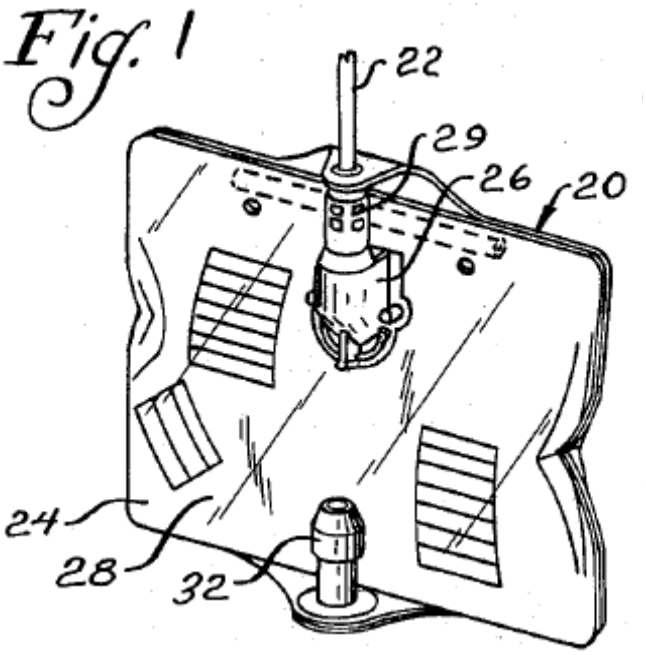
Accordingly, Solazzo in view of Serany discloses claim 13[d][i]. (Ex.1002, ¶¶166-176.)

(ii) "*the fluid receptacle including an anti-reflux device …*"

Claim 13[d][ii] requires "*the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*."

As discussed above in Section III.C, Applicants admitted that anti-reflux devices were associated with Foley catheters, and they never challenged Examiner Poon's finding that a fluid receptacle including an anti-reflux device coupled to a coiled tube was known. (Ex.1004, 73-76, 106-108, 262, ¶41 (Meyst).) It was also well-known in the art to include such a device with a flexible fluid receptacle, such as disclosed in Serany. (Ex.1006, 3:26-32, Fig. 6.) Boedecker is an example of a prior art anti-reflux device.

It issued in the 1970s and describes that pressure exerted against the flexible walls of such receptacles may cause urine to back up into the drainage tube, catheter, and/or patient's bladder, possibly causing trauma or retrograde bacterial movement to the bladder. (Ex.1034, 1:19-35.) Boedecker thus teaches "an anti-reflux device for a collection bag of simplified and improved reliability." (Ex.1034, 1:45-47.) As shown below, a liquid collection bag 24 is connected to "drainage tube 22."



The "drainage tube 22 is connected to and communicates with a connector or a drip chamber 26, which is secured to a wall 28 of the bag 24[.]" (Ex.1034, 2:48-52; Ex.1002, ¶181.) "[V]alve element 34 prevents the reflux of urine from the bag into the connector 26 and drainage tube 22" as shown in Figure 2 below. (Ex.1032, 3:30-32.)

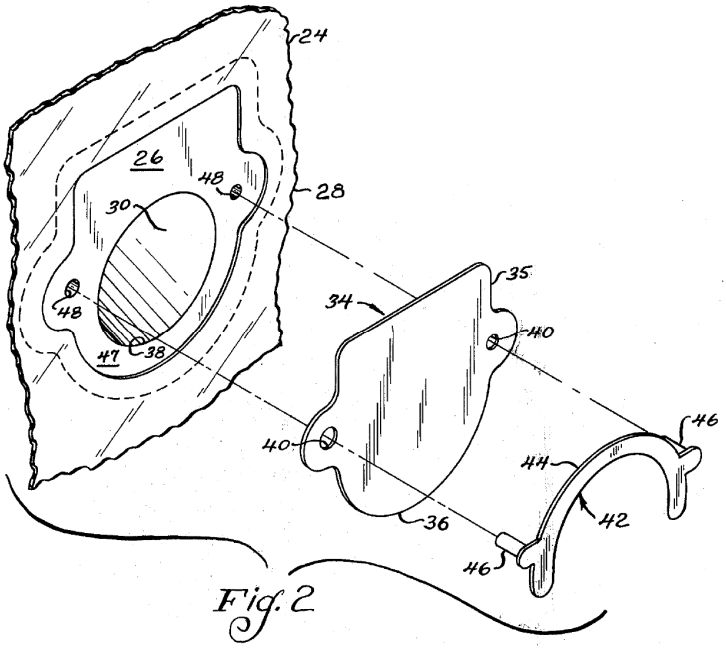


Fig. 2

Thus, the end of the drainage tube 22 is coupled to the anti-reflux device of Boedecker. Accordingly, Boedecker teaches "the *fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*." (Ex.1002, ¶¶180-82.)

It would have been obvious to replace the flexible drainage receptacle 46 of Serany with the "liquid collection bag 24" of Boedecker, such that Serany's drainage tubing 49 would be connected to Boedecker's connector 26 of liquid collection bag 24. (Ex.1002, ¶¶183-186.) Serany and Boedecker are analogous art because both references teach a catheter connected to a flexible fluid receptacle via a drainage tube. Specifically, Serany shows this teaching through Figure 6, and Boedecker states: "During catheterization, urine drains through the catheter and drainage tube to the receptacle for collection." (Ex.1034, 1:13-17.)

The motivation is expressly stated in Boedecker. Boedecker explains that "flexible receptacles or bags … may cause a reflux of urine from the bag into the drainage tube, and possibly the catheter and patient's bladder" due to the "pressure exerted against the side walls of the flexible bag." (Ex.1034, 1:19-25.) Further, "the refluxing urine dramatically increases the possibility of retrograde bacterial movement from the bag to the patient's bladder, with possible deleterious results to the patient." (Ex.1034, 1:25-35.) To prevent the reflux of urine from the drainage receptacle of Serany into a patient's bladder through drainage tubing 49, a POSITA would have been motivated to substitute the drainage receptacle of Serany with the urine collection bag (including an anti-reflux device) as taught by Boedecker. (Ex.1002, ¶185.)

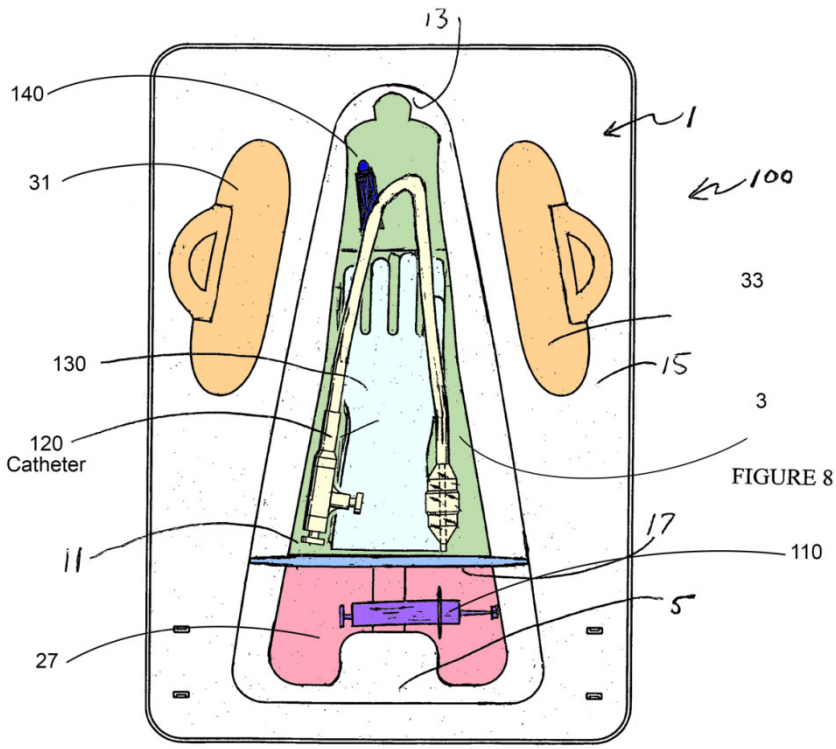
Furthermore, doing so would merely involve a simple substitution of one container (a urine collection receptacle as taught by Serany including connector 50) for another known type of container (a urine collection receptacle as taught by Boedecker including connector 26) to produce predictable results (preventing urine reflux). (Ex.1002, ¶185.)

Accordingly, Solazzo in view of Serany and Boedecker discloses claim 13[d][ii]. (Ex.1002, ¶¶166-187.)

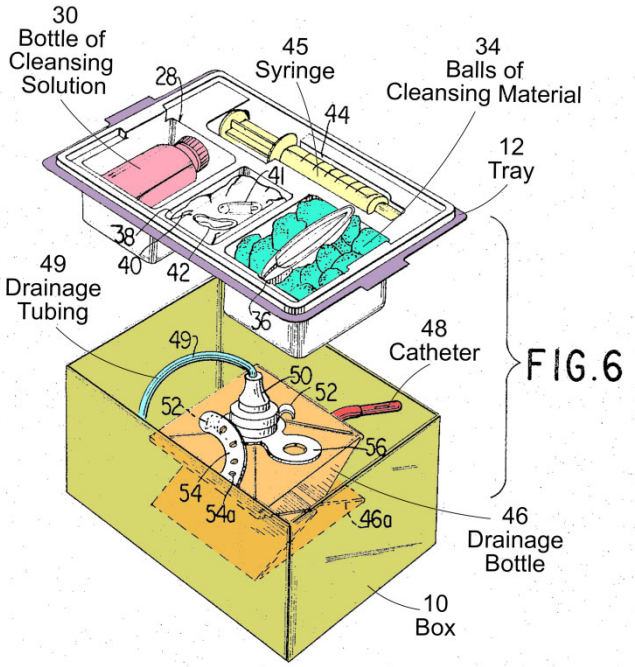
(iii) ***"the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray…"***

Claim 13[d][iii] requires "*the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*."

Solazzo discloses a catheter assembly "*disposed within the second compartment of the single level tray*." Specifically, Foley catheter 120 is disposed in second compartment 3 (almost up to its top edge) of the single level tray of Solazzo:



Serany discloses "*at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*" as shown in Figure 6:



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

Specifically, the drainage bag of Serany is designed to fit in a catheter tray in a collapsed form on the bottom of a tray with the coiled tube wrapped around the drainage receptacle. The second compartment of Solazzo would hold the closed-system Foley catheter of Serany with this same configuration, i.e., with the second compartment base member of Solazzo ("shallow area 11B") beneath the fluid bag and the attached tubing and Foley catheter wrapped around and/or on top of the bag. (Ex.1002, ¶193.) Replacing the drainage receptacle of Serany with a drainage receptacle including an anti-reflux device would not alter this configuration because both are flexible receptacles that may be placed in the bottom of a tray. (Ex.1002, ¶193.)

Serany provides further motivation to arrange the items of a closed-system Foley catheter such that the drainage receptacle is on the bottom of the tray. (Ex.1002, ¶194.) Serany discloses a tray that provides "components in their preferred order of use" and "proper order of use." (Ex.1006, 1:9-12; 1:23-25.) A healthcare provider would need access to the drainage tubing before a fluid receptacle because it is attached to the Foley catheter. (Ex.1002, ¶194.) Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Solazzo with "*at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*." (Ex.1002, ¶¶192-94.)

Accordingly, Solazzo in view of Serany discloses claim 13[d][iii]. (Ex.1002, ¶¶188-95.)

Thus, Solazzo in view of Serany and Boedecker renders claim 13 obvious.

2) Claim 14

For the reasons at claim 13[d][iii], Solazzo in view of Serany discloses "*wherein the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube*. (Ex.1002, ¶¶188-98.)

Thus, Solazzo in view of Serany and Boedecker renders claim 14 obvious.

3) Claim 16

a. ***16[a]:*** *"the single level tray defines a top opening ..."*

Solazzo discloses "*the single level tray defines a top opening through which the first compartment and the second compartment can be accessed*."

Specifically, Solazzo discloses a single level tray that defines a top opening for accessing the two compartments 3 and 27, as shown in Figure 1:

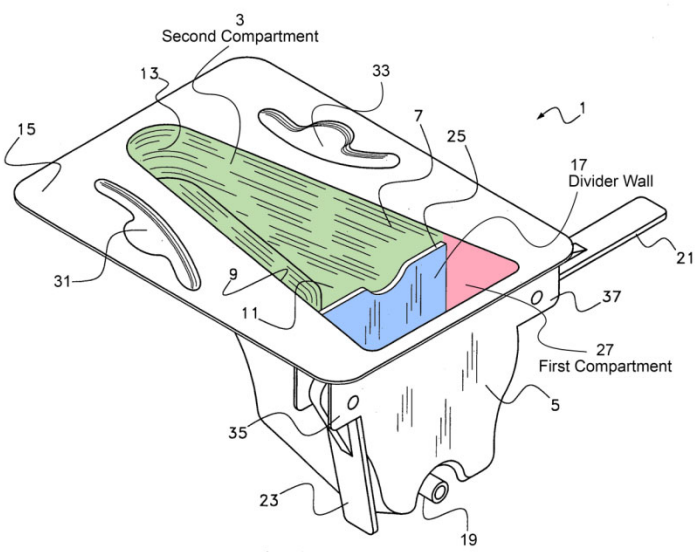


Fig. 1

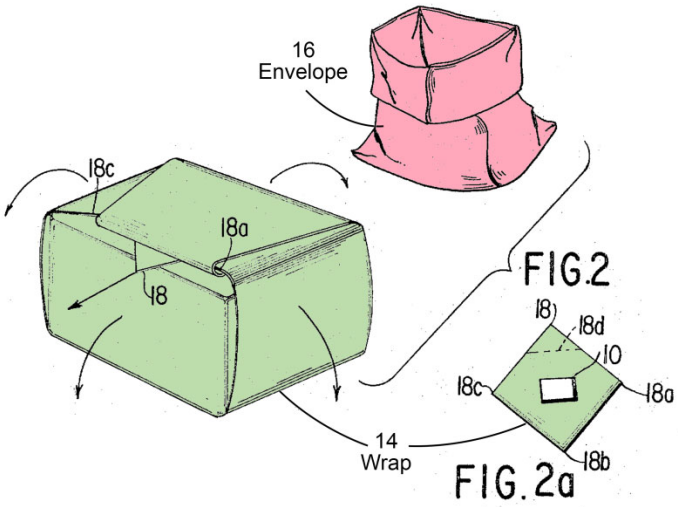
Accordingly, Solazzo discloses claim 16[a]. (Ex.1002, ¶¶199-02.)

b. ***16[b]:*** *"a sterile wrap disposed about the single level tray covering at least the top opening"*

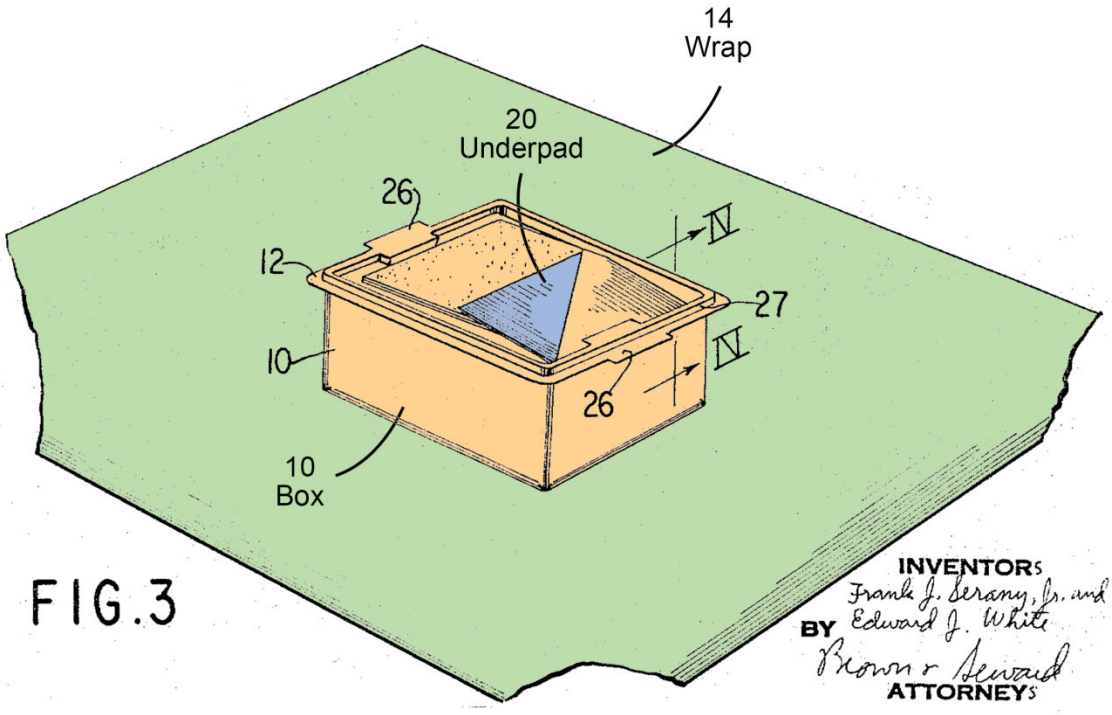
Claim 16[b] requires "*a sterile wrap disposed about the single level tray covering at least the top opening*."

Solazzo discloses a single level tray with a top opening, but does not state 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," as shown in green at annotated Figure 2 (below). (Ex.1006, 1:60-63.)



The wrap 14 ensures that "components are maintained sterile until the package is opened." (Ex.1006, 1:13-16.) When the sterile wrap 14 is unfolded, as shown in annotated Figure 3, 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 of 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, ¶209.)

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. (Ex.1006, 1:13-16; Ex.1002, ¶210-11.) Thus, wrapping the tray of Solazzo in Serany's wrap would preserve the sterility of Solazzo's components inside the tray.

Accordingly, Solazzo in view of Serany discloses claim 16[b]. (Ex.1002, ¶¶203-13.) Thus, Solazzo in view of Serany and Boedecker renders claim 16 obvious.

4) Claim 17

Claim 17 requires "*wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed*."

For the reasons at claim 16, Solazzo in view of Serany discloses "*the sterile wrap...unwrapped from about the top opening*."

Solazzo discloses a tray with a top opening. The tray holds a *first syringe*, ("inflation syringe") *second syringe* ("lubrication tube 140" – replaceable with a syringe), and an *indwelling catheter"* ("Foley catheter 120"):

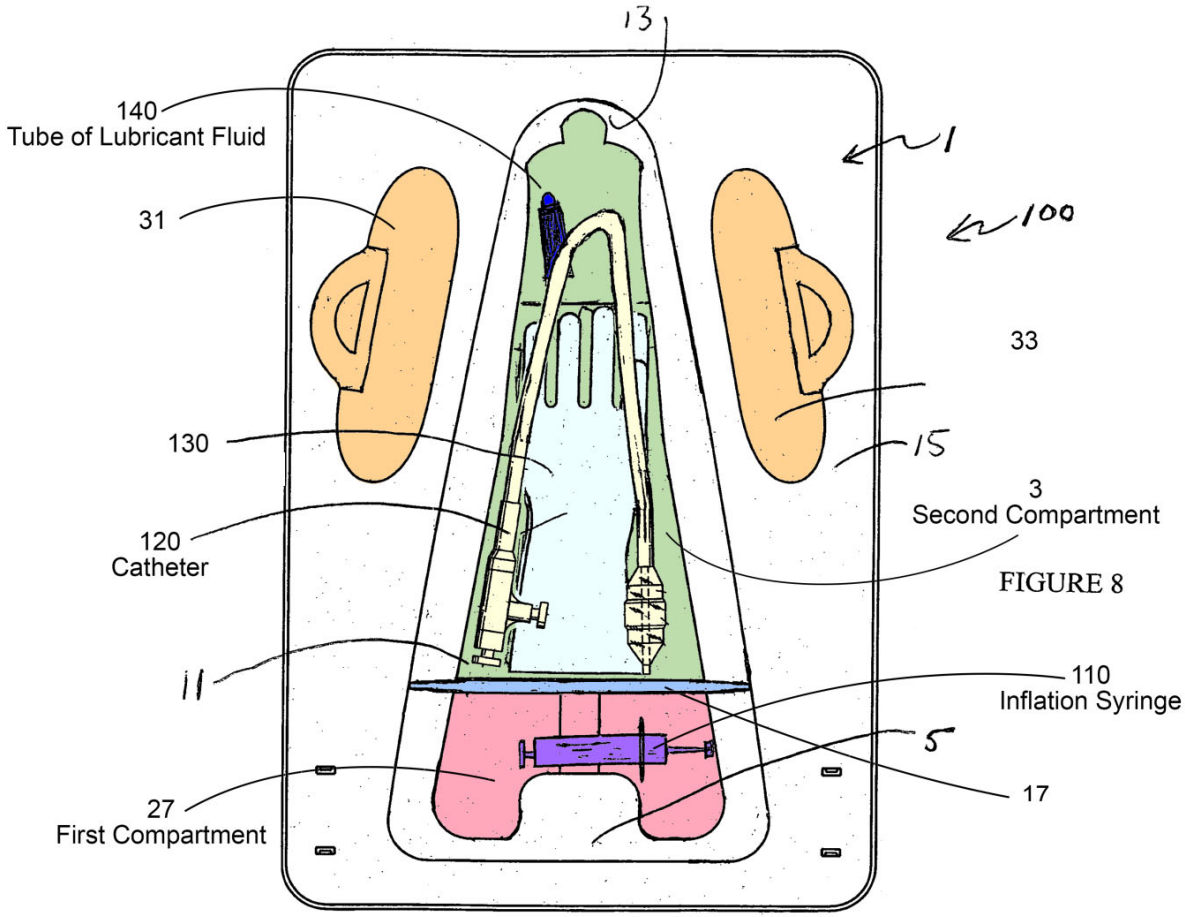


FIGURE 8

"*When the sterile wrap is unwrapped from about the top opening*" of the tray of Solazzo, the components shown in Figure 8 are revealed because Solazzo has an open top and does not teach any items in between the opening and the components shown in Figure 8 that would obstruct the view. (Ex.1002, ¶217.)

Accordingly, Solazzo in view of Serany discloses claim 17. (Ex.1002, ¶¶214-219.) Solazzo in view of Serany and Boedecker therefore renders claim 17 obvious.

B. Ground 2 (Claims 13, 14, 16, and 17) – Obvious Based on Solazzo, Serany, and Peterson

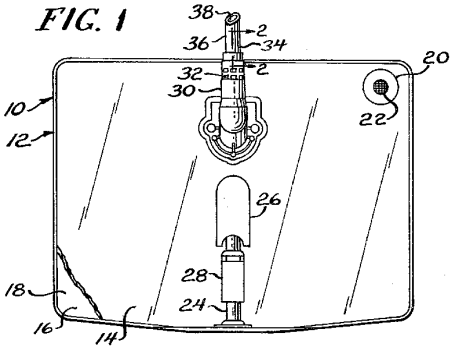
1. Summary of Peterson

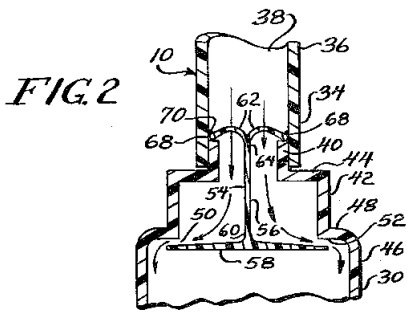
Peterson issued on June 15, 1982. Peterson is therefore prior art to the '400 patent under at least 35 U.S.C. § 102(b).

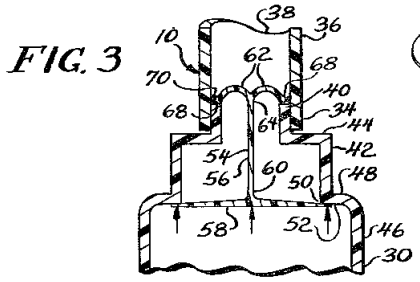
Peterson is directed to a flexible drainage receptacle having an anti-reflux valve to prevent reflux of urine, which can occur when the receptacle is inadvertently squeezed during catheterization. (Ex.1036, 1:1-26.) Preventing reflux is necessary because refluxing urine increases the possibility of retrograde movement of bacteria toward the bladder. (Ex.1036, 26-33.)

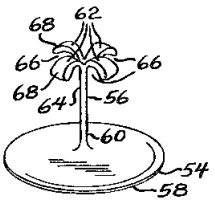
Peterson's anti-reflux device 10 includes a valve element 54 seated shut within a drip chamber or connector 30, which couples a drainage tube 36 to the receptacle 12. (Ex.1036, 3:40-45.) When urine passes from the tube 36 to the

connector 30, a disc of the valve element 54 is temporarily unseated to permit passage of urine into the receptacle 12. (Ex.1036, 3:48-56; Ex.1002, ¶131.)









2. The Combination

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

1) Claim 13

a. ***Preamble and 13[a]:*** *"A single level tray including a first compartment base member…"*

For the reasons at Ground 1, claim 13[a], Solazzo discloses "*a single level tray including a first compartment base member and a second compartment base member, the single level tray defining a first compartment and a second compartment, the first compartment base member forming a portion of a boundary of the first compartment, the second compartment base member forming a portion*

of a boundary of the second compartment, the single level tray including a barrier separating the first compartment from the second compartment."

b. 13[b]: *"a first syringe …"*

For the reasons at Ground 1, claim 13[b], Solazzo discloses "*a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid*."

c. 13[c]: *"a second syringe… "*

For the reasons at Ground 1, claim 13[c], Solazzo discloses "*a second syringe disposed within the single level tray, the second syringe containing a lubricant*."

d. 13[d]: *"a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle …"*

(i) "*…a catheter assembly…*"

For the reasons at Ground 1, claim 13[d][i], Solazzo in view of Serany discloses "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.*"

(ii) "*the fluid receptacle including an anti-reflux device …*"

Claim 13[d][ii] requires "*the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*."

Serany teaches a *fluid receptacle* made out of a flexible plastic material to allow the "bottle 46" to be folded flat in the box 10. (Ex.1006, 3:26-32.)

It was also well-known in the art to include an anti-reflux device with a fluid receptacle, as admitted by Applicants and disclosed in Serany. (Ex.1006, 3:26-32, Fig. 6; Ex.1004, 73-76, 106-108, 262, ¶41 (Meyst).)

Peterson is entitled "Drainage Receptacle with Anti-Reflux Device" and teaches "an anti-reflux device of simplified construction." (Ex.1036, 1:36-38.) The "drainage receptacle 12" of Peterson is connected to "drainage tube 36" via connector 30. (Ex.1036, 2:34-38, Fig. 1.)

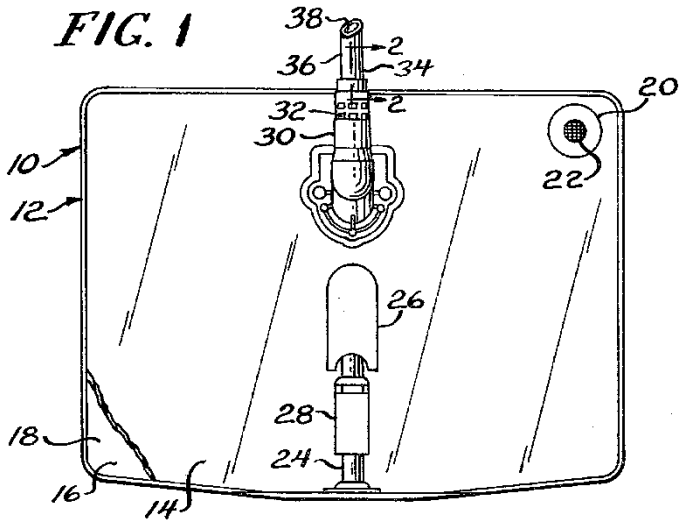


FIG. 2

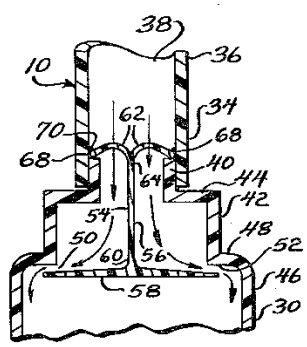
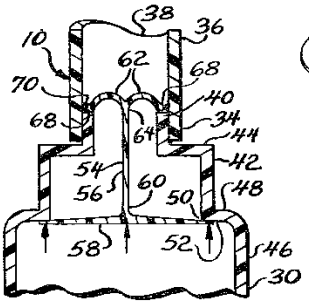


FIG. 3



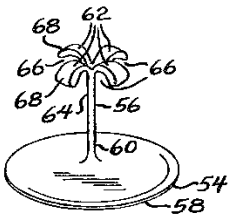


FIG. 4

As shown in Figures 2-4, Peterson teaches an "anti-reflux device 10" with a valve element 54 that prevents the reflux of urine. (Ex.1036, 3:29-39) The valve element is part of the connector 30. (Ex.1036, Figs 1-4.) Thus, the end of the drainage tube 36 is coupled to the anti-reflux device. (Ex.1002, ¶231.) Accordingly, Peterson discloses "the *fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*."

It would have been obvious to a POSITA to add the anti-reflux device of Peterson to the flexible drainage receptacle 46 of Serany, such that Serany's drainage tubing 49 would be connected to Peterson's connector 30 of liquid collection bag 12. (Ex.1002, ¶¶232-34.) Serany and Peterson are analogous art because both references teach a catheter connected to a flexible fluid receptacle via

drainage tube. Specifically, Serany shows this teaching in Figure 6, and Peterson describes urine flowing from a catheter through a drainage tube and into a drainage receptacle. (Ex.1036, 2:46-67.)

The motivation to makes these changes are express in Peterson. (Ex.1002, ¶233.) Peterson explains that "if the flexible plastic walls 14 and 16 of the receptacle 12 are squeezed during catheterization, the urine may reflux from the chamber 18 into the lumen 38 of the drainage tube 36 and possibly the lumen of the catheter." (Ex.1036, 2:62-65.) Further, "the refluxing urine may cause retrograde movement of bacteria toward the patient's bladder with possible deleterious effects to the patient." (Ex.1036, 1:66-68.) To prevent the reflux of urine from the drainage receptacle of Serany into a patient's bladder through drainage tubing 49, a POSITA would have been motivated to substitute the drainage receptacle of Serany with the urine collection bag (including an anti-reflux device) as taught by Peterson. (Ex.1002, ¶234.)

Furthermore, doing so would merely involve a simple substitution of one container (a urine collection receptacle as taught by Serany including connector 50) for another known type of container (a urine collection receptacle with an anti-reflex device as taught by Peterson including connector 30) to produce predictable results (preventing urine reflux). (Ex.1002, ¶234.)

Alternatively, it would have been obvious to a POSITA to add the anti-reflux device of Peterson to the drainage receptacle 46 of Serany, which is attached to a detachable connection fitting 50 that connects Serany's catheter drainage tube 49. (Ex.1006, 3:34-36.) Serany's connection fitting 50 would be fitted with the anti-reflux valve element 54 of Peterson. The motivation would be to prevent urine reflux as discussed above. (Ex.1002, ¶234.)

Furthermore, doing so would merely involve applying a known technique to a known device ready for improvement to yield predictable results. Serany's drainage receptacle 46, with its connection fitting 50, is a base device ready for improvement. Peterson's use of an anti-reflux valve element 54 was a known technique that could be applied to Serany's connection fitting 50 to improve Serany's drainage receptacle from experiencing urine reflux. (Ex.1002, ¶235.)

Accordingly, Solazzo in view of Serany and Peterson discloses claim 13[d][ii].

(iii) ***"the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray…"***

For the reasons at Ground 1, claim 13[d][iii], Solazzo in view of Serany discloses "*the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being*

outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube."

Thus, Solazzo in view of Serany and Peterson renders this claim obvious.

2) Claim 14

For the reasons at claim 13[d][iii], Solazzo in view of Serany discloses "*wherein the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube*.

Thus, Solazzo in view of Serany and Peterson renders this claim obvious.

3) Claim 16

a. *16[a]:* *"the single level tray defines a top opening ..."*

For the reasons at Ground 1, claim 16[a], Solazzo discloses "*the single level tray defines a top opening through which the first compartment and the second compartment can be accessed*."

b. *16[b]:* *"a sterile wrap disposed about the single level tray covering at least the top opening"*

For the reasons at Ground 1, claim 16[b], Solazzo in view of Serany discloses "*a sterile wrap disposed about the single level tray covering at least the top opening*."

Thus, Solazzo in view of Serany and Peterson renders claim 16 obvious.

4) Claim 17

For the reasons at Ground 1, claim 17, Solazzo in view of Serany discloses "*wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed*."

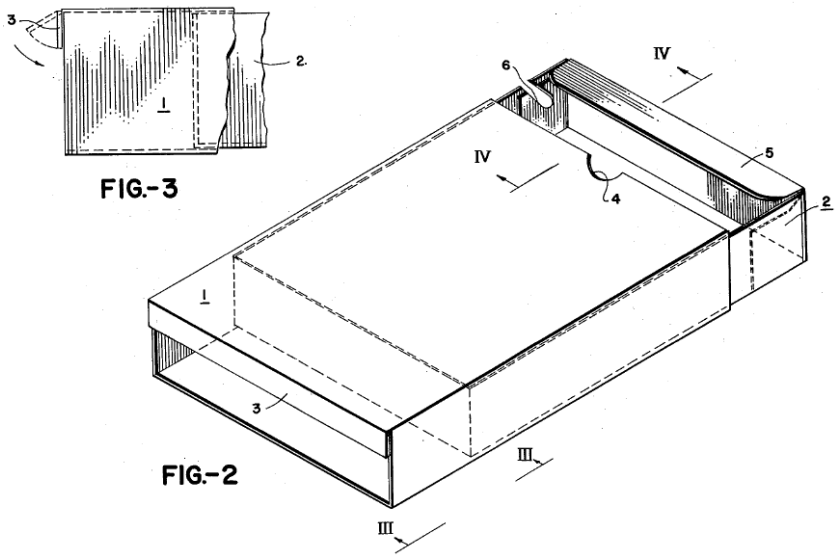
Thus, Solazzo in view of Serany and Peterson renders this claim obvious.

C. Ground 3 (Claims 13 and 14) – Obvious Based on Solazzo, Disston, and Boedecker

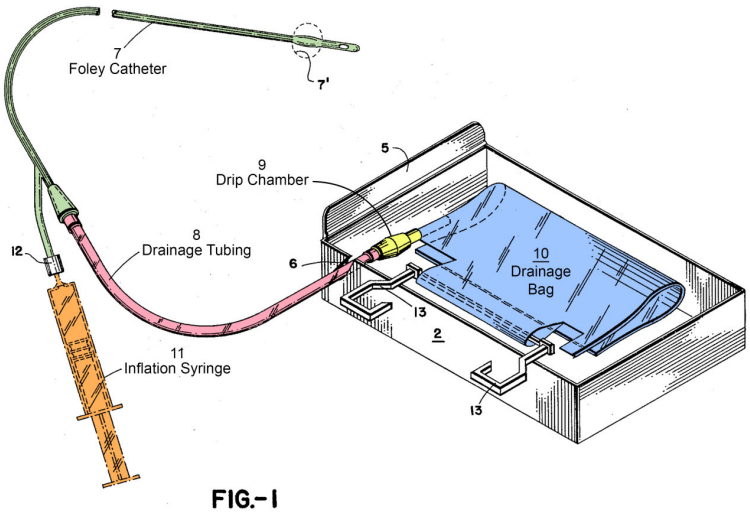
1. Summary of Disston

Disston issued on January 19, 1965. Disston is therefore prior art to the '400 patent under at least 35 U.S.C. § 102(b).

Disston is directed to a single-level, wrapped catheterization tray package that "provide[s] for the first time a complete, properly organized, conveniently arranged, sterile set of equipment for catheterization, the entire drainage system being pre-assembled." (Ex.1008, 1:59-67, 2:60-63; Figs. 2-3.) The single-level tray 2 contains catheterization devices "arranged in such order and position as to be most conveniently available when the container is opened." (Ex.1008, 2:15-23.)



The package includes "a pre-assembled catheter-drainage tube-drip chamber-drainage bag," including a Foley catheter 7, drainage tube 8, drip chamber 9, drainage bag 10, with "suitable adapters being interposed, if necessary, between the catheter and tube and/ or between the drip chamber and bag." (Ex.1008, 1:33-34, 2:15-23; Fig. 1; Ex.1002, ¶118.)



Disston acknowledges that urine reflux is undesirable and instructs: "hold the drip chamber higher than the bag and prevent spillage or back flow when the catheter is first inserted and before the bag and its support have been installed on the bed rail." (Ex.1008, 1:35-42; Ex.102, ¶119.)

2. The Combination

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

1) Claim 13

a. Preamble and 13[a]: *"A single level tray including a first compartment base member…"*

For the reasons at Ground 1, claim 13[a], Solazzo discloses "*a single level tray including a first compartment base member and a second compartment base member, the single level tray defining a first compartment and a second compartment, the first compartment base member forming a portion of a boundary of the first compartment, the second compartment base member forming a portion of a boundary of the second compartment, the single level tray including a barrier separating the first compartment from the second compartment.*"

b. 13[b]: *"a first syringe …"*

For the reasons at Ground 1, claim 13[b], Solazzo discloses "*a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid*."

c. 13[c]: *"a second syringe…"*

For the reasons at Ground 1, claim 13[c], Solazzo discloses "*a second syringe disposed within the single level tray, the second syringe containing a lubricant*."

d. ***13[d]:*** *"a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle …"*

(i) "…*a catheter assembly*…"

Claim 13[d][i] requires "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.*"

For the reasons at Ground 1, claim 13[d], Solazzo discloses an indwelling catheter including an inflatable portion (i.e., Foley catheter 120) disposed in the second compartment (compartment 3), but does not expressly mention a Foley catheter that is *pre-connected* to a drainage bag via coiled tubing. This arrangement has been known for over 50 years, as evidenced by Applicants' admission during the examination of the '400 patent and by Disston. (Ex.1004, 259, ¶33 (Meyst).)

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

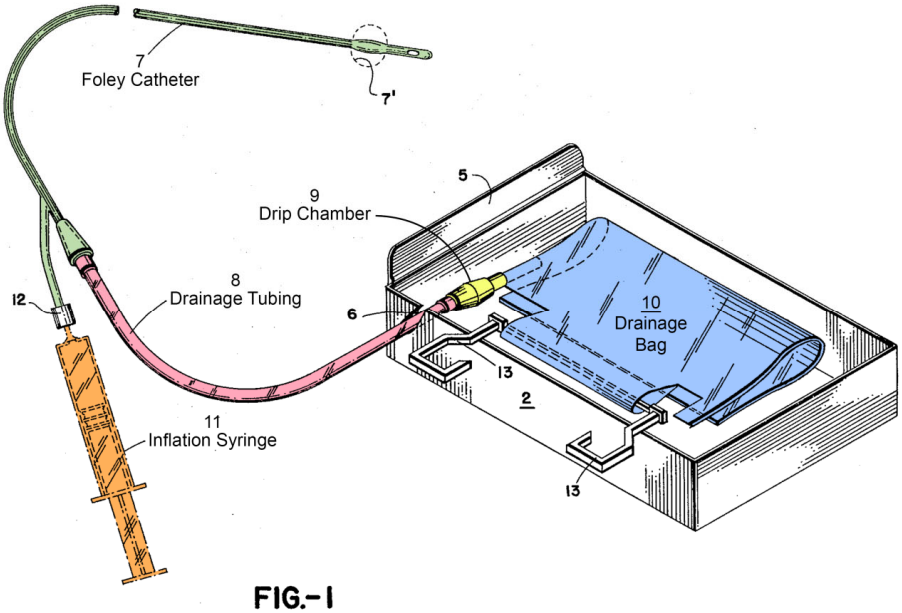


FIG.-1

The drainage tube 8 is coiled as shown in Figure 1. The drainage tube of Disston would also be coiled around a drainage bag when stored in the tray of Solazzo to fit the tubing in the box and prevent kinks. (Ex.1002, ¶255.) Thus, Disston discloses "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.*"

In view of Disston, a POSITA would have been motivated to include a closed-system Foley catheter (including "*a catheter assembly including a coiled*

tube coupling an indwelling catheter to a fluid receptacle") in the tray of Solazzo for multiple reasons. (Ex.1002, ¶257.)

First, Disston teaches pre-connected systems that are "ready for use." (Ex.1008, 1:35.) Including a pre-connected Foley system that is "ready for use" in the tray of Solazzo reduces the steps in a Foley catheterization procedure because a fluid/drainage bag does not need to be fetched and connected to the Foley catheter. (Ex.1003, ¶35.)

Second, as Applicants admitted, it was known by 2009 that Foley catheters (such as shown by Solazzo) caused CAUTI. (Ex.1004, 239, ¶29 (Weintraub).) It was further known in the art that closed-system Foley catheters (i.e., Foley catheters that are pre-connected to a drainage bag via tubing) reduce the risk of infection. Nursing Standard notes that providing a "closed system" was a standard practice and dramatically reduced infection rates. (Ex.1010, 51-52; Ex.1002, ¶390.) Thus, reducing the risk of infection would have motivated a POSITA to utilize Disston's closed-system Foley catheter in Solazzo's tray. (Ex.1002, ¶¶256-257)

Furthermore, placing the closed-system Foley catheter in Solazzo's tray does not eliminate the catheterization and irrigation features of the tray. (Ex.1002, ¶287; Ex.1003, ¶¶41-42.)

Accordingly, Solazzo in view of Disston discloses claim 13[d][i]. (Ex.1002, ¶¶250-260.)

(ii) "*the fluid receptacle including an anti-reflux device …*";

Claim 13[d][ii] requires "*the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*."

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

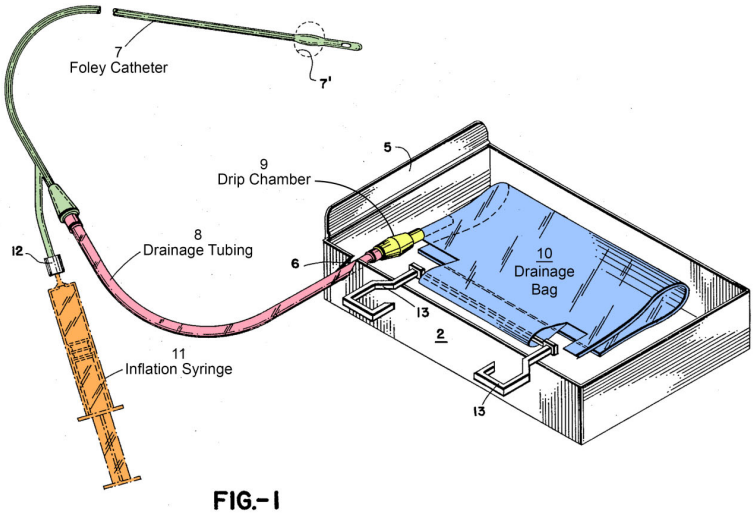
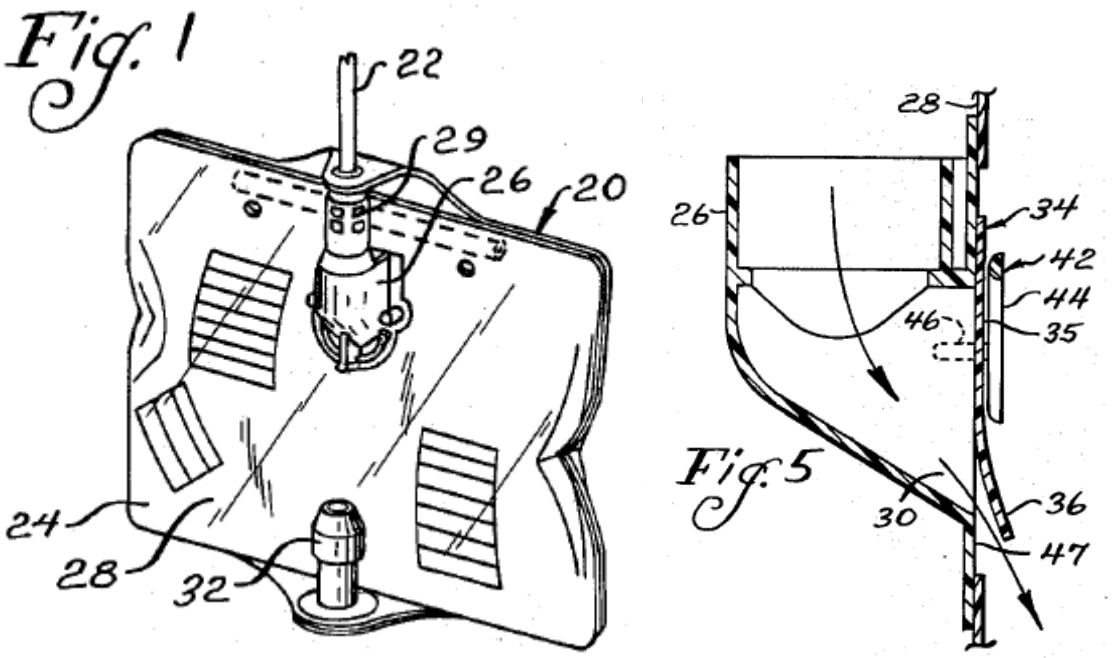


FIG.-1

Disston does not expressly recite a *fluid receptacle* including an anti-reflux device. It was also well-known in the art to include an anti-reflux device with a fluid receptacle, as admitted by Applicants. (Ex.1004, 73-76, 106-108, 262, ¶41 (Meyst).) Moreover, Disston is concerned with the problem of urine "back flow." Disston notes that drip chamber 9 is held higher than bag via a notch in the tray to prevent urine "back flow." (Ex.1008, 1:35-46.)

Boedecker teaches an anti-reflux device including a valve element 34 provided at an inlet opening of a liquid collection bag 24, which is a fluid receptacle for urinary catheterization. (Ex.1034, 1:7-9, 2:63-3:3.) A connector or drip chamber 26 couples the inlet opening to a drainage tube 22, which further connects to a catheter. (Ex.1034, 2:49-60.) Boedecker's anti-reflux device flexes open at the inlet opening to permit urine flow to enter the bag, and seals shut against the connector 26 to prevent the collected flow from escaping. (Ex.1034, 3:20-30.)



It would have been obvious to a POSITA to modify Disston in view of Boedecker. (Ex.1002, ¶¶269-75.) Disston addresses the problem of urine "back flow," but requires an extra step to accomplish: placing the tubing in a notch in the tray to keep the drip chamber 9 higher than drainage bag 10. The drip chamber 26

of Boedecker (including an anti-reflux device) prevents urine backflow without the need to keep the drip chamber higher than the drainage bag because of the provision of valve element 34. It would thus have been obvious to replace the drainage bag 10 of Disston with the "liquid collection bag 24" of Boedecker, such that Disston's drainage tubing 8 would be connected to Boedecker's connector 26 of liquid collection bag 24. Such a modification would solve the problem of urine reflux while eliminating a step of the catheterization procedure. (Ex.1002, ¶¶269-71.)

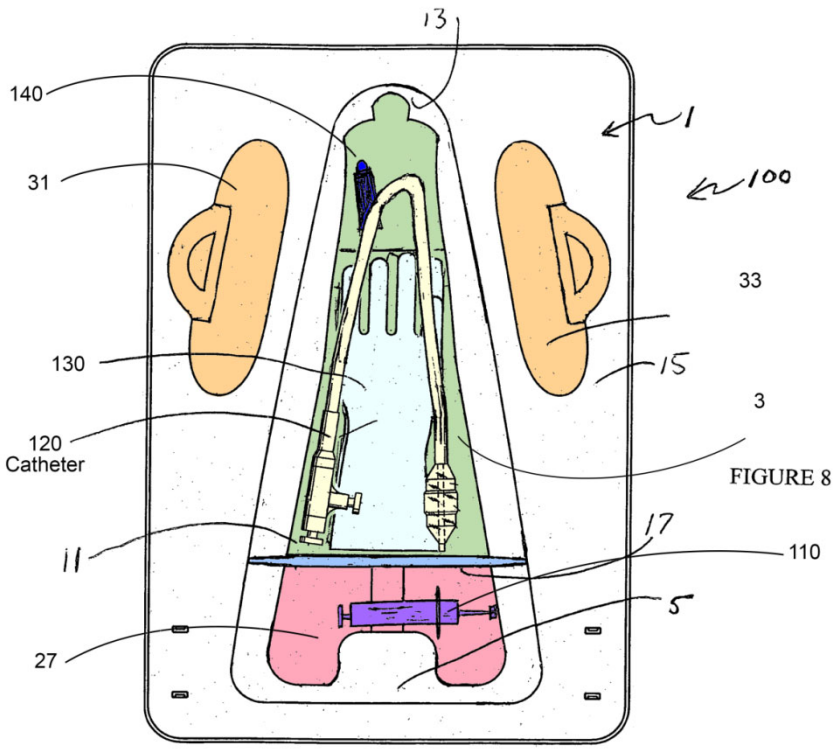
Furthermore, Boedecker provides express motivation to add an anti-reflux device to Disston by noting that "flexible receptacles or bags … may cause a reflux of urine from the bag into the drainage tube, and possibly the catheter and patient's bladder" due to the "pressure exerted against the side walls of the flexible bag." (Ex.1034, 1:19-25.) Further, Boedecker states that "refluxing urine dramatically increases the possibility of retrograde bacterial movement from the bag to the patient's bladder, with possible deleterious results to the patient." (Ex.1034, 1:25-35.) To prevent the reflux of urine from the drainage bag of Disston into a patient's bladder through drainage tubing 8, a POSITA would have been motivated to substitute the drainage bag of Disston with the urine collection bag (including an anti-reflux device) as taught by Boedecker. (Ex.1002, ¶272.)

Finally, doing so would merely involve a simple substitution of one container (a urine collection receptacle as taught by Disston including connector 9) for another known type of container (a urine collection receptacle as taught by Boedecker including connector 26) to produce predictable results. (Ex.1002, ¶275.)

Accordingly, Solazzo in view of Disston and Boedecker teaches claim 13[d][ii]. (Ex.1002, ¶251-76.)

(iii) *"the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray…"*

Claim 13[d][iii] requires "*the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*." Solazzo discloses a catheter assembly "*disposed within the second compartment of the single level tray*." Specifically, Foley catheter 120 is disposed in second compartment 3 (almost up to its top edge) of the single-level tray of Solazzo:



Disston discloses "*at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*." Specifically, Disston discloses a Foley catheter 7 connected to coiled drainage tubing 8 connected to a drainage receptacle (drainage bag 10). (Ex.1008 at 2:15-23; Fig. 1.)

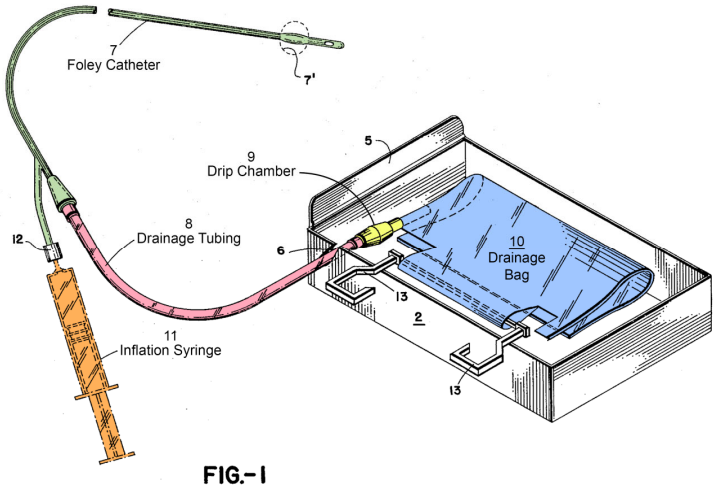


FIG.-1

As shown in Figure 1, the *fluid receptacle* (drainage bag 10) is between the bottom of box 10 (a base member) and the coiled tube (drainage tubing 8). The drainage tubing is provided outside of the fluid receptacle. Examiner Poon further noted that the feature of the fluid receptacle beneath the coiled tube was admitted art. As discussed above in Section III.C, Applicants never challenged this finding. (Ex.1004, 73-76, 106-108.)

Therefore, when the closed-system Foley catheter of Disston is added to the second compartment of Solazzo where the Foley catheter is placed, the following limitation is met: "*the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is*

between the second compartment base member and the coiled tube." (Ex.1002, ¶¶278-82.)

Specifically, the drainage bag of Disston is designed to fit in the bottom of a catheter tray, and the coiled tube can be placed on top of or wrapped around the drainage receptacle. The second compartment of Solazzo would hold the closed-system Foley catheter of Disston with this same configuration, i.e., with the second compartment base member of Solazzo ("shallow area 11B") beneath the fluid bag and the attached tubing and Foley catheter wrapped around and/or on top of the bag. (Ex.1002, ¶282.) Replacing the drainage receptacle of Disston with a drainage receptacle including an anti-reflux device would not alter this configuration because both are flexible receptacles that may be placed in the bottom of a tray. (Ex.1002, ¶282.)

Disston provides further motivation to arrange the items of a closed-system Foley catheter such that the drainage receptacle is on the bottom of the tray. Specifically, Disston discloses catheterization components that are "arranged in such order as to be most conveniently available when the container is opened…." (Ex.1008, 2:15-19.) A healthcare provider would need access to the drainage tubing before a fluid receptacle because it is attached to the Foley catheter. (Ex.1002, ¶283.) Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Solazzo such that "*at least a portion of the*

coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube." (Ex.1002, ¶¶283-84.)

Accordingly, Solazzo in view of Disston discloses claim 13[d][iii]. Thus, Solazzo in view of Disston and Boedecker renders claim 13 obvious. (Ex.1002, ¶¶277-85.)

2) Claim 14

For the reasons at claim 13[d][iii], Solazzo in view of Disston discloses "*wherein the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube*. (Ex.1002, ¶¶277-87.)

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

D. Ground 4 (Claims 16 and 17) – Obvious Based on Solazzo, Disston, Boedecker, and Serany

1. The Combination

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

1) Claim 16

a. *16[a]:* *"the single level tray defines a top opening ..."*

For the reasons at Ground 1, claim 16[a], Solazzo discloses "*the single level tray defines a top opening through which the first compartment and the second compartment can be accessed*."

b. *16[b]:* *"a sterile wrap disposed about the single level tray covering at least the top opening"*

For the reasons at Ground 1, claim 16[b], Solazzo in view of Serany discloses "*a sterile wrap disposed about the single level tray covering at least the top opening*."

Thus, Solazzo in view of Disston, Boedecker, and Serany renders claim 16 obvious.

2) Claim 17

For the reasons at Ground 1, claim 17, Solazzo in view of Serany discloses "*wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed.*"

Thus, Solazzo in view of Disston, Boedecker, and Serany renders claim 17 obvious.

E. Ground 5 (Claims 13, 14, 16, and 17) – Obvious Based on Solazzo and Nursing Standard

1. Summary of Nursing Standard

The Nursing Standard article was published at least by March 26, 2009. (Ex.1025.) Nursing Standard is therefore prior art to the '400 patent under at least 35 U.S.C. § 102(a).

Nursing Standard describes an "all-in-one Foley tray" with "commonly used products" that have been available in the U.S. for a number of years. (Ex.1010, 52.) Box 1 (copied below) lists such contents included in the tray, which is wrapped such that a user can "open the outer packaging of the Foley tray" and "open the paper cover [i.e., wrap] to reveal the contents." (Ex.1010, 52-53.)

BOX 1

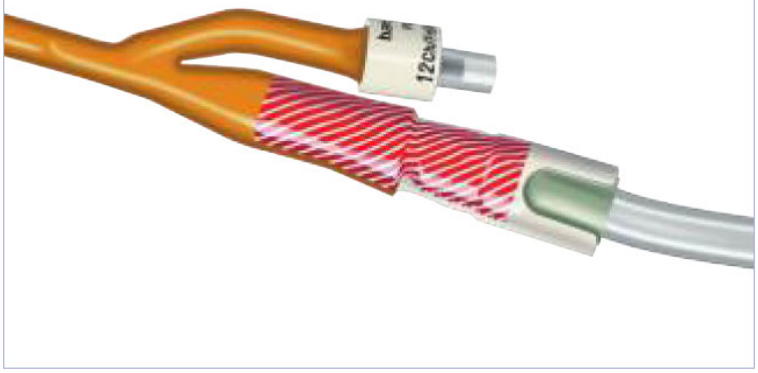
Contents of an all-in-one Foley tray

- Two pairs of latex-free gloves.
- Apron.
- Rubbish bag.
- Waterproof surface blanket.
- Sterile field/patient protection fenestrated drape.
- Vial 0.9% sodium chloride solution.
- Five gauze swabs.
- 10ml prefilled syringe of sterile water.
- 10ml syringe.
- Syringe of urethral lubricant.
- Foley catheter stabilisation device.
- Pre-connected catheter and drainage bag (choice of catheters and drainage bags).

The Foley tray includes a "pre-connected catheter and drainage bag," which it notes is a "closed system." (Ex.1010, 52; Fig. 1.) The article emphasizes that a "closed system" catheter dramatically reduces CAUTIs. (Ex.1010, 51.)

FIGURE 1

Pre-connected system



Further, Nursing Standard states that reflux of urine toward the bladder is associated with infection, and that by 2009, "[t]he majority of bags ... have an anti-reflux valve to prevent the backflow of urine." (Ex.1010, 51.)

2. The Combination

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

1) Claim 13

a. ***Preamble and 13[a]:*** *"A single level tray including a first compartment base member…"*

For the reasons at Ground 1, claim 13[a], Solazzo discloses "*a single level tray including a first compartment base member and a second compartment base member, the single level tray defining a first compartment and a second compartment, the first compartment base member forming a portion of a boundary of the first compartment, the second compartment base member forming a portion*

of a boundary of the second compartment, the single level tray including a barrier separating the first compartment from the second compartment."

b. ***13[b]:*** *"a first syringe …"*

For the reasons at Ground 1, claim 13[b], Solazzo discloses "*a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid*."

c. ***13[c]:*** *"a second syringe… "*

For the reasons at Ground 1, claim 13[c], Solazzo discloses "*a second syringe disposed within the single level tray, the second syringe containing a lubricant*."

d. ***13[d]:*** *"a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle …"*

(i) "…*a catheter assembly*…"

Claim 13[d][i] requires "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.*"

For the reason at Ground 1, claim 13[d], Solazzo discloses an indwelling catheter including an inflatable portion (i.e., Foley catheter 120) disposed in the second compartment (compartment 3), but does not expressly mention a Foley catheter that is *pre-connected* to a drainage bag via coiled tubing. But Applicants

admitted during the examination of the '400 patent that such an arrangement was well-known. (Ex.1004, 259, ¶33 (Meyst) ("Foley catheters are typically pre-connected to a drainage receptacle via a long coiled tubing.").)

Moreover, Nursing Standard notes that providing a tray with a "closed system" catheter was a standard practice before the time of the invention: "Catheters should be connected to a sterile catheter bag or valve, creating a closed system." (Ex.1010, 52.) Further, the risk of infection drops by over 80% when using a closed system. (Ex.1010, 51.)

A POSITA would understand that Nursing Standard teaches a closed-system Foley catheter with coiled drainage tubing. (Ex.1002, ¶302.) By the time of the publication of the Nursing Standard article in 2009, coiled drainage tubing was ubiquitous because the tubing needed to be coiled to fit in the box. (Ex.1003, 44-15.) The drainage tube of Nursing Standard could also be coiled around the drainage bag when stored in the tray of Solazzo to fit the tubing in the box while optimizing space and to prevent kinks. (Ex.1002, ¶¶302-03.)

In view of Nursing Standard, a POSITA would have been motivated to include a closed-system Foley catheter (including "*a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle*") in the tray of Solazzo for multiple reasons. (Ex.1002, ¶304.)

First, pre-connected systems are ready for use. Including a pre-connected Foley system that is "ready for use" in the tray of Solazzo reduces the steps in a Foley catheterization procedure because a fluid/drainage bag does not need to be fetched and connected to the Foley catheter. (Ex.1003, ¶35.)

Second, as Applicants admitted, it was known by 2009 that Foley catheters (such as shown by Solazzo) caused CAUTI. (Ex.1004, 239, ¶29 (Weintraub).) It was further known in the art that closed-system Foley catheters (i.e., Foley catheters that are pre-connected to a drainage bag via tubing) reduce the risk of infection. Nursing Standard emphasizes that closed-system Foley catheters reduce the rate of CAUTIs. (Ex.1003, ¶35; Ex.1010, 51.)

Accordingly, Solazzo in view of Nursing Standard discloses claim 13[d][i]. (Ex.1002, ¶¶296-307.)

(ii) "*the fluid receptacle including an anti-reflux device …*"

Claim 13[d][ii] requires "*the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device*." For the reasons at claim 13[d][i], it would have been obvious to include a closed-system Foley catheter (such as the catheter assembly of Nursing Standard) in the tray of Solazzo.

The Nursing Standard further teaches a closed-system Foley catheter with an anti-reflux device and even notes that "the majority of bags, including specialised

belly bags, have an anti-reflux valve to prevent the backflow of urine." (Ex.1010, 51.)

To prevent the reflux of urine from the drainage receptacle into a patient's bladder, a POSITA would have been motivated to include a closed-system Foley catheter with an anti-reflux device as taught by Nursing Standard. This provides further motivation to replace the Foley catheter of Solazzo with the closed-system taught by Nursing Standard. (Ex.1002, ¶311.)

Accordingly, Solazzo in view of Nursing Standard discloses claim 13[d][ii]. (Ex.1002, ¶¶308-12.)

(iii) ***"the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray…"***

Claim 13[d][iii] requires "*the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*."

Solazzo discloses a catheter assembly "*disposed within the second compartment of the single level tray*." Specifically, Foley catheter 120 is disposed in second compartment 3 (almost up to its top edge) of the single-level tray of Solazzo:

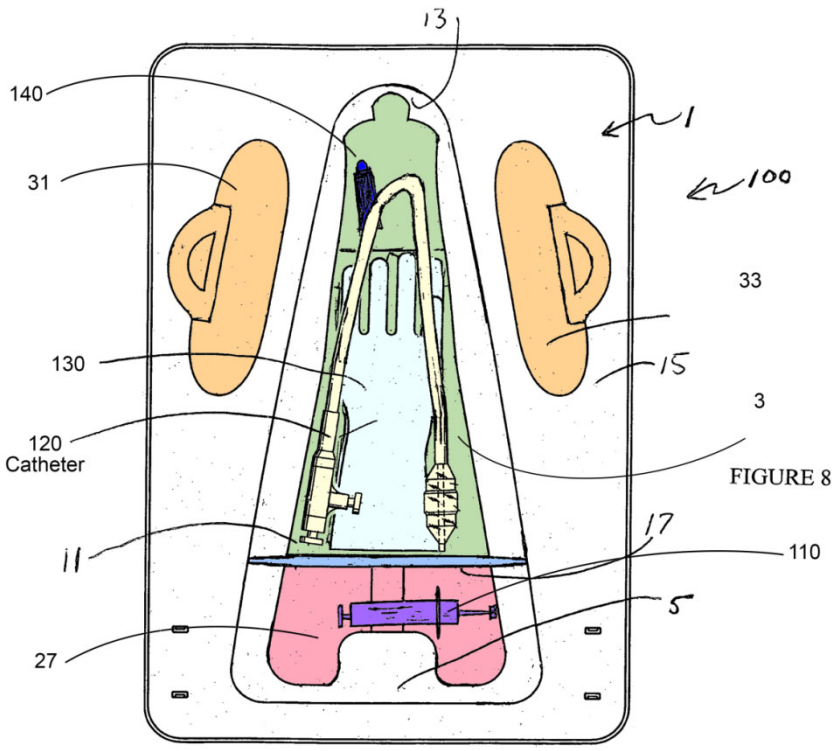


FIGURE 8

For the reasons at claim 13[d][i], the second compartment of Solazzo would hold the closed-system Foley catheter of Nursing Standard.

It was well-known in the art to arrange items inside a catheter tray in their order of use, as discussed at Grounds 1 and 3, claim 13[d][iii]. Examiner Poon further noted that the feature of the fluid receptacle beneath the coiled tube was admitted art. As discussed above, Applicants never challenged this finding of Examiner Poon. (Ex.1004, 73-76, 106-108, 262.) Moreover, a healthcare provider would need access to the drainage tubing before a fluid receptacle because it is attached to the Foley catheter. (Ex.1002, ¶316.) Accordingly, it would have been obvious to arrange a closed-system Foley catheter in the tray of Solazzo such that

"*at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube*." (Ex.1002, ¶316.)

Accordingly, Solazzo in view of Nursing Standard discloses claim 13[d][iii]. (Ex.1002, ¶¶313-17.) Thus, Solazzo in view of Nursing Standard renders claim 13 obvious.

2) Claim 14

For the reasons at claim 13[d][iii], Solazzo in view of Nursing Standard discloses "*wherein the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube*."

Thus, Solazzo in view of Nursing Standard renders claim 14 obvious.

3) Claim 16

a. ***16[a]:*** *"the single level tray defines a top opening ..."*

For the reasons at Ground 1, claim 16[a], Solazzo discloses "*the single level tray defines a top opening through which the first compartment and the second compartment can be accessed*."

b. ***16[b]:*** *"a sterile wrap disposed about the single level tray covering at least the top opening"*

Claim 16[b] requires "*a sterile wrap disposed about the single level tray covering at least the top opening*."

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

Nursing Standard teaches a wrapped Foley catheter kit: "Open the outer packaging of the Foley tray and slide it on to the top of a clean trolley. Open the paper cover to reveal the contents." (Ex.1010, 53.)

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

It would have been obvious to a POSITA at the time of the invention to combine the wrap (or "paper cover") taught by Nursing Standard with the catheterization tray of Solazzo. Nursing Standard and Solazzo are analogous art because they both disclose trays for holding a Foley catheter and related medical devices. The wrap of Nursing Standard 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, ¶¶324-25.)

Accordingly, Solazzo in view of Nursing Standard renders claim 16 obvious. (Ex.1002, ¶¶320-28.)

4) Claim 17

Claim 17 requires "*wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed*."

For the reasons at claim 16, Solazzo in view of Nursing Standard discloses "*a sterile wrap disposed about the single level tray covering at least the top opening*."

Solazzo discloses a tray with a top opening. The tray holds a *first syringe*, ("inflation syringe") *second syringe* ("lubrication tube 140" – replaceable with a

syringe), and an *indwelling catheter"* ("Foley catheter 120"):

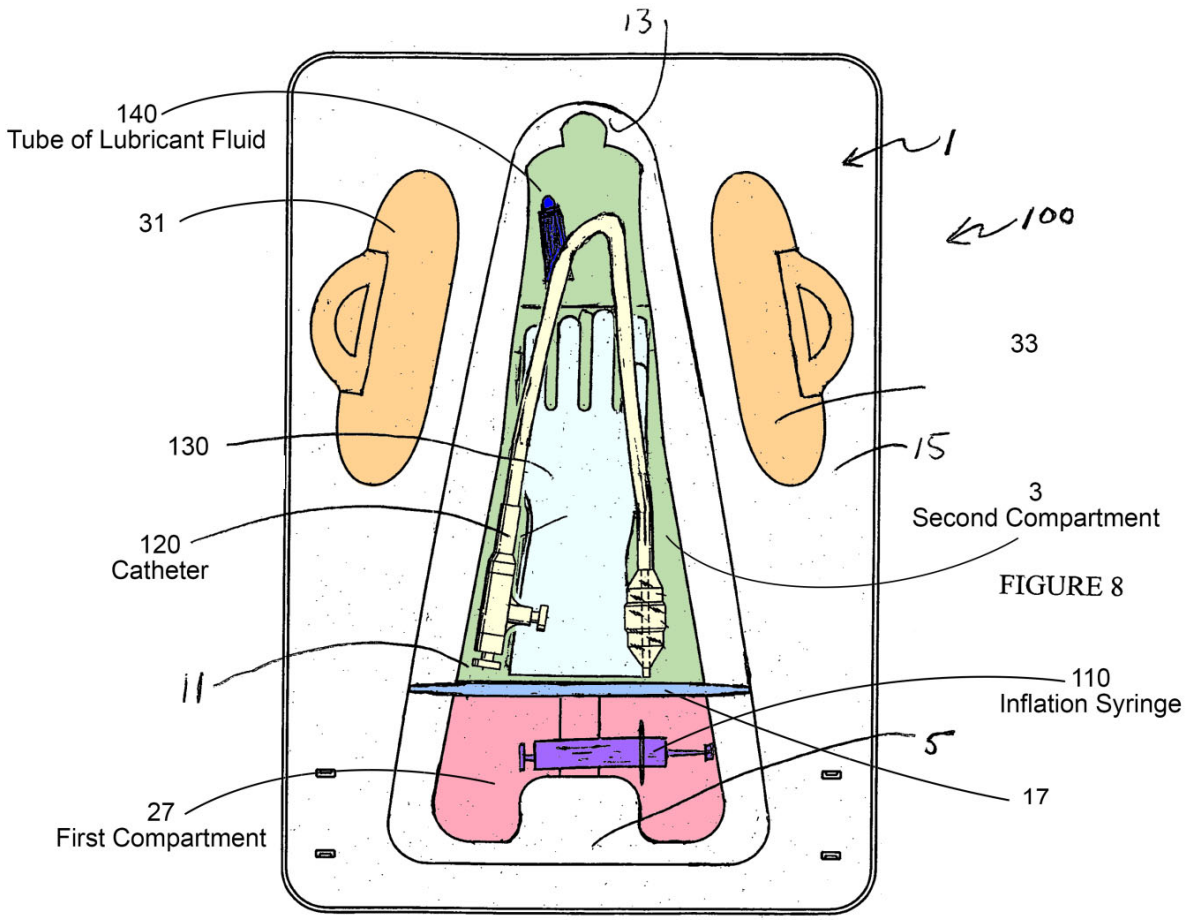


FIGURE 8

"*When the sterile wrap is unwrapped from about the top opening*" of the tray of Solazzo, the components shown in Figure 8 are necessarily revealed because Solazzo has an open top and does not teach any items in between the opening and the components shown in Figure 8 that would obstruct the view. (Ex.1002, ¶332.)

Nursing Standard also describes a Foley catheterization procedure that includes the following step: "open the paper cover [i.e., wrap] to reveal the contents." (Ex.1010, 52-53.) In view of *Nursing Standard*, a POSITA would have understood that covering the tray of Solazzo in a wrap and then unwrapping it

would necessarily mean that the items inside the tray including "*at least the first syringe, the second syringe, and the indwelling catheter are revealed*." (Ex.1002, ¶333.)

Accordingly, Solazzo in view of Nursing Standard renders claim 17 obvious. (Ex.1002, ¶¶329-34.)

VI. 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 '400 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.

VII. SECTION 325(d) IS INAPPLICABLE

Neither the original examination of the '400 patent, nor the *inter partes* reviews in *Medline I* raised substantially the same art or arguments in the same way as the current Petition. Thus, § 325(d) is inapplicable to this proceeding. *See Becton, Dickinson and Company v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017).

A. Original Examination

The primary reference in this Petition—Solazzo—is materially different and not cumulative of the art discussed or applied during the original examination of the '400 patent, i.e., Exs. 1014, 1037-1041, 1047-1049. None of the references

applied by the Examiner included an indwelling catheter. Nor did the applied references include an anti-reflux device.

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

B. IPRs In *Medline I*

Section 325(d) should not be applied in view of the IPRs in *Medline I*. None of the grounds of the IPRs utilized Solazzo. Nor would Solazzo be considered cumulative of the art raised in any of the grounds of the IPRs. In particular, Solazzo provides a single level Foley catheter tray that includes multiple compartments and syringes, in contrast to the art raised in the IPRs.

VIII. NOTICES AND STATEMENTS

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

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

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

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 '400 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.

IX. CONCLUSION

Bard 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. **480100000022**.

Dated: November 7, 2018

Respectfully submitted,

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

I hereby certify that this Petition for *Inter Partes* Review has 13,518 words (as counted by the "Word Count" feature of the Microsoft Word™ word-processing system), exclusive of "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

Dated: November 7, 2018

By /Mehran Arjomand/
Mehran Arjomand

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

I hereby certify that the attached Petition for *Inter Partes* Review and supporting materials were served as of the below date by UPS, which is a means at least as fast and reliable as U.S. Express Mail, on the Patent Owner at the correspondence address indicated for U.S. Patent No. 9,808,400.

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Dated: November 7, 2018

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